



REPORT OF THE
NOMINATING COMMITTEE

2010-2015
COUNCIL OF EXPERTS

March 26, 2010

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PART I

MEMORANDUM FROM THE NOMINATING COMMITTEE FOR THE 2010 – 2015 COUNCIL OF EXPERTS

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

**PART I. MEMORANDUM FROM THE NOMINATING COMMITTEE
FOR THE 2010 – 2015 COUNCIL OF EXPERTS**

We are pleased to present the Report of the Nominating Committee for the 2010-2015 Council of Experts (NC-CoE) to the Members and Delegates of the USP Convention. You are responsible for electing chairs for the 20 Expert Committees from among the worthy candidates presented in this report.

We ask that as you consider this remarkable slate of candidates you bear in mind the opportunities and challenges that lie ahead for USP in the next five years and beyond. The composition of the Council of Experts is critical to USP as it fulfills its mission — to improve the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. The Council of Experts plays a crucial leadership role in this endeavor.

In an effort to provide the USP Convention membership with exceptional candidates, the NC-CoE issued the first Call for Candidates in March 2009. This international call to action began USP's recruiting of distinguished experts in pharmaceutical science, analytical chemistry, biochemistry, measurement science, food and dietary supplement science, and other applied sciences to assist USP in its standards-setting activities. The NC-CoE met in person January 31 and February 1, 2010 to select the final candidates included in this report. The Committee gave careful thought to the scientific and leadership capabilities of each candidate as well as the nature of the work that each Expert Committee would perform over the next five years.

The information presented in the report is designed to help you formulate your decision about how you will vote. It begins with a list of candidates by Expert Committee, an alphabetical list, and demographic information for the candidates. Following these lists are summaries for each candidate, which includes: facts about education; professional experience; USP experience; a biography focusing on relevant scientific work and accomplishments; and the candidate's statement of interest. Candidates for each Expert Committee are shown together on facing pages to facilitate your review.

Dr. Foster will formally present the Report of the Nominating Committee for the Council of Experts during the business session on Thursday, April 22, and voting will take place on Friday, April 23, 2010. Additional nominations from the floor of the Convention must be seconded by ten (10) members of the Convention. Each nomination must be submitted on the official form and presented at once to the Secretary of the Convention.

Delegates of the USP Convention have an important responsibility in electing the Council of Experts. The CoE is entrusted with the scientific decisions of USP's primary compendial work. The next five years will present amazing opportunities, as well as critical challenges, for our organization, and these will come at the national and international level. The men and women you elect and their Expert Committees will need to develop and implement scientifically sound standards, novel approaches, and new initiatives, and USP must have the best and the brightest experts for the task.

Respectfully submitted,



René H. Bravo, M.D., F.A.A.P., Chair
President, USP Convention



Thomas S. Foster, Pharm.D., Vice Chair
Chair, Biopharmaceutics Expert Committee



**MEMBERS OF THE NOMINATING COMMITTEE
FOR THE 2010–2015 COUNCIL OF EXPERTS**

CHAIR

René H. Bravo, M.D., F.A.A.P., President, USP Convention

VICE CHAIR

Thomas S. Foster, Pharm.D., Chair, Biopharmaceutics Expert Committee

CHAIRMAN OF THE COUNCIL OF EXPERTS (EX-OFFICIO)

Roger L. Williams, M.D., Chair, Council of Experts

COMMITTEE MEMBERS REPRESENTING THE 2005-2010 COUNCIL OF EXPERTS

James E. Akers, Ph.D., Chair, Microbiology and Sterility Assurance Expert Committee
Gregory E. Amidon, Ph.D., Chair, Excipients General Chapters Expert Committee
Michael A. Cutrera, M.Sc., Chair, Monograph Development – Pulmonary and Steroids Expert Committee
James E. DeMuth, Ph.D., Chair, General Chapters Expert Committee
Andrew G. Ebert, Ph.D., Chair, Food Ingredients Expert Committee
Jean F. Huxsoll, Ph.D., Chair, Biologics and Biotechnology – Blood and Blood Products Expert Committee
Joy A. Joseph, M.S., Chair, Dietary Supplements – Nonbotanicals Expert Committee
David W. Newton, Ph.D., Chair, Sterile Compounding Expert Committee
Timothy J. Wozniak, Ph.D., Chair, Monograph Development – Cough, Cold, and Analgesics Expert Committee

COMMITTEE MEMBERS REPRESENTING THE USP CONVENTION

Hendrik J. de Jong, Ph.D., European Federation for Pharmaceutical Sciences
Gordon R. Johnston, R.Ph., Generic Pharmaceutical Association
Yana R. Mille, R.Ph., U.S. Food and Drug Administration, Center for Drug Evaluation and Research
Michael Mayersohn, Ph.D., University of Arizona College of Pharmacy
Philip C. Smith, Ph.D., University of North Carolina School of Pharmacy

**COMMITTEE MEMBERS APPOINTED BY USP CHIEF EXECUTIVE OFFICER AND
EXECUTIVE VICE PRESIDENT**

John Doull, M.D., Ph.D., University of Kansas Medical Center
Milind Joshi, Ph.D., J.B. Chemicals Ltd., India
Laurie E. Locasio, Ph.D., National Institute of Standards and Technology
Glenn A. Van Buskirk, Ph.D., American Association of Pharmaceutical Scientists





PART II

LIST OF CANDIDATES BY EXPERT COMMITTEE

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART II. LIST OF CANDIDATES BY EXPERT COMMITTEE

MONOGRAPHS – SMALL MOLECULES 1

Patricia C. Tway, Ph.D.
Glenn A. Van Buskirk, Ph.D.

MONOGRAPHS – SMALL MOLECULES 2

Tina Engel, Ph.D.
Ernest Parente, Ph.D.

MONOGRAPHS – SMALL MOLECULES 3

Philip Nethercote, Ph.D.
Bernard Olsen, Ph.D.

MONOGRAPHS – SMALL MOLECULES 4

Richard C. Adams, M.B.A.
Michael A. Cutrera, M.Sc.

MONOGRAPHS – BIOLOGICS AND BIOTECHNOLOGY 1

Adrian F. Bristow, Ph.D.
Michael G. Mulkerrin, Ph.D.

MONOGRAPHS – BIOLOGICS AND BIOTECHNOLOGY 2

Jean F. Huxsoll, Ph.D.
William E. Tente, M.S.

MONOGRAPHS – EXCIPIENTS

Lawrence H. Block, Ph.D.
Richard C. Moreton, Ph.D.

MONOGRAPHS – DIETARY SUPPLEMENTS

Dennis K. J. Gorecki, Ph.D.
Wayne R. Wolf, Ph.D.

MONOGRAPHS – FOOD INGREDIENTS

Roger A. Clemens, Dr.P.H.
Andrew G. Ebert, Ph.D.

GENERAL CHAPTERS – CHEMICAL ANALYSIS

Anthony C. Bevilacqua, Ph.D.
Timothy J. Wozniak, Ph.D.

GENERAL CHAPTERS – PHYSICAL ANALYSIS

Gregory E. Amidon, Ph.D.
Gregory P. Martin, M.S.

GENERAL CHAPTERS – BIOLOGICAL ANALYSIS

Charles S. Craik, Ph.D.
Wesley E. Workman, Ph.D.



GENERAL CHAPTERS – DOSAGE FORMS

James E. DeMuth, Ph.D.

Gordon L. Flynn, Ph.D.

GENERAL CHAPTERS – MICROBIOLOGY

James E. Akers, Ph.D.

Anthony M. Cundell, Ph.D.

GENERAL CHAPTERS – PACKAGING, STORAGE, AND DISTRIBUTION

Michael N. Eakins, Ph.D.

Mary G. Foster, Pharm.D., BFA

NOMENCLATURE, SAFETY, AND LABELING

Mary Baker, M.B.A., Pharm.D.

Thomas P. Reinders, Pharm.D.

COMPOUNDING

Lisa D. Ashworth, B.S., R.Ph.

Gigi S. Davidson, B.S., R.Ph., DICVP

REFERENCE STANDARDS

Matthew W. Borer, Ph.D.

Robert L. Watters, Ph.D.

STATISTICS

Timothy Schofield, M.A.

Robert Singer, M.S.

TOXICOLOGY

John Doull, M.D., Ph.D.

Robert E. Osterberg, Ph.D.





PART III

ALPHABETICAL LIST OF CANDIDATES AND DEMOGRAPHIC INFORMATION

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

PART III. ALPHABETICAL LIST OF CANDIDATES

NAME	GENDER	PROFESSION	LOCATION	PAGE
Richard C. Adams, M.B.A.	Male	Government (retired)	Maryland, USA	18
James E. Akers, Ph.D.	Male	Consultant	Missouri, USA	38
Gregory E. Amidon, Ph.D.	Male	Academia	Michigan, USA	32
Lisa D. Ashworth, B.S., R.Ph.	Female	Practitioner	Texas, USA	44
Mary Baker, M.B.A., Pharm.D.	Female	Generic Industry	Illinois, USA	42
Anthony C. Bevilacqua, Ph.D.	Male	Equipment Manufacturer	Massachusetts, USA	30
Lawrence H. Block, Ph.D.	Male	Academia	Pennsylvania, USA	24
Matthew W. Borer, Ph.D.	Male	Innovator Industry	Indiana, USA	46
Adrian F. Bristow, Ph.D.	Male	Standards-setting Org.	Herts, UK	20
Roger A. Clemens, Dr.P.H.	Male	Academia	California, USA	28
Charles S. Craik, Ph.D.	Male	Academia	California, USA	34
Anthony M. Cundell, Ph.D.	Male	Innovator Industry	New Jersey, USA	39
Michael A. Cutrera, M.Sc.	Male	Consultant	Pennsylvania, USA	19
Gigi S. Davidson, B.S., R. Ph., DICVP	Female	Academia	North Carolina, USA	45
James E. DeMuth, Ph.D.	Male	Academia	Wisconsin, USA	36
John Doull, M.D., Ph.D.	Male	Academia	Kansas, USA	50
Michael N. Eakins, Ph.D.	Male	Consultant	New Jersey, USA	40
Andrew G. Ebert, Ph.D.	Male	Consultant	Georgia, USA	29
Tina Engel, Ph.D.	Female	Innovator Industry	Ohio, USA	14
Gordon L. Flynn, Ph.D.	Male	Academia	Michigan, USA	37
Mary G. Foster, Pharm.D., BFA	Female	Innovator Industry	Pennsylvania, USA	41
Dennis K. J. Gorecki, Ph.D.	Male	Academia	Saskatchewan, Canada	26
Jean F. Huxsoll, Ph.D.	Female	Innovator Industry	California, USA	22
Gregory P. Martin, M.S.	Male	Consultant	Pennsylvania, USA	33
Richard C. Moreton, Ph.D.	Male	Consultant	Massachusetts, USA	25
Michael G. Mulkerrin, Ph.D.	Male	Innovator Industry	California, USA	21
Philip Nethercote, Ph.D.	Male	Innovator Industry	Ayrshire, UK	16
Bernard Olsen, Ph.D.	Male	Consultant	Indiana, USA	17
Robert E. Osterberg, Ph.D.	Male	Consultant	Virginia, USA	51
Ernest Parente, Ph.D.	Male	Innovator Industry	Kansas, USA	15
Thomas P. Reinders, Pharm.D.	Male	Academia	Virginia, USA	43
Timothy Schofield, M.A.	Male	Innovator Industry	Pennsylvania, USA	48
Robert Singer, M.S.	Male	Consultant	California, USA	49
William E. Tente, M.S.	Male	Innovator Industry	North Carolina, USA	23
Patricia C. Tway, Ph.D.	Female	Consultant	Pennsylvania, USA	12
Glenn A. Van Buskirk, Ph.D.	Male	Consultant	New Jersey, USA	13
Robert L. Watters, Ph.D.	Male	Government	Maryland, USA	47
Wayne R. Wolf, Ph.D.	Male	Government	Maryland, USA	27
Wesley E. Workman, Ph.D.	Male	Innovator Industry	Missouri, USA	35
Timothy J. Wozniak, Ph.D.	Male	Innovator Industry	Indiana, USA	31





PART IV

CANDIDATES' BIOGRAPHICAL INFORMATION

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

MONOGRAPHS – SMALL MOLECULES 1 EXPERT COMMITTEE

PATRICIA C. TWAY, PH.D.



Education

1981: Ph.D. (Analytical Chemistry), Seton Hall University
1969: M.S. (Physical Chemistry), Rutgers University
1967: B.A. (Chemistry), Mount Holyoke College

Professional Experience

1/2009 to present President, CMC Technical Navigator
1/1969 to 12/2008 Vice President, Analytical and Regulatory Sciences, Merck & Co.

USP Experience

Other Relevant Experience

Biography

Patricia C. Tway, Ph.D., is an analytical chemist with nearly 40 years experience in pharmaceutical product development and in-line product support. In recent years, her major focus has been on the development of strong technical product programs consistent with the concepts of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and Quality by Design (QbD). Her expertise includes: pharmaceutical product development; analytical method development and validation; chemistry, manufacturing and controls (CMC) support for both new and in-line products; and stability. She is founder and President of CMC-Technical Navigator LLC, a consulting company providing expertise in all aspects of CMC product development from initial Investigational New Drug (IND) through New Drug Application (NDA). Her broad background allows her to support the analytical, process, stability, and filing aspects of a program. Most recently, as Vice President of Regulatory and Analytical Sciences at Merck, Dr. Tway led a group of over 200 scientists focused on product development and in-line product support. Over the past few years, Dr. Tway worked closely with the Food and Drug Administration (FDA) through Pharmaceutical and Research Manufacturers of America (PhRMA), the Product Quality Research Institute (PQRI), and other forums to develop and further expand the concept of strong science-based development programs and submissions to better meet the needs of regulatory agencies, industry, and patients. Dr. Tway's career at Merck included extensive experience in both the Research and Manufacturing Divisions. She initially focused on analytical research, method development, method validation, and analytical support for drug substance development and release for clinical studies. Her responsibilities expanded to include CMC support for both new and in-line products globally, as well as for divisional validation and stability guidelines. She integrated the technical CMC components into a robust submission that assured product quality. Recent accomplishments include successful approval of JANUVIA® in over 60 countries using QbD and real time release, and the filing and rapid approval of GARDASIL®. She is a member of the FDA Advisory Board for Pharmaceutical Science and she served as co-chair of a workshop on Pharmaceutical Quality Assessment for the American Association of Pharmaceutical Scientists (AAPS).

Statement of Interest

I have worked in the pharmaceutical industry for almost 40 years and understand the important role that USP plays in setting scientifically-based standards to assure that pharmaceutical products are safe and efficacious for the public. This role becomes even more important with the globalization of the pharmaceutical industry and the economic focus to drive health care costs down. This changed environment places a heavy burden on industry, regulatory agencies, and pharmacopeias. I am very interested in using my strong science background and many years of industry experience in a different capacity, with the same goal of assuring safe and efficacious drugs that patients can afford. Being a part of the development of standards that will meet the needs of all of industry and the American public will be extremely interesting. A particular area of interest to me will be the continuing integration of pharmacopeia standards with the concepts of international harmonization and QbD.



MONOGRAPHS – SMALL MOLECULES 1 EXPERT COMMITTEE

GLENN A. VAN BUSKIRK, PH.D.



Education

1979: Ph.D. (Pharmaceutical Sciences), Rutgers University
1973: M.S. (Pharmaceutical Sciences), Rutgers University
1970: B.S. and B.Pharm. (Pharmacy), Rutgers College of Pharmacy

Professional Experience

8/2005 to present Managing Partner, Nonclinical Drug Development Consulting Services
8/1998 to 6/2005 Vice President, Nonclinical Drug Development, Purdue Pharma LLP
7/1995 to 7/1998 Vice President, Pharmaceutical and Analytical Development, Novartis Pharmaceuticals
6/1976 to 7/1995 Senior Director, Worldwide, R.W. Johnson Pharmaceutical Research Institute
6/1970 to 6/1976 Scientist, Ciba-Geigy Corp.

USP Experience

10/2009 to present Member, Council of Experts Nominating Committee

Other Relevant Experience

6/1991 to 1/1997 Co-leader of a series of Scale-up and Post-Approval Change (SUPAC) Workshops sponsored by American Association of Pharmaceutical Scientists, Food and Drug Administration, and USP covering oral, liquid, and, transdermal dosage forms

Biography

Glenn A. Van Buskirk, Ph.D., is the Managing Partner of Nonclinical Drug Development Consulting Services (NDDCS), LLC. Dr. Van Buskirk is a seasoned professional with more than 40 years of international product development and management experience. His consulting practice specializes in pharmaceutical dosage form design, scale-up, registration, launch, and post-approval change strategy. Prior to establishing NDDCS, Dr. Van Buskirk held senior management positions within the R&D organizations of Purdue Pharma, Novartis Pharmaceuticals, and Ortho-McNeil Pharmaceuticals. During his 35 year career within pharmaceutical R&D, Glenn rose to levels of responsibility encompassing broad areas of product development. His scientific and managerial experience includes analytical, biotechnology, preformulation, formulation, chemical development, drug metabolism, drug safety and molecular spectroscopy groups located in the US, Europe and Japan. During his career Dr. Van Buskirk gained multi-disciplinary experience in the development, analysis, control, registration, and launch of over 30 marketed products representing a broad array of dosage form types including oral solid (immediate release and extended release), semisolid, parenteral, transdermal, dry powder inhalation, biotechnology, and over-the-counter products.

Throughout his career, Glenn has been an active participant in and held a variety of leadership positions in AAPS, PhRMA, and PQRI. One of his accomplishments was the development of a series of jointly sponsored (AAPS/FDA/USP) workshops that dealt with the topic of Scale-Up and Post Approval Changes to oral solid, liquid, semisolid, and, transdermal dosage forms. The output of these workshops became the basis of the SUPAC Guidance documents still in use by the FDA.

Statement of Interest

I have a long-standing scientific working relationship with members of the USP as characterized by the SUPAC Workshops. These workshops also included scientists from academia, FDA, multi-national pharmaceutical companies and non-US regulatory bodies. The workshops spanned a period of about 5 years and resulted in the publication of a series of SUPAC Guidance documents. Having worked this past year on the USP Council of Experts Nominating Committee I know I would enjoy the opportunity to work with a USP Expert Committee to update and improve the current state of regulatory standards for small molecules. I believe my 40 years of hands-on product development experience would be a useful asset to the USP. I have proven leadership skills and a long history of successful collaborations that are critical to the success of USP's Expert Committee.



MONOGRAPHS – SMALL MOLECULES 2 EXPERT COMMITTEE

TINA ENGEL, PH.D.



Education

1992: Ph.D. (Chemistry), Ohio State University
1977: B.S. (Chemistry, Cum Laude), University of Michigan

Professional Experience

6/1992 to present Principal Scientist, The Procter and Gamble Company
5/1977 to 8/1988 Scientist, Battelle Columbus Laboratories

USP Experience

2005 to 2010 Member, Monograph Development – Cough, Colds and Analgesics Expert Committee

Other Relevant Experience

Mid-Western Compendial Discussion Group (MWCDG)
Chair, MWCDG/USP Subcommittee, Consumer HealthCare Products Association

Biography

Tina Engel, Ph.D., manages the Raw Materials Testing Laboratory and the Reference Standards program for The Procter and Gamble Company's (P&G) Consumer Health Care Business Unit. She is currently a member of USP's Monograph Development – Cough, Cold, and Analgesics (MD-CCA) Expert Committee. She began her career in 1977 at the Battelle Columbus Institute where she developed and validated analytical methods for various governmental and industrial clients, taking on contract management responsibilities in addition to her technical activities. Dr. Engel left Battelle in 1988 to pursue her doctorate in Analytical Chemistry from Ohio State University under the guidance of Dr. Susan Olesik. Her doctoral work focused on supercritical fluid extraction and chromatography as well as the development and characterization of new chromatographic stationary phases. After earning her doctorate in 1992, Dr. Engel took a position with P&G, providing problem-solving expertise to P&G's Health Care Global Business Unit.

Statement of Interest

My experience as a member of the MD-CCA Expert Committee has been positive. I believe I have contributed to the USP mission of improving the health of people around the world through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. At the same time, I have been able to entertain my personal passion around developing new compendial approaches to non-prescription drug products. I also value the relationships I have developed with USP staff and other USP expert volunteers. I have learned much in the past five years, but am sure I still have more to contribute.



MONOGRAPHS – SMALL MOLECULES 3 EXPERT COMMITTEE

PHILIP NETHERCOTE, PH.D.



Education

1987: Ph.D. (Chemistry), Stirling University
1982: B.Sc. (Chemistry), Heriott-Watt University

Professional Experience

2/2010 to present Head, GMS Analytical Center of Excellence, GlaxoSmithKline (GSK)
2/2007 to 2/2010 Director, New Product Support, GSK
1/2004 to 2/2007 Analytical Development and Operational Excellence Lead, GSK
1/2001 to 1/2004 Analytical Development Manager/API Analytical Group Lead, GSK, Singapore
6/1996 to 12/2000 New Product Introduction – Actives Manager – Analytical, Glaxo Wellcome

USP Experience

9/2009 Speaker, 2009 USP Annual Scientific Meeting

Other Relevant Experience

1/2004 to present Chair, GSK's Analytical Standards Setting Committee

Biography

Phil Nethercote, Ph.D., is the Head of the Analytical Center of Excellence for GSK, providing expert analytical support to over 80 manufacturing sites worldwide. Dr. Nethercote joined Glaxo in 1987 at the UK. Active Pharmaceutical Ingredient (API) manufacturing site in Montrose as an analytical development scientist in the New Product Introduction department. He held a number of roles in quality assurance and in 1998 was appointed as functional leader of the analytical development groups across all of the GlaxoWellcome API manufacturing sites. In 2000, Dr. Nethercote moved to Singapore to lead the Analytical Development group. He returned to the UK in 2004 in a joint role as analytical lead for the GSK API supply organization and Operational Excellence Champion for the GSK API Technical Organization. In 2007, he was appointed to Director of New Product Support within the GSK Quality Analytical Sciences team, with responsibility for ensuring that all drug product and API analytical methods developed in support of new product introductions met the needs of the GSK manufacturing organization.

Statement of Interest

In my 23 years with Glaxo\GlaxoWellcome\GSK, I have been involved in supporting the introduction of over 30 New Chemical Entities from development into commercial manufacture (including supporting the development of USP and European Pharmacopoeia (EP) monographs for a number of these). As a consequence, I feel I have a sound understanding of what is required to establish appropriate quality standards for new drugs.

Since 2004 I have played a lead role in GSK's program to implement Quality by Design for manufacturing processes and as a consequence of my dual roles in both analytical science and operational excellence I was able to recognize the potential of applying QbD principles to the development, validation and transfer of analytical methods. I have subsequently led the development of GSK's efforts on application of QbD to analytical methods and have played a lead role in industry forums and at various international conferences on this topic.

As someone who has been a champion for operation excellence, I have a passion for elimination of "waste" and my training in this area has equipped me with skills, knowledge and tools that I apply on a regular basis to ensure that the processes and meetings that I am involved with operate as effectively and efficiently as possible. This, combined with my experience in leading an international standard setting group (as the Chair of GSK's Analytical Standards setting body for the past six years) and passion for global thinking leads me to believe I have the appropriate background, knowledge, and skills required to lead one of USP's Small Molecules Expert Committees and that in these times of rapid change I can bring fresh ideas and innovative thinking to that role.



MONOGRAPHS – SMALL MOLECULES 3 EXPERT COMMITTEE

BERNARD OLSEN, PH.D.



Education

1979: Ph.D. (Analytical Chemistry), University of Wisconsin, Madison
1975: B.S. (Chemistry), Nebraska Wesleyan University

Professional Experience

7/2009 to present Consultant, Olsen Pharmaceutical Consulting, LLC
1/2009 to 7/2009 Managing Director, Aptuit and Aptuit Consulting
10/1979 to 12/2008 Progressively responsible jobs, culminating as Senior Research Fellow, Eli Lilly and Company

USP Experience

1/2010 to present Member, USP Pharmacopeial Education Planning Committee
11/2009 Speaker at USP Annual Scientific Meetings in Jordan, Egypt, and Turkey
6/2009, 9/2009 Speaker at USP-Sindusfarma Forced Degradation and HPLC workshops in Brazil
3/2006 to 9/2006 Member, Planning Committee for Impurities Track Symposium (Annual Scientific Meeting)
2005 to 2010 Vice Chair, Monograph Development – Oncology, Ophthalmology, and Dermatology Expert Committee
2000 to 2005 Member, Pharmaceutical Analysis 6 Expert Committee

Other Relevant Experience

2007 to present Adjunct Professor, Purdue University, Department of Industrial and Physical Pharmacy
2007 to present Member, Editorial Advisory Board, Journal of Pharmaceutical and Biomedical Analysis
2001 to 2004 Member, Product Quality Research Institute, working group on drug substance specifications

Biography

Bernard Olsen, Ph.D., is an independent consultant to the pharmaceutical industry. He has over 29 years of experience at Eli Lilly and Company, where he was a Senior Research Fellow focused on the chemistry, manufacturing, and control (CMC) aspects of drug substances and drug products. He has contributed to the development and support of over 25 commercial drugs and numerous developmental drugs including cephalosporin and macrolide antibiotics, oncolytics, and central nervous system drugs. He has published and given invited lectures at international venues on a wide array of drug development and analytical topics including high performance liquid chromatography and other separation techniques, impurity determination and control, genotoxic impurities, physical property characterization of drug substances and products, drug counterfeiting, pharmacopeial standards, regulatory aspects of drug development, and quality control.

Statement of Interest

I have been active with USP as an Expert Committee member for ten years. I would like to continue in this role or expand to chair one of the Small Molecules Expert Committees. I have seen the value that USP brings to public health through a scientific and thoughtful standards-setting process that considers the viewpoints of multiple stakeholders. I believe that my technical background and 30 years of experience in the pharmaceutical industry can contribute to USP's mission.



MONOGRAPHS – SMALL MOLECULES 4 EXPERT COMMITTEE

RICHARD C. ADAMS, M.B.A.



Education

1976: M.B.A., University of New Haven
1969: B.S. (Chemistry), University of Maine

Professional Experience

4/2010 to present Retired FDA
4/2004 to 4/2010 Deputy Division Director, Division Chemistry II, FDA, CDER, (OGD)
5/1990 to 3/2004 Team Leader, Antibiotic Drug Review and Chemistry Reviewer, Evaluation of Antibiotic Abbreviated New Drug Applications (ANDAs), FDA CDER, OGD
7/1983 to 8/1986 Project Leader, Pfizer Inc.
1/1972 to 7/1983 Senior Research Scientist, Pfizer Inc.

USP Experience

5/2004 to present Interactions with Compendial Operations staff to identify/resolve CDER/USP issues
6/1999 to 2/2002 Multiple interactions with USP staff regarding development of definitions/method of implementation of *Mean Kinetic Temperature*

Other Relevant Experience

6/2006 to 8/2006 Chair, OGD Ad Hoc Advisory Panel; Draft Guidance: OGD Current Thinking ANDA Stability Requirements
3/2001 to 3/2003 Chair, Center for Drug Evaluation and Research (CDER) Chemistry, Manufacturing and Control Coordinating Committee (CMCCC) Stability Technical Committee
3/1999 to 3/2001 Vice Chair: CMCCC Stability Technical Committee

Biography

Richard F. Adams, M.B.A., is Deputy Director, Division of Chemistry II in the FDA OGD, CDER. Prior to joining CDER, he worked with the Central Research Facility of Pfizer, Inc., with responsibilities in Discovery Research, Production Process Development, and Process R&D. He later became a Chemistry Reviewer, Team Leader, and Deputy Director for CDER. He has served on numerous office and technical committees and ad hoc working groups and has chaired the Center Stability Technical Committee.

Statement of Interest

I am retiring from FDA in April 2010. Although I am not interested in additional employment, I am interested in staying in touch with many of the issues which have occupied me for the last 40 years. I believe that my background equips me to make significant contributions to many USP initiatives.



MONOGRAPHS – SMALL MOLECULES 4 EXPERT COMMITTEE

MICHAEL A. CUTRERA, M.SC.



Education

1979: M.Sc. (Chemistry), University of Oregon
1976: B.Sc. (Chemistry), Massachusetts Institute of Technology (MIT)

Professional Experience

1/2010 to present President, MITER Group, LLC
9/2007 to 11/2009 Vice President, QA/RA, G&W Laboratories, Inc.
4/1999 to 9/2007 Director, Analytical Research, G&W Laboratories, Inc.

USP Experience

1/2008 to present Member, Council of Experts Nominating Committee
2005 to 2010 Chair, Monograph Development – Pulmonary and Steroids Expert Committee
2000 to 2005 Vice Chair, Pharmaceutical Analysis 1 Expert Committee

Other Relevant Experience

Biography

Michael Cutrera, M.Sc., is currently President of MITER Group, LLC, a pharmaceutical consulting business. Previously, he was Vice President, QA/RA at G&W Laboratories, Inc., a manufacturer of generic pharmaceuticals, where he initially served as Director of Analytical Research. He has 30 years of experience in analytical laboratory management, analytical research, method validation, instrument qualification and Current Good Manufacturing Practices (cGMP) compliance. During his career, he has worked for American McGaw Laboratories, Marion-Merrell Dow, R. P. Scherer Corporation, Integra LifeSciences Corporation, and IBAH Biopharm, Inc. From 2002 to 2007 he was Chair of the annual Technology Transfer Conference sponsored by the Institute of International Research, and from 1990 to 2004 he was co-chair of the Pharmaceutical Analysis Symposium of the annual Rocky Mountain Conference on Analytical Chemistry. He has chaired many technical conferences and presented numerous seminars, short courses, and training programs nationwide on analytical method validation, laboratory instrument qualification, impurities analysis, reference standard characterization, technology transfer, cleaning validation, and dissolution testing.

Statement of Interest

I have an excellent combination of background, experience, and familiarity with all aspects of analytical method development in the pharmaceutical industry and the USP standards-setting process to be a strong contributor to the advancement of USP's activities, which I fully support.



MONOGRAPHS – BIOLOGICS AND BIOTECHNOLOGY 1

EXPERT COMMITTEE

ADRIAN F. BRISTOW, PH.D.



Education

1976: Ph.D., University of Newcastle upon Tyne
1973: B.S. (Biochemistry), University of Newcastle upon Tyne

Professional Experience

4/2004 to present Head, Technology Development and Infrastructure, National Institute
for Biological Standards and Control (NIBSC)
4/1994 to 4/2004 Head of Endocrinology, NIBSC
9/1979 to 4/1994 Principal Scientist, Division of Endocrinology, NIBSC

USP Experience

2009 to present Principal Investigator, NIBSC-USP Memorandum of Understanding
9/2007 Member, Resolution 3 Advisory Panel; Speaker at the 2009 USP Annual Scientific Meeting

Other Relevant Experience

1/1996 to present Member, European Department for Quality of Medicines (EDQM), Biological Standardization
Program Steering Committee
10/1995 to present Member, World Health Organization (WHO), Expert Committee on Biological
Standardization
4/1985 to present Member, British Pharmacopoeia Committee H
9/1983 to present Member, European Pharmacopoeia Group of Experts No. 6

Biography

Adrian F. Bristow, Ph.D., is Head of Technology Development and Infrastructure at the National Institute for Biological Standards and Control (NIBSC), producing and characterizing biological active recombinant proteins, including engineered monoclonal antibodies. He joined NIBSC in 1979 after completing Ph.D. studies in molecular enzymology at Newcastle University and Post-doctoral research studies on molecular Endocrinology of the hypothalamo-pituitary-adrenal axis at the University of Sussex. He worked in the Division of Endocrinology as a senior scientist until 1994 and as Head of the division until 2004. His research interests focus principally on characterization of the biological and physico-chemical properties of biological and biotechnological medicinal substances, and on principles of Biological Standardisation. In addition to his work at NIBSC, Dr. Bristow has been a member of the biologicals expert groups of both the European Pharmacopoeia and British Pharmacopoeia (BP) for over 20 years, and is also a member of the steering committee of the EDQM Biological Standardisation Programme. He also regularly attends the WHO Expert Committee on Biological Standardisation, and has a central scientific role in developing and coordinating the NIBSC/WHO Biological Reference Material Program.

Dr. Bristow's significant contributions include playing a lead role in elaborating pharmacopeial specifications for a number of recombinant proteins, including insulins, growth hormone, erythropoietin, follicle stimulating hormone, and granulocyte colony-stimulating factor (GCSF). In recent years he has made a particular focus on biological standardization and developed a synthesis which attempts to reconcile the biology-based approach taken by the WHO with the approach based on metrological traceability, adopted by the clinical chemistry community.

Statement of Interest

Service on a USP Expert Committee would be a natural extension of my work with the European and British Pharmacopoeias, over many years, on standards-setting and reference materials in the field of biological and biotechnological medicines.



MONOGRAPHS – BIOLOGICS AND BIOTECHNOLOGY 1

EXPERT COMMITTEE

MICHAEL G. MULKERRIN, PH.D.



Education

1983: Ph.D. (Biochemistry), University of Georgia
1981: M.S. (Biochemistry), University of Georgia
1976: B.S. (Biochemistry), University of Massachusetts

Professional Experience

9/2006 to present Vice President, Process Development, OncoMed Pharmaceuticals
3/2006 to 9/2006 Senior Director, Process Development, Amgen
7/2000 to 3/2006 Senior Director, Process Development, Abgenix, Inc.
1/1984 to 3/2000 Senior Scientist, Genentech, Inc.

USP Experience

1/2005 to present Member, Biologics and Biotechnology – Proteins and Polysaccharides Expert Committee
2005 to 2010 Chair, Monoclonal Antibody Manufacturing Ad Hoc Advisory Panel
2005 to 2010 Chair, Protein A Ad Hoc Advisory Panel
2003 to 2004 Member, Expert Panel for Resolution 2, Equivalence of Complex Actives

Other Relevant Experience

Scientific Advisory Board, IBCUSA

Biography

Michael G. Mulkerrin, Ph.D., is the Vice President of Process Development at OncoMed where he is responsible for the development and manufacturing of the antibodies in the OncoMed Pharmaceuticals portfolio. He joined OncoMed in 2006 after serving as Senior Director of Process Sciences at Amgen, Senior Director of Process Development at Abgenix, and Senior Scientist at Genentech. During his sixteen years at Genentech, Dr. Mulkerrin worked in Protein Chemistry, Biocatalysts, Protein Engineering, and Analytical Chemistry. Dr. Mulkerrin was the chemistry, manufacturing and controls (CMC) team leader at Abgenix for the ABX-IL8 and ABX-MA1 projects and at Genentech for the Raptiva project, where he led the Characterization team. In these leadership roles, he has contributed to three Biologic License Applications (BLAs) leading to approved products with numerous Investigational New Drug (IND) applications. He also has a long history of interactions with regulatory agencies throughout the world. He has participated as a member of the Scientific Advisory Committee for the Well Characterized Biologics meetings in the U.S. and Europe as well as the Downstream Production and Antibody Purification meetings. He continues to present the work of OncoMed as an invited speaker to meetings in the US and Europe. Dr. Mulkerrin has also coauthored numerous papers, book chapters, and reviews.

Since 2005, Dr. Mulkerrin has served on the USP Biologics and Biotechnology – Proteins and Polysaccharides (BB PP) Expert Committee. He chairs the subcommittee for the development of a USP general chapter on Monoclonal Antibody Manufacturing as well as the Ad Hoc advisory panel Protein A monographs and reference standards. He has also served as a member of the organizing committee for USP's Bioassay workshops, chaired a workshop session, and chaired and organized a USP Annual Science Meeting session. Dr. Mulkerrin has given presentations on behalf of the USP at a number of international meetings.

Statement of Interest

In the past eight years I have had the privilege of serving on the Expert Panel for Resolution 2 and then serving as a member of the BB PP Expert Committee. As a member of the BB PP Expert Committee, I have had the opportunity to Chair the Protein A Ad Hoc Advisory Panel. This panel was very successful as we brought four monographs through the process to publication in the USP. This work has been particularly rewarding as I have had opportunities to lead teams of terrific colleagues and bring the monographs and reference standards forward. In this next cycle I look forward to a leadership role in shepherding monographs through to publication.



MONOGRAPHS – BIOLOGICS AND BIOTECHNOLOGY 2

EXPERT COMMITTEE

JEAN F. HUXSOLL, PH.D.



Education

2002: Ph.D. (Health Care Management), Senior University International

1988: M.S. (Quality Assurance), San Jose State University

1964: B.A. (Bacteriology), University of California, Los Angeles

Professional Experience

3/2003 to present Senior Director QA Compliance, Bayer (formerly Novartis, Chiron)

8/1996 to 3/2003 Director, Compliance Management and Audits, Bayer Corporation

6/1992 to 8/1996 Vice President, QA, Matrix Pharmaceutical, Inc.

6/1987 to 6/1992 Senior Director, Operations or Manufacturing, Somatrix Therapy Corporation and Applied Immune Sciences

USP Experience

2/2009 to present

Member, Council of Experts Nominating Committee

8/2008 to present

Member, Council of Experts Executive Committee

2006 to present

Chair, Blood and Blood Products Expert Committee

2000 to 2005

Vice Chair, Blood and Blood Products Expert Committee

Other Relevant Experience

1/2002 to 12/2008

Regulatory Affairs Professional Society Certification Committee

1/1997 to 1/2003

Chairperson and variety of positions, Food, Drug and Cosmetic Division of American Society for Quality (ASQ)

Biography

Jean F. Huxsoll, Ph.D., has more than 40 years experience in the pharmaceutical, drug, and biologics industries. She has worked in quality control, quality assurance, regulatory affairs, regulatory compliance, and manufacturing. She has published and taught courses related to cGMP, aseptic filling, quality assurance, and auditing. Dr. Huxsoll was awarded the ASQ Edwards Medal, recognized for her leadership in the application of modern quality control methods, especially through the organization and administration of such work in 2002. She was a Malcolm Baldrige Award Examiner for four years, a Judge for the California State Quality Award for three years, and was elected an ASQ Fellow. She served on the California State Awards Council for two years, has been a member of the *BioPharm* magazine Editorial Advisory Board for over five years, and has held a number of positions in various organizations including the West Coast Chapter of the Parenteral Drug Association, ASQ's Food, Drug and Cosmetic Division, the Regulatory Affairs Professional Society, and the International Society for Pharmaceutical Engineers. She is a member of the American Society of Microbiology and the American Association for the Advancement of Science.

Statement of Interest

The quality and safety of medicines is critical, but tied into this there must be realistic and sound standards. I have participated in a number of activities as a USP volunteer that I believe have a direct impact on the safety and quality of medicines. My goal would be to assist in continuing to develop standards and information to improve patient care.



MONOGRAPHS – BIOLOGICS AND BIOTECHNOLOGY 2

EXPERT COMMITTEE

WILLIAM E. TENTE, M.S.



Education

1983: M.S. (Microbiology), University of Rhode Island
1979: B.S. (Cell Biology and Microbiology), University of Rhode Island

Professional Experience

3/2008 to present Vice President, Manufacturing and Regulatory Affairs, Humacyte Inc.
7/2007 to 3/2008 Independent Consultant
7/2002 to 7/2007 Vice President, Operations, Neurotech USA
12/1997 to 7/2002 Director, Operations, Chimeric Therapies
10/1992 to 2/1997 Director, Bio-Process Development and Clinical Manufacturing, CytoTherapeutics, Inc.
10/1986 to 10/1992 Scientist, Bio-Process Development, Ares-Serono Group
12/1983 to 10/1986 Process Development Sciences, Schering Biotechnology

USP Experience

2005 to 2010 Chair, Biologics and Biotechnology – Cell, Gene, and Tissue Therapies (BB CGT) Expert Committee
2000 to 2005 Member, Biologics and Biotechnology – Cell and Gene Therapy Expert Committee
1997 to 2000 Member, Biologics and Biotechnology – Cell and Gene Therapy Subcommittee

Other Relevant Experience

Biography

William E. Tente, M.S., has over 27 years of experience in product and bioprocess development for a variety of recombinant DNA (rDNA) therapeutic proteins, biologics, cell and gene therapy, and tissue-engineered products, especially in the areas of manufacturing, quality, and regulatory affairs. He currently is the Vice President of Manufacturing and Regulatory Affairs at Humacyte, Inc., which is developing regenerative medicine products. From 2002 to 2007, he was the Vice President of Operations for Neurotech USA, which is developing encapsulated cell technology products for the long term delivery of therapeutic protein factors to the back of the eye to treat chronic diseases of the retina. From 1997 to 2002, he was the Director of Operations of Chimeric Therapies, Inc. and was responsible for manufacturing, quality control, and logistics for bone marrow processing and transplantation operations. From 1992 to 1997, he was the Director of Clinical Production at CytoTherapeutics, Inc., where he was responsible for biological process development, manufacturing, and quality control for an encapsulated pain cell therapy product. Mr. Tente also has held managerial and research positions in process development and production of cell-culture-based recombinant pharmaceuticals [Gonal-F® (recombinant human follicle stimulating hormone, marketed worldwide for ovulation induction in infertile women), Luveris® (recombinant luteinizing hormone, marketed worldwide for ovulation induction in infertile women) and Ovidrel® (recombinant human chorionic gonadotropin hormone, marketed worldwide for treating anovulation in infertile women)] at the Ares Serono Group and Schering Biotechnology.

Statement of Interest

I have been a committed member of the BB CGT Expert Committee since 1997. I am an advocate for the development of cell, gene and tissue engineered products as well as vaccines and other biological products. My product development experience in these fields uniquely qualifies me for this position.



MONOGRAPHS – EXCIPIENTS EXPERT COMMITTEE

LAWRENCE H. BLOCK, PH.D.



Education

1969: Ph.D. (Pharmacy – Chemistry, Pharmacology/Physiology), University of Maryland
1966: M.S. (Pharmacy – Chemistry), University of Maryland
1962: B.S. (Pharmacy), University of Maryland

Professional Experience

1975 to present Professor of Pharmaceutics, Duquesne University
1973 to present Consultant to the pharmaceutical industry and related organizations, including Whitehall-Robins Healthcare, Biosyn, Thar Designs, SommaTech, FMC Corporation, Upsher-Smith Laboratories, Travenol Laboratories, and Hoffman-LaRoche
1970 to present Member, Graduate Faculty, Duquesne University

USP Experience

2005 to 2010 Chair, Excipient Monographs 2 Expert Committee
2005 to 2010 Member, Council of Experts
2002 to 2005 Member, Expert Committee on Excipient Monograph Content
2000 to 2009 Invited presentations/Seminars/Talks – USP Symposia on Excipients; Annual Scientific Meetings; International Excipient Workshop
1986 to present USP Convention Delegate

Other Relevant Experience

Biography

Lawrence H. Block, Ph.D., is Professor of Pharmaceutics in the Division of Pharmaceutical Sciences at the Mylan School of Pharmacy and Graduate School of Pharmaceutical Sciences at Duquesne University. Dr. Block served as Chair of the Department of Medicinal Chemistry and Pharmaceutics at Duquesne from 1985 to 1999. He is a past chairperson of both the Teachers of Pharmaceutics Section of the American Association of Colleges of Pharmacy (AACP) and the Basic Pharmaceutical Sciences Section of the American Pharmacists Association (APhA). In 2000, Dr. Block received Duquesne University's President's Award for Excellence in Scholarship. He is a Fellow of both the American Association of Pharmaceutical Scientists (AAPS) and the APhA Academy of Pharmaceutical Research and Science. Dr. Block has authored more than 100 publications and mentored more than 70 Pharm.D., M.S., and Ph.D. research students. His research interests include excipient characterization, rheology, pharmaceutical engineering, drug and cosmetic delivery system technology, and pharmacokinetics. He has served as a visiting scholar at Kobe Gakuin University in Kobe, Japan and visiting professor of pharmaceutical sciences at the Center for Pharmacogenetics at the University of Pittsburgh School of Pharmacy.

Statement of Interest

USP's responsibility for the development and promulgation of rigorous public standards of quality for drugs and excipients warrants our commitment to and involvement in the process whereby those standards are developed or enhanced in accordance with advances in science and technology. Given the critical nature of excipients in drug dosage forms, and especially in drug delivery systems, the content of the *United States Pharmacopeia–National Formulary's (USP-NF)* excipient monographs must be a reflection of both the complexity of excipient composition and excipient utilization, if at all possible. My intention is to continue to facilitate the process of review and evaluation so that the *USP-NF's* utility and preeminence are commensurate with its internationally recognized role.



MONOGRAPHS – EXCIPIENTS EXPERT COMMITTEE

RICHARD C. MORETON, PH.D.



Education

1992: Ph.D. (Pharmaceutics), University of Wales
1987: M.Sc. (Pharmaceutical Analysis), University of Strathclyde
1971: B.Pharm., University of Nottingham

Professional Experience

7/2007 to present Vice President, Pharmaceutical Sciences, FinnBrit Consulting
8/2002 to 7/2007 Vice President, Pharmaceutical Sciences, Idenix Pharmaceuticals Inc.
5/2001 to 2/2002 Vice President, Research and Development, Genpharm Inc.
3/2000 to 5/2001 Senior Director, Technical Operations, Penwest Pharmaceuticals Co.

USP Experience

2009 to present Co-Chair, <1195> Significant Change Guide for Bulk Pharmaceutical Excipients Ad Hoc Advisory Panel
2005 to 2010 Vice Chair, Excipient Monographs 2 Expert Committee
2000 to 2005 Member, Excipient Test Methods Expert Committee

Other Relevant Experience

2003 to 2004 Chair, International Pharmaceutical Excipients Council (IPEC)-Americas
Representative, Drug Product Technical Committee, PQRI
Representative, Development Technical Committee, PQRI
2005 to 2007 Chair, AAPS Excipients Focus Group
Liason to the Containers and Closures Working Group, Dairy Products Technology Center/
Development Technical Committee (DPTC/DTC)

Biography

Richard C. Moreton, Ph.D., is a registered pharmacist in the United Kingdom (UK) with over thirty years of experience in the pharmaceutical industry. He has worked as a formulation scientist developing a variety of different dosage forms, and also in QA/Quality Control (QC), regulatory affairs, and technical service and support in excipients and drug delivery. Dr. Moreton is a past chair of IPEC-Americas, and is still active on several IPEC committees, including GMP, Quality by Design (QbD) and Excipient Composition. He is also a past Chair of the American Association of Pharmaceutical Scientists' Excipient Focus Group. Dr. Moreton is a member of the International Steering Committee of the Handbook on Pharmaceutical Excipients and the Editorial Advisory Board of Pharmaceutical Technology. He has authored, co-authored, and lectured extensively in the areas of excipients, drug delivery, and formulation at universities, training courses, and symposia in the U.S. and Europe. Dr. Moreton is an Honorary Teaching Fellow in the Department of Pharmacy at the University of Manchester, UK.

Statement of Interest

As an industrial formulation scientist, excipients are an essential part of the “tools of the trade,” so to speak. In the past 40 years, we have made tremendous advances in therapeutics and surgical techniques, but in large measure I could argue that the excipient world has advanced less; but we do expect a lot more of our excipients in order to be able to develop the robust medicines that patients need for the newer, less stable, less soluble, and more sophisticated drug molecules being designed by our medicinal chemistry colleagues. Good pharmacopeial monographs, based on good science and understanding, are essential for the development of robust formulations, particularly in the current QbD world. Many excipient monographs require updating, and there are many excipients for which we need to develop monographs. This work was started some years ago, and I am honored to have been part of it during the 2005-2010 Revision Cycle, but there is still a long way to go. I would be very honored to be able to lead and continue to work on the project during the next revision cycle, and to help USP in other ways.



MONOGRAPHS – DIETARY SUPPLEMENTS EXPERT COMMITTEE

DENNIS K. J. GORECKI, PH.D.



Education

1973: Ph.D. (Medicinal Chemistry), University of Saskatchewan
1969: B.S.P. (Pharmacy), University of Saskatchewan

Professional Experience

11/1982 to present Tenured Professor, College of Pharmacy and Nutrition, University of Saskatchewan
7/1998 to 8/2009 Dean of Pharmacy and Nutrition, University of Saskatchewan
7/2005 to 6/2006 President, Canadian Council for the Accreditation of Pharmacy Programs
7/1999 to 6/2001 President, Association of Deans of Pharmacy of Canada (ADPC)

USP Experience

2005 to 2010 Member, Dietary Supplements – General Chapters Expert Committee
2000 to 2005 Member, Dietary Supplements – Botanicals Expert Committee
7/1998 to 6/1999 Chair, Division of Standards Development Executive Committee
7/1998 to 6/1999 Member, Committee of Revision Nominating Committee Representing Division of Standards Development

Other Relevant Experience

1/2010 to present Drug Advisory Committee of Saskatchewan, Chair – Appointed by Minister of Health
3/2010 to present Blueprint for Pharmacy Steering Committee, Elected Chair
1/1988 to 6/1999 Saskatchewan Drug Quality Assessment Committee, Member – Appointed by Minister of Health

Biography

Dennis K. J. Gorecki, Ph.D., is a Professor of Pharmacy in the College of Pharmacy and Nutrition at the University of Saskatchewan. He served as Dean of Pharmacy and Nutrition from 1998 to 2009. Dr. Gorecki has also served in other leadership roles, including President of the ADPC, President of the Canadian Council for the Accreditation of Pharmacy Programs and Chair of the Health Sciences Deans at the University of Saskatchewan. Recently, he spearheaded the development of a white paper on governance and administrative structure for the Health Sciences, and for the new Academic Health Sciences facility being established at the University of Saskatchewan. Dr. Gorecki has provided academic expertise, vision, and leadership in a host of initiatives to advance public health, the education of health professionals, and directions for the future health workforce in Canada. He represented the ADPC on the national Blueprint for Pharmacy Taskforce and the Moving Forward Pharmacy Human Resources Sector Study, which recently released a number of important recommendations that will ultimately affect the pharmacy profession. He is currently representing pharmacy on the National Task Force to Review the Future of Canada's Academic Health Sciences Centres. Dr. Gorecki has research interests and expertise in drug design, pharmaceutical and quality control analysis, pharmacopeial standards of drugs and dietary supplements, and the analysis of natural products. He has published over 100 research articles, abstracts, and technical reports. For the past 19 years, Dr. Gorecki has provided expertise, oversight, and distinguished service to USP through service on Dietary Supplements Expert Committees, the Division of Standards Development Executive Committee, and the Committee of Revision Nominating Committee.

Statement of Interest

I have gained considerable experience in the drug standards-setting process as undertaken by the USP, beginning in 1990 with the Subcommittee on Vitamins, Minerals, and Enterals. This Subcommittee played an important role in the establishment of the now widely accepted standards for dietary supplements. Since then I have served in numerous other roles within the Organization, including as Chairperson of the then Division of the Standards Development Executive Committee. I sincerely believe that, with the vast knowledge I have gained and my interest in drug and drug product standards, I can continue to contribute to the mandate of the USP in a meaningful way during the next cycle.



MONOGRAPHS – DIETARY SUPPLEMENTS EXPERT COMMITTEE

WAYNE R. WOLF, PH.D.



Education

1998: M.S. (Technology Management), University of Maryland University College
1969: Ph.D. (Chemistry), Kent State University
1965: B.S. (Chemistry), Kent State University

Professional Experience

7/1971 to present Research Chemist, U.S. Department of Agriculture (USDA)
5/1994 to 2/1995 Acting Research Leader
 Nutrient Data Lab, Agricultural Research Service (ARS), USDA
10/2002 to 9/2003 Acting National Program Leader
 Human Nutrition, ARS, USDA
5/1988 to 7/1993 Visiting Research Associate, National Institute Standards and
 Technology (NIST)
7/1967 to 7/1971 Captain, Research Chemist, U.S. Air Force

USP Experience

2005 to 2010 Vice Chair, Dietary Supplements – Non-Botanicals Expert Committee

Other Relevant Experience

1/1990 to present AOAC – 2003 Fellow; Founder and Chair, Technical Division on Reference Materials
9/1983 to present Founded and organized a series of International Symposia on Biological and Environmental
 Reference Materials.
1/1975 to present Responsible for and collaborated in numerous certification projects for food/dietary
 supplement Standard Reference Materials (SRMs) from NIST

Biography

Wayne R. Wolf, Ph.D., is a Research Chemist for the USDA. He began his work at the USDA in 1971 in the Human Nutrition Division of the Agricultural Research Service, working in analytical method development to determine components in foods and biological materials, focusing on trace elements and vitamins. His present research focuses on the development of analytical methods for determining water soluble vitamins in foods and dietary supplements. Dr. Wolf has published over 300 papers, book chapters, and abstracts. Two methods from his research group have been recognized as Peer Validated Methods by AOAC International. Dr. Wolf has also been involved in aspects of the development of food based Reference Materials, in collaboration with NIST and the international metrology community. In 1983, he initiated and founded a series of 12 International Symposia on Biological and Environmental Reference Materials, for which he received significant recognition. In 1989, Dr. Wolf chaired a Subcommittee on Reference Materials for the AOAC International Task Force on Methods of Analysis for Nutrition Labeling, which led to his founding of the AOAC Technical Division on Reference Materials (TDRM). As the Founding Chair of TDRM, Dr. Wolf proposed the current AOAC Proficiency Testing Program and the establishment of formal procedures to matching specific Reference Materials to AOAC methods. He served on a number of AOAC committees, including the Editorial Board and the Methods Committee on Food and Nutrition. In 2003, Dr. Wolf was elected as a Fellow of AOAC International in recognition of his service.

Statement of Interest

My extensive professional expertise in chemical analysis of ingredients and development of reference materials for foods and dietary supplements has been with an overarching goal to help to improve the measurement systems in these areas. Present service on the Dietary Supplements – Non-Botanicals Expert Committee has shown me the value of these committees as an appropriate venue to expand my contributions to this goal. I can contribute positively to the expanding role to improve metrology aspects of USP activities.



MONOGRAPHS – FOOD INGREDIENTS EXPERT COMMITTEE

ROGER A. CLEMENS, DR.P.H.



Education

1978: Dr.P.H. (Nutrition/Biological Chemistry), University of California, Los Angeles
1973: M.P.H. (Nutrition), University of California, Los Angeles
1972: B.A. (Bacteriology), University of California, Los Angeles

Professional Experience

2006 to present Associate Director, Regulatory Science and Adjunct Professor, Pharmacology and Pharmaceutical Sciences, University of Southern California (USC) School of Pharmacy
1999 to present Vice President, Science and Technology, PolyScience Consulting
2001 to 2006 Director, Analytical Research Services and Complimentary Therapeutics Laboratory and Adjunct Professor, Molecular Pharmacology and Toxicology, USC

USP Experience

2009 to present Member, Pharmacopeial Education Programming Committee
2005 to 2010 Member, Dietary Supplements – Non-Botanicals Expert Committee
Member, Food Ingredients Expert Committee
Member, Gastroenterology Information Expert Committee

Other Relevant Experience

1979 to present Various leadership roles and responsibilities, including 2010 incoming Chair-elect, Institute of Food Technologists (IFT)
2008 to 2010 Member, USDA, 2010 Dietary Guidelines Advisory Committee
2009 to 2010 Public Member, American Dietetic Association, Commission on Dietetic Registration
2007 to 2011 External Assessor, Grant Application Review, National Health and Medical Research Council of Australia

Biography

Roger R. Clemens, Dr.P.H., is Associate Director of the Regulatory Science program and adjunct Professor of Pharmacology and Pharmaceutical Sciences at the USC School of Pharmacy, and is the Scientific Advisor for the E.T. Horn Company. He is an appointed member of the USDA 2010 Dietary Guidelines Advisory Committee, with primary responsibilities in food safety, dietary lipids, and health. As spokesperson for the IFT, he has been cited and interviewed by more than 500 domestic and international health journalists' discussions on contemporary health, nutrition, and food safety issues. He is the contributing public member of the Commission on Dietetic Registration for the American Dietetic Association. Dr. Clemens is a professional member and Fellow of IFT and a former member of the IFT Board of Directors. He has served on several IFT expert panels, including Functional Foods and Making Decisions about the Risks of Chemicals in Foods with Limited Scientific Information. He established and contributes to the monthly Food, Medicine, and Health column published in *Food Technology*. He is also a Fellow of the American College of Nutrition and the Marilyn Magaram Center for Food Science, Nutrition and Dietetics. As an active member of the American Society for Nutrition (ASN), Dr. Clemens serves as a spokesperson and chairs its Public Information Committee. He served as the Scientific Advisor for Nestlé USA for more than 21 years and is currently a member of three USP Expert Committees.

Statement of Interest

It has been an exceptional professional experience to have served on several USP committees during the 2005-2010 cycle. I look forward to continued service as USP carves a unique and important role in the food science, nutrition and health continuum through the establishment of higher ingredient standards and publication of outstanding food ingredient monographs.



MONOGRAPHS – FOOD INGREDIENTS EXPERT COMMITTEE

ANDREW G. EBERT, PH.D.



Education

1962: Ph.D. (Pharmacology), Purdue University
1960: M.S. (Pharmacology), Purdue University
1957: B.S. (Pharmacy), Brooklyn College of Pharmacy

Professional Experience

11/2004 to present Founder and President, ETM, Inc.
2004 to present Consultant, The Kellen Company
1985 to 2004 Senior Vice President, The Kellen Company
1983 to 1985 Vice President, Food Technology and QA, Pet Inc.

USP Experience

2006 to 2010 Chair, Food Ingredients Expert Committee
2006 to 2010 Member, Council of Experts
2006 Chair, Food Ingredients Stakeholder Forum

Other Relevant Experience

1988 to 1995 President, International Food Additives Council (IFAC)
Consultant Committee on Revisions, *Food Chemicals Codex (FCC)*, 5th Edition
Member, Committee on Revisions, *FCC*, 4th Edition
Observer/Non-Governmental Organization (NGO), Codex Committee on Food Additives

Biography

Andrew G. Ebert, Ph.D., has comprehensive experience in management, demonstrated achievements in scientific and product safety matters, and a worldwide reputation in food safety and regulation. He is founder and President of ETM, Inc. and a consultant to the Kellen Company. He joined the Kellen Company as Senior Vice President in 1985, following rapid progression in technical management with several food and pharmaceutical companies. At Kellen, Dr. Ebert assumed a variety of management and scientific responsibilities in local, national, and international food and drug regulatory, scientific, and legal matters. Dr. Ebert has devoted considerable time and energy to the Food and Drug Administration's Food, Science, and Nutrition Advisory Committee (an original member and one of only four representatives selected from industry when the committee was formed) and the *Food Chemicals Codex (FCC)*. Dr. Ebert has served on the revision committees of three of the seven editions of the *FCC* and currently chairs the USP Food Ingredients Expert Committee, charged with revising the *FCC*. He has authored several dozen papers, abstracts, and book chapters; contributed editorial columns; given numerous talks and briefings to industrial and consumer groups; and testified as an expert witness before the Select Senate Committees on Nutrition and Human Needs and Labor and Human Resources. He has been a guest lecturer at MIT's Department of Nutrition and Food Science. He is founder and Chair of the International Glutamate Technical Committee and has served on the Board of Directors of the Glutamate Association, U.S.A. and the National Food Processors Association. Dr. Ebert has also served as the Executive Director or President of IFAC, the Processed Apples Institute, and the Lignin Institute. He has been an observer at numerous meetings of the Food and Agricultural Organization (FAO)/WHO Codex Alimentarius Food Standards Programme. Dr. Ebert is also a member of the American Society for Pharmacology and Experimental Therapeutics and the Society of Toxicology. He is an IFT Fellow, was Chair of IFT's Toxicology and Safety Evaluation Division and the Committee on Codex Alimentarius, and received the 2004 IFT Bernard L. Oser Award for Excellence in Food Ingredient Safety Research. He is a member of Sigma Xi, the New York Academy of Sciences, and the Academy of Pharmaceutical Sciences. He was a Trustee of the Nutrition Foundation and chaired the Foundation's Food and Nutrition Liaison Committee.

Statement of Interest

I wish to continue over three decades of experience in participating in the development/revision of the *Food Chemicals Codex (FCC)*. The *FCC* is a unique compendium providing regulators, food processors and consumers with a valuable series of minimum standards for food ingredients. It is worthy of support from all who work to assist the USP.



GENERAL CHAPTERS – CHEMICAL ANALYSIS EXPERT COMMITTEE

ANTHONY C. BEVILACQUA, PH.D.



Education

1991: Ph.D. (Chemistry), Tufts University
1987: M.S. (Chemistry), Tufts University
1984: B.S. (Chemistry), University of Massachusetts at Boston

Professional Experience

2/1994 to present Director of Research and Product Development, Mettler-Toledo
Thornton, Inc.
2/1991 to 2/1994 Process Engineer, Mobil Solar Energy Corporation

USP Experience

2005 to 2010 Chair, Pharmaceutical Waters Expert Committee
2000 to 2005 Chair, Pharmaceutical Waters Expert Committee
1/1996 to 5/2000 Developed conductivity methods, answered questions, consulted scientific liaisons

Biography

Anthony C. Bevilacqua, Ph.D. is the Director of Research and Product Development at Mettler-Toledo Thornton, Inc., focusing on improved high temperature conductivity measurements, the impact of CO₂ on pure water, the use of ultrapure water as a conductivity solution standard, and other analytical methods related to high purity waters and other liquid analyses. Based on this work, Dr. Bevilacqua was the conductivity consultant to the USP and PhRMA throughout the mid-1990s during the development and implementation of USP General Chapters <645> *Water Conductivity* and <643> *Total Organic Carbon* (TOC) used for Purified Water and Water for Injection (WFI). Dr. Bevilacqua developed the theory, methods, and limits used for conductivity testing of these waters today. He has led national and international conferences on the impact of pharmacopeial requirements for Purified Water and WFI systems, as well as the effect of on-line real time measurements for in-process control of water systems. In the early 1990's, he worked on the manufacture of solar cells and solar panels for Mobil Solar Energy Corporation as a Process Development Scientist. Dr. Bevilacqua has authored more than 10 articles and 100 presentations related to water monitoring instrumentation, process control, water chemistry, and USP, European Pharmacopoeia Commission (EP), and Japanese Pharmacopoeia Commission (JP) requirements. He has chaired the USP Pharmaceutical Waters (PW) Expert Committee for the last ten years. Principal accomplishments of the Expert Committee include the harmonization of key chemical test methods (conductivity and TOC) with EP and JP, the updating of definitions and tests for packaged and Sterile Water monographs, development of USP training programs, and an exceptional record of rapid and complete response to public questions. He has co-authored chapters in the International Society for Pharmaceutical Engineering (ISPE) Water and Steam Baseline Guide and a Japan Parenteral Drug Association (PDA) water treatment book. He serves on the ISPE Critical Utilities Steering Committee with responsibility for organization of educational seminars. Dr. Bevilacqua is an active member of ISPE, PDA, American Chemical Society, the American Institute of Chemical Engineers, and American Society for Testing and Materials (ASTM) Technical Committee D19 on Water, and the Process Analytical Technology (PAT) Initiative of ASTM Technical Committee E55 on the Manufacture of Pharmaceutical Products.

Statement of Interest

I find the work as a USP expert volunteer professionally stimulating and challenging. As I work with members in my current Expert Committee or with other Expert Committees/disciplines/pharmacopoeias, or take questions from the public, I get to see the challenges of industry and public health that are much broader than my direct expertise. The exposure to alternative methods of water production, new analytical methods, and new demands from industry (green engineering, recycling, alternative test methods, for example) are just some of the challenges that expand my world. Also, I believe I have made a difference in the harmonization of Pharmaceutical Waters globally, and I can continue to leverage my experience to support USP activities and develop standards for the delivery of safe medicines and foods globally.



GENERAL CHAPTERS – CHEMICAL ANALYSIS EXPERT COMMITTEE

TIMOTHY J. WOZNIAK, PH.D.



Education

1984: Ph.D. (Analytical Chemistry), Indiana University
1978: B.S. (Chemistry), College of Wooster

Professional Experience

1/2004 to present Research Fellow, Eli Lilly & Company
1/2002 to 12/2003 Research Advisor, Eli Lilly & Company
1/1992 to 12/2001 Senior Research Scientist and Research Scientist, Eli Lilly & Company

USP Experience

2005 to 2010 Chair, Monograph Development – Cold, Cough and Analgesics Expert Committee
1/2004 to present Member, Council of Experts Nominating Committee
2000 to 2005 Chair, Pharmaceutical Analysis 2 Expert Committee; Member, Reference Standards Expert Committee and Executive Committee of the Council of Experts
1995 to 2000 Member, Chemistry 4 Subcommittee

Other Relevant Experience

2001 to 12/2003 AOAC working group to define International Organization for Standardization (ISO) standards for analytical laboratory accreditation
3/1984 to 6/1985 NIST, Standards Group

Biography

Timothy J. Wozniak, Ph.D., has over 25 years of experience in the pharmaceutical industry. He is currently a Research Fellow in Analytical Sciences R&D at Eli Lilly & Company, responsible for all aspects of development and registration for new drug products conducted globally, and mentoring scientists internally and externally in the disciplines of drug product development. His research experience includes automation, analytical methods and specifications, control strategy and standards setting, monograph development, and statistical experimental design. Dr. Wozniak has had extensive experience interacting with global regulatory authorities and trade organizations (AAPS, AOAC, PhRMA), influencing guidelines, policies, and practices related to the development of pharmaceuticals. He was one of the organizing committee members for the AAPS-FDA Industry Forum on QbD that led to a white paper on the concepts. He was involved in the definition of the AOAC ISO standard for analytical laboratory accreditation and several PhRMA Acceptable Analytical Practices. Dr. Wozniak has served on several task forces and in leadership roles within the AAPS to advance the education and practices of pharmaceutical scientists. He has served as a USP volunteer for 15 years. In addition to his service noted above, he was a member of the Working Group on HPLC Columns, Excipient Verification and Qualification Advisory Group, International Task Force, Convention Resolution 18 Advisory Group to enhance the engagement of convention members, and Fellowship Program Subcommittee. He also worked to improve USP's interactions on the FDA-industry initiative on QbD.

Statement of Interest

USP has evolved during my tenure from a U.S.-based standards-setting organization, with the mission to ensure the quality of medicines and standards for physicians, healthcare providers and patients, to one that is recognized globally. I have been privileged and take great satisfaction in participating in its evolution, with an emphasis on establishing and maintaining standards for drug substances and products (*USP-NF*). With the global increase in drug product adulteration/counterfeiting, the importance of the role of USP standards has increased significantly. I feel my qualifications will help deal with these problems. My desire is to continue my participation in the standards-setting process, specifically for general chapters which provide foundational science to all monographs, to establish high quality standards to ensure the safety of our medicines globally. Due to the complexity of the processes by which medicines are produced, including the increased role of imported raw materials and drug products, the need for flexible approaches to evaluate and ensure their quality can be met through tools such as performance-based methodology, for which I have been involved in their development. Since general chapters are referenced in every monograph, flexible approaches to their use is critical for implementing cutting-edge technology where required to assess quality. I believe my experience benefits the evolution of USP standards to meet these difficult challenges. I also enjoy my activities to recruit and mentor future USP volunteers, through Council of Experts, its Nominating Committee, and other programs.



GENERAL CHAPTERS – PHYSICAL ANALYSIS EXPERT COMMITTEE

GREGORY E. AMIDON, PH.D.



Education

1979: Ph.D. (Pharmaceutical Chemistry), University of Michigan
1978: M.S. (Pharmaceutical Chemistry), University of Michigan
1974: B.S. (Medicinal Chemistry, University of Michigan)

Professional Experience

9/2007 to present Research Professor, University of Michigan
6/2003 to 9/2007 Research Fellow, Pfizer, Inc.
6/1999 to 6/2003 Senior Research Advisor, Pharmacia Corporation
6/1992 to 6/1999 Senior Scientist IV, Pharmacia & Upjohn

USP Experience

2005 to 2010 Chair, Excipient General Chapters Expert Committee
2005 to 2010 Member, Executive Committee of the Council of Experts
2000 to 2005 Chair, Excipient Methods Expert Committee
1995 to 2000 Chair, Excipient Methods Expert Committee
1990 to 1995 Member, Excipients Subcommittee and Packaging and Stability Subcommittee

Other Relevant Experience

1996 to present Member, USA Steering Committee, Handbook of Pharmaceutical Excipients
1994 to present Member, Editorial Advisory Board, Journal of Pharmaceutical Sciences,

Biography

Gregory E. Amidon, Ph.D., is a Research Professor at the University of Michigan. Prior to joining the University of Michigan in 2007, he worked in the pharmaceutical industry for 28 years. He most recently served as Research Fellow with Pfizer leading the Michigan Materials Assessment Laboratory responsible for the physical and mechanical property characterization of compounds, excipients and formulations in early development. Dr. Amidon has held various research positions in pharmaceutical R&D for Pharmacia, Pharmacia & Upjohn, and originally The Upjohn Company. He has published extensively and is recognized for his expertise in the physical, chemical and mechanical property characterization of active pharmaceutical ingredients, excipients, and products as well as the development of scientific strategies for oral solid dosage form development. He is a frequent invited speaker on these topics at national and international forums. Dr. Amidon has served USP since 1990 in a variety of roles and has collaborated with USP Expert Committee members, USP staff, and others to develop or update over twenty USP test and informational general chapters that relate to the physical characterization and performance of pharmaceutical materials and products. Dr. Amidon is a member and Fellow of the American Association of Pharmaceutical Scientists and a past recipient of the Ebert Prize from the American Pharmaceutical (now Pharmacists) Association.

Statement of Interest

The availability of reliable, useful, high quality public standards is fundamentally important to patients. It assures the availability of high quality products in a transparent and cost effective way by facilitating communication among suppliers, manufacturers, consumers, and regulatory agencies. I have been involved in a variety of activities with USP since 1990. I am proud of the contributions that USP has made possible through its process of proposing, revising, and implementing standards, and of facilitating public discussion to improve pharmaceutical ingredients. A large part of my career has focused on the physical and chemical characterization of drugs and excipients and how these properties influence dosage form performance. My involvement with USP in the area of Physical Analysis would be an excellent fit with my background, interest, and passion.



GENERAL CHAPTERS – PHYSICAL ANALYSIS EXPERT COMMITTEE

GREGORY P. MARTIN, M.S.



Education

1980: M.S. (Analytical Chemistry), Villanova University
1974: B.S. (Chemistry), Drexel University

Professional Experience

1/2009 to present President, Complectors Consulting, LLC
11/1980 to 5/1982, Director, Merck Research Laboratories
4/1986 to 11/2008
5/1982 to 4/1986 Kiwi Brands, Quality Control Manager
6/1975 to 11/1980 Senior Bioanalytical Chemist, Wm. H. Rorer, Inc.

USP Experience

11/2008 to present Trainer, Pharmacopeial Education Department (contractor)
2005 to 2010 Vice Chair, General Chapters Expert Committee
2000 to 2005 Member, Pharmaceutical Analysis 4 Expert Committee
6/1999 to /2001 Member, Biopharmaceutical Issues Project Team

Other Relevant Experience

6/1999 to 6/2004 Member, PhRMA Dissolution Expert Committee
3/2009 to present Steering Committee, AAPS In Vitro Release and Dissolution Testing Focus Group

Biography

Gregory P. Martin, M.S., has over 30 years experience in the pharmaceutical industry. He is President of Complectors Consulting, where he provides consulting and technical training in pharmaceutical analytical chemistry, including dissolution, method development and validation lifecycle, residual solvents, excipients, and instrument qualification. As Director of Pharmaceutical Analytical Chemistry at Merck Research Laboratories, Mr. Martin had a leadership role in the global harmonization of analytical development procedures, Mr. Martin was involved in providing analytical support for over 100 compounds in development. He has served as an expert volunteer at USP for over 12 years, most recently in the role of Vice Chair of the General Chapters Expert Committee, where he contributed significantly to general chapters on chromatography, method validation and verification, residual solvents, analytical instrument qualification, dissolution development, and others.

Statement of Interest

USP serves a crucial role for the global pharmaceutical community. I would like to continue to contribute to that role to assure that USP provides optimal guidance to the community in a way that provides true value but is not unnecessarily burdensome, providing leadership and developing guidances. My interests are primarily focused in pharmaceutical analytical chemistry, particularly as it relates to dissolution, analytical method lifecycle (from development and validation through transfer), impurities, residual solvents and excipients. My background of 30 years in pharmaceutical development (including large and small pharma, innovators, and generics) and my experience with USP, especially the General Chapters Expert Committee, has prepared me well to contribute significantly to the advancement of the USP.



GENERAL CHAPTERS – BIOLOGICAL ANALYSIS EXPERT COMMITTEE

CHARLES S. CRAIK, PH.D.



Education

1981: Ph.D. (Chemistry), Columbia University
1978: M.A. (Chemistry), Columbia University
1976: B.S. (Chemistry), Allegheny College

Professional Experience

1/1999 to present Director, Chemistry and Chemical Biology Graduate Program,
University of California, San Francisco (UCSF)
1/1995 to present Professor, Departments of Cellular and Molecular Pharmacology,
UCSF
1/1985 to 1/1995 Assistant Professor to Professor, Pharmaceutical Chemistry,
Biochemistry and Biophysics, UCSF

USP Experience

7/2009 Speaker, USP Enzyme Workshop

Other Relevant Experience

Biography

Charles S. Craik, Ph.D., is the architect and Director of the Chemistry and Chemical Biology Graduate Program at the UCSF Comprehensive Cancer Center. Through this program, faculty have been training future scientists to make strong contributions at the interface of chemistry and biology since 1998. This graduate program spans seven departments at UCSF and the University of California, Berkeley. He is an internationally known chemical biologist and expert on proteases. Dr. Craik uses site-specific mutagenesis, protein engineering, structure-function studies, and structure-based drug design to develop strategies for detecting and targeting proteases that play a role in infectious diseases, including AIDS, herpes virus infections, Chagas disease, malaria, and cancers. He has developed innovative strategies for targeting the AIDS virus, HIV, and in related work, he led a team that identified and determined the structure and function of the protease made by the virus associated with Kaposi's sarcoma, a complication of AIDS. He and his collaborators are using information they are learning about this drug target to develop an antiviral for Herpes virus infections. Dr. Craik's lab has recently identified proteases needed by tumors but not by normal cells. He and his collaborators have developed a promising strategy for using their activity for early cancer detection and for blocking the function of these proteases without compromising the vital workings of our own normal proteases. Dr. Craik is an executive committee member of the QB3 institute, a cooperative effort among the UC campuses at San Francisco, Berkeley and Santa Cruz to develop technologies for improving human health.

Statement of Interest

I am interested in defining the role of enzymes in complex biological systems and the standardization of enzyme measurements and activity assignments. I have consulted for numerous pharmaceutical and biotechnology companies and am founder of Catalyt Biosciences.



GENERAL CHAPTERS – BIOLOGICAL ANALYSIS EXPERT COMMITTEE

WESLEY E. WORKMAN, PH.D.



Education

1983: Ph.D. (Microbiology), Louisiana State University
1981: M.S. (Microbiology), Louisiana State University
1979: B.S. (Medical Technology) Kansas State University

Professional Experience

12/2003 to present Associate Research Fellow/Team Leader, Pfizer Inc.
10/1998 to 2/2003 Analytical Project Leader, Searle/Pharmacia/Pfizer
4/1996 to 10/1998 Analytical Technology Director, Monsanto
7/1985 to 4/1996 Senior Research Scientist through Senior Group Leader, Monsanto,

USP Experience

1/2008 to present Chair, Heparin/Unfractionated Low Molecular Weight Heparin Ad Hoc Advisory Panels
2000 to 2010 Member, Reference Standards Expert Committee
12/2005 to 1/2008 Member, Nucleic Acid-Based Techniques Ad Hoc Advisory Panel
2000 to 2005 Vice Chair, Pharmaceutical Analysis 5 Expert Committee
1/1992 to present Member, Biologics and Biotechnology – Proteins and Polysaccharides Expert Committee

Other Relevant Experience

Biography

Wesley E. Workman, Ph.D., has over twenty-four years' experience in the biopharmaceutical industry, working at various management and technical positions and serving as the analytical leader for successful biopharmaceutical product approvals. For the past six years, Dr. Workman has lead the Technical Services function in the Biopharma Quality Organization within Pfizer Global Manufacturing. Dr. Workman and his laboratory support the ongoing manufacture and technology transfer of a number of commercial recombinant proteins, oligonucleotides, glycosaminoglycans, enzymes, and blood products. He has been a USP Expert Committee volunteer since 1992 and has participated on a number of Ad Hoc Advisory Panels.

Statement of Interest

I have had the privilege of being a USP volunteer for many years and contributed to the USP mission in a variety of ways. One of my most meaningful roles was as author for some of the general chapters for biological analysis (i.e., USP Biotechnology-Derived Articles general chapter series). My involvement with biological analysis general chapters began in 1996 with a chapter on total protein assays [*Pharmacopeial Forum*, 22(4), p. 2527, formerly known as <1047>] and most recently included a chapter on residual DNA analysis of biopharmaceuticals (<1130>, *Pharmacopeial Forum*, 33(5), p. 1025, 2007). During that time, I had the opportunity to serve as the USP reviewer for similar chapters submitted by other pharmacopeias for harmonization, and represented the USP at pharmacopeial harmonization meetings on biological analysis chapters. I am currently a member of an Advisory Panel writing a general chapter that is in progress. The biological analysis general chapters have evolved over the years. I have observed this evolution and gained an understanding of the value of a general chapter, and what elements should be included to make a general chapter valuable. This evolution continues today with general chapters describing process/ancillary materials and the development of procedural standards to support analytical platforms described in the general chapters. It is both challenging and rewarding to develop a general chapter that is not only useful to analytical scientists but is also informative to other pharmaceutical professionals, as well as the public that is served by the USP. I am seeking the role as Chair of General Chapters – Biological Analysis because biological analysis is my profession and my interest. I have the desire to work with others as they develop new general chapters, mentoring them as needed, and celebrating their success. I look forward to working with others so that, through the new general chapters we develop, we leave something valuable to the pharmaceutical profession that those who follow us can build upon.



GENERAL CHAPTERS – DOSAGE FORMS EXPERT COMMITTEE

JAMES E. DEMUTH, PH.D.



Education

1974: Ph.D. (Pharmacy Continuing Education), University of Wisconsin-Madison
1972: M.S. (Pharmacy Continuing Education), University of Wisconsin-Madison
1970: B.S. (Pharmacy), Drake University

Professional Experience

12/1974 to 12/2009 Professor, University of Wisconsin-Madison

USP Experience

2005 to 2010 Chair, General Chapters Expert Committee
2000 to 2005 Chair, Biostatistics Expert Committee

Other Relevant Experience

Biography

James E. De Muth, Ph.D., is a professor in Extension Services in Pharmacy and the School of Pharmacy at the University of Wisconsin-Madison. His primary responsibilities are the development, implementation, and evaluation (relying heavily on statistical methodology) of continuing education offerings for individuals in the pharmaceutical industry and pharmacists within the U.S. In recent years, Dr. De Muth has focused primarily on outreach programs for scientists working in the pharmaceutical industry, creating two new Land O'Lakes Conferences (bioanalytical and drug metabolism/applied pharmacokinetics), expanded spring on-campus short courses (including new courses on toxicology, stability, drug metabolism and nanoparticles), created a three course series on applied drug development, and expanded onsite and regional short courses. Dr. De Muth has authored over 40 research articles in the pharmacy and adult education literature and the textbook, *Basic Statistics and Pharmaceutical Statistical Applications*. He has taught over 130 statistical short courses in the U.S., Canada, Puerto Rico, Western Europe, China, and the Middle East. For over 20 years, he also served on the Institutional Review Board of Covance Laboratories in Madison. Dr. De Muth received the 1993 Rufus A. Lyman Award for most notable original research and/or scholarly work published in the American Journal of Pharmaceutical Education and the 2000 William A. Blockstein Award from the AACP for contributions to the field of continuing pharmaceutical education. Dr. De Muth has led USP Expert Committees for the past ten years, chairing the Biostatistics and General Chapters Expert Committees.

Statement of Interest

I have past experience with USP and the desire to continue to help with the setting of public standards to assure the highest quality drugs for patients.



GENERAL CHAPTERS – DOSAGE FORMS EXPERT COMMITTEE

GORDON L. FLYNN, PH.D.



Education

1965: Ph.D. (Pharmacy), University of Wisconsin, Madison
1960: B.S. (Pharmacy), Rutgers, the State University

Professional Experience

9/2001 to present Professor Emeritus, Pharmaceutics, University of Michigan College of Pharmacy
9/1972 to 8/2001 Professor, University of Michigan College of Pharmacy
8/1988 to 10/1989 Vice President, Cygnus Transdermal Systems
7/1965 to 8/1972 Senior Scientist, The Upjohn Company

USP Experience

2005 to present Member, Dermatology Expert Committee

Other Relevant Experience

Biography

Gordon L. Flynn, Ph.D., has worked in the pharmaceutical industry and academia for more than 30 years. The majority of his career was spent at the University of Michigan School of Pharmacy, but he had several sabbatical and adjunct assignments at the University of Utah Department of Dermatology, the University of California San Francisco, and the University of Michigan Dental Research Institute. He was the recipient of many prestigious awards and recognition, including the 2000 Distinguished Alumnus Award from the University of Wisconsin School of Pharmacy, the 1999 Distinguished Alumnus Award from Rutgers University College of Pharmacy, and the 1973 Ebert Prize from the American Pharmaceutical (now Pharmacists) Association. He is a charter member of the American Association of Pharmaceutical Scientists (AAPS) and elected an AAPS Fellow in 1986. Dr. Flynn was also an Elected Fellow of the Academy of Pharmaceutical Sciences in 1975. Dr. Flynn holds approximately 12 U.S. patents and has published about 185 book chapters and peer-reviewed scientific articles.

Statement of Interest

I am finishing the writing of a book on dosage form science, which fits in to what USP is doing with its standards-setting activities.



GENERAL CHAPTERS – MICROBIOLOGY EXPERT COMMITTEE

JAMES E. AKERS, PH.D.



Education

1976: Ph.D. (Medical Microbiology), University of Kansas School of Medicine
1971: B.S. (Cell Biology and Physiology), University of Kansas

Professional Experience

1/1990 to present President, Akers Kennedy & Associates
7/1988 to 12/1990 Director, Quality and Regulatory Affairs, WelGen (an affiliate of Wellcome Biotech/Burroughs Wellcome)
9/1981 to 7/1988 Manager, Microbiology/Compliance, Burroughs Wellcome, Co. (Now GSK)
9/1977 to 6/1981 Instructor-Assistant Professor, East Carolina School of Medicine
9/1976 to 8/1977 Instructor/Post-doctoral fellow, Kansas State University

USP Experience

2005 to 2010 Member, Council of Experts Executive Committee
2005 to 2010 Chair, Microbiology and Sterility Assurance Expert Committee
2000 to 2005 Member, Microbiology Expert Committee
4/1993 to 9/2000 Member, Advisory Panel supporting the Microbiology Subcommittee, particularly in areas relating to clean room management and laboratory systems and technology

Other Relevant Experience

8/1987 to 8/1999 Parenteral Drug Association (PDA), Member, Board of Directors
1991 to 1993 PDA, President
9/1984 to present Chair, PDA Research Committee; Chair, PDA Science Advisory Board; Member, Technical Report task forces for T/Rs/ No. 1 (sterilization by moist heat), No. 13 Environmental Monitoring, No. 22 media fill testing, and No. 34.; Member, numerous program committees

Biography

James E. Akers, Ph.D., has nearly 30 years experience in the pharmaceutical industry and is the co-founder and President of Akers Kennedy & Associates, a biological/pharmaceutical technical consulting firm. Dr. Akers served as President of the PDA from 1991 to 1993 and as a member of the PDA Board of Directors from 1986 to 1999. He has lectured worldwide and taught numerous pharmaceutical technology courses, including training for the U.S. FDA. Having edited a book on isolation technology, he is preparing a second book on the topic. Dr. Akers has also authored 11 textbook chapters and more than 100 technical and review articles on a variety of subjects, including validation, aseptic processing, contamination control, environmental monitoring and control, biotechnology, isolator technology, sterilization and disinfection, sterility testing, media fill testing, hazard analysis and critical control points, pharmaceutical microbiology, and regulatory compliance.

Statement of Interest

I have served as a USP volunteer since 1993 and I am the current Chair of the Microbiology and Sterility Assurance Expert Committee. I am a strong believer in the mission of USP and the central scientific role USP plays in standard setting for the analysis of healthcare products and ingredients. The USP Microbiology Expert Committee is very active and working hard to evaluate and consider how best to implement newer technologies for microbiological analysis. I am interested in providing continuity and leadership so that the Expert Committee can efficiently complete the activities we initiated over the last five years. I am also vitally interested in using my contacts within industry and the practitioner community to ensure the recruitment of new scientists for our committee so that we it can continue to be a vibrant and active contributor to USP's success.



GENERAL CHAPTERS – MICROBIOLOGY EXPERT COMMITTEE

ANTHONY M. CUNDELL, PH.D.



Education

1971: Ph.D. (Microbiology), Lincoln University, Canterbury, New Zealand
1968: M.S. (Biochemistry), Victoria University of Wellington, New Zealand
1967: B.S. (Biochemistry and Chemistry), Victoria University of Wellington, New Zealand

Professional Experience

3/2006 to present Director, Pharmaceutical Sciences Microbiology, Merck Research Laboratories (Formally Schering-Plough Research Institute)
3/2005 to 2/2006 Consultant, Independent Microbiological Consultant
7/1990 to 2/2005 Associate Director, Microbiological Development, Wyeth Pharmaceuticals
9/1981 to 6/1990 Associate Director, Quality Assurance, New York Blood Center

USP Experience

2005 to 2010 Member, Microbiology and Sterility Assurance (MSA) Expert Committee
2000 to 2005 Member, Analytical Microbiology Expert Committee

Other Relevant Experience

3/1997 to 6/2000 Chair, Parenteral Drug Association (PDA) Task Force responsible for the Technical Report No. 33, *The Development, Validation, and Implementation of New (Rapid) Microbiological Methods*

Biography

Anthony M. Cundell, Ph.D., is the Director of Pharmaceutical Sciences Microbiology at the Schering-Plough Research Institute, managing a 16-person R&D microbiology lab. Dr. Cundell was a member of the team at the New York Blood Center responsible for the development and implementation of the solvent/detergent viral inactivation process for human coagulation factors. He chaired the PDA Task Force responsible for the publication of the groundbreaking 2000 Technical Report #33, *The Evaluation, Validation, and Implementation of New Microbiological Testing Methods*. In addition, Dr. Cundell has published extensively in the areas of rapid microbial methods, water activity determination, sterilization processes, microbial identification, and risk assessment. He contributed to and co-edited *Water Activity Applications in the Pharmaceutical Industry*, published in 2009. He was a 2005-2010 member of the PDA organizational committee for the Annual Pharmaceutical Microbiology Conference.

Statement of Interest

As a member of the 2000-2005 and 2005-2010 Microbiology Expert Committees, I have been an active participant in the USP revision process as the primary author of seven general test and informational chapters and worked with fellow committee members to make the MSA Expert Committee one of the most productive USP Expert Committees. I would like the opportunity to contribute within the framework of the new USP committee organization, to continue the work especially in the areas of microbial requirements in *USP-NF* monographs, rapid microbial testing technologies, nutritional supplements, and sterility assurance.

GENERAL CHAPTERS – PACKAGING, STORAGE, AND DISTRIBUTION

EXPERT COMMITTEE

MICHAEL N. EAKINS, PH.D.



Education

1972: Ph.D. (Physiology), University of London

1968: B.Sc. (Physiology and Zoology), University of London

Professional Experience

1/2003 to present Principal Consultant, Eakins & Associates

8/1994 to 12/2002 Senior Director, International Packaging Center, Bracco S.p.A.

8/1994 to 8/1998 Senior Director, Product Internationalization, Bracco S.p.A.

8/1984 to 8/1994 Director, Diagnostics Development, Bristol Myers Squibb

USP Experience

2005 to 2010

Member and Vice Chair, Packaging and Storage Expert Committee

2010

Prepared a two-day teaching course for USP on parenteral packaging and pre-filled syringes

2007, 2008, 2009

USP's 2007, 2008, 2009 Annual Scientific Meetings, presenter on parenteral packaging, anti-counterfeiting technologies, and counterfeit drugs

Other Relevant Experience

2007 to present

Published five papers on pre-filled syringes; chaired five international conferences on pre-filled syringes and three conferences on containers and barrier systems

2008 to 2009

Gave five presentations on the revision of <1079> to conferences in North America and Europe

2006 and 2007

Chair, Parenteral Drug Association's (PDA) Pharmaceutical Anti-Counterfeiting Forums in Bethesda, Maryland and Berlin

Biography

Michael N. Eakins, Ph.D., has spent his career in pharmaceutical R&D in both the UK and U.S.A. He is the Founder and Principal Consultant of Eakins & Associates, a consulting company dedicated providing advice in the areas of parenteral packaging, pre-filled syringes, extractables and leachables, and anti-counterfeiting strategies and technologies. He spent eight years at Bracco S.p.A., first as Senior Director for Product Internationalization and then as Senior Director for the International Packaging Center. For ten years, Dr. Eakins was the Director of Bristol-Myers Squibb's Diagnostics Development Department, responsible for the development of all diagnostic products. Dr. Eakins has held research positions in the Medical Research Council's Cyclotron Unit (UK) and at E. R. Squibb & Sons (U.S.) in the area of radiopharmaceutical research.

Statement of Interest

As Vice Chair of the Packaging and Storage Expert Committee (PSEC), I have been active in revising current general chapters, especially <660> *Containers—Glass* and <1079> *Good Storage and Shipping Practices*, and in developing a new General Chapter <670> *Pharmaceutical Coil* and providing the *Stimuli* article on <670> in the *Pharmacopeial Forum*. I have also been an active speaker at USP Annual Scientific Meetings. I would like to serve in the next cycle to continue the work outlined in the strategic plan that I helped develop for the PSEC and bring my expertise in glass and plastic parenteral packaging, extractables and leachables, and anti-counterfeiting technologies to support the USP.



**GENERAL CHAPTERS – PACKAGING, STORAGE, AND DISTRIBUTION
EXPERT COMMITTEE**

MARY G. FOSTER, PHARM.D., B.F.A.



Education

1983: B.S. and Pharm.D., University of Kentucky
1976: B.F.A., Western Kentucky University

Professional Experience

11/2009 to Present VP Quality, Corporate (30 sites worldwide), Catalent Pharma Solutions
4/2007 to 11/2009 VP Regulatory Compliance, Corporate, Catalent Pharma Solutions
7/2003 to 4/2007 Vice President Regulatory Compliance, Cardinal Health Inc.,
Pharmaceutical Technologies and Services Division
8/1995 to 6/2003 Vice President Quality and Regulatory Affairs (13 sites the U.S. and
European Union), PCI, Inc.

USP Experience

2005 to 2010 Member, Packaging and Storage Expert Committee
12/2009 Member, Excipients General Chapters, <1197> *Good Distribution Practices for Bulk Pharmaceutical
Excipients* Joint Advisory Panel
2/2010 to present Recommended USP Advisory Panel on Dissolution for Liquid Filled Capsules; under creation
2010 USP Webinar PF General Chapter <1079> May 2010
2009 to 2010 Presented USP Annual Scientific Meetings on General Chapter <1079> Storage and
Transportation of Drug Products
2007 to 2010 Various presentations to industry General Chapter <1079>: PDA, IQPC, IATA
2006 Presented USP workshop in Brazil Sindusfarma on packaging and labeling of drug products

Other Relevant Experience

1989 to present Director, cGMP Training: Center for Professional Advancement: teaching FDA cGMPs in
USA and EU annually
3/2010 Nominated for 2010-2011 Advisory Board for IATA
3/2009 to 3/2010 Advisory Board, International Air Transportation Association (IATA)
2005 to 2007 Advisory Board, New Jersey Institute of Technology
1985 to 1987 National Institutes of Health (NIH) Committee Member, Distribution of drug products across
the globe

Biography

Responsible for the creation of a Quality Management System for a new company that was formed from divestiture (Cardinal to Catalent). Responsible for developing connections within the industry and world-wide regulatory bodies to ensure a continuous understanding and improvement process for quality processes. Over 30 years experience in human pharmaceutical/biotechnology, veterinary, and over-the-counter monograph products; dietary supplements; medical devices and cosmetics, all-in-one or a combination of regulatory compliance, regulatory affairs, quality control, and quality assurance capacities for manufacturing, packaging, holding, and transportation of product encompassing global operations. Leadership experience in the roles of manager, director, and vice-president within a multi-cultural, diverse staff. Experience in oral, sterile, packaging, and printed component businesses and expertise in FDA, Health Canada and EU cGMPs and device Quality System development and implementation; with direct interface with South America, Australia and Japan in the development of compliance programs. Subject matter expert in creating and maintaining a compliant regulatory U.S. Drug Enforcement Administration environment.

Statement of Interest

I understand and value the work carried out by USP expert committees because I have experienced the positive results from our committee's outcomes. The guidance and standards that are created assure quality and safety for finished product. My main focus with committee oversight and work is to remain active in the revision process for current chapters and work on the creation of new chapters to provide future guidance and best standards of practice.



NOMENCLATURE, SAFETY, AND LABELING EXPERT COMMITTEE

MARY BAKER, B.S., M.B.A., PHARM.D.



Education

2000: M.B.A., Northwestern University Kellogg School of Management
1982: Pharm.D. (Pharmacy), University of Minnesota
1979: B.S. (Pharmacy), Purdue University

Professional Experience

5/2004 to present Medical Manager and Clinical Fellow, Hospira, Inc. Global Clinical Research and Development
12/1989 to 5/2004 Clinical Project Manager/Medical Specialist/Medical Writer, Abbott Laboratories Hospital Products Division
10/1984 to present Clinical Pharmacist (on call), Highland Park Hospital Pharmacy
6/1984 to 10/1984 Clinical Pharmacist, Childrens Memorial Hospital Chicago

USP Experience

2005 to 2010 Member, Nomenclature Expert Committee
2005 to 2010 Member, Sterile Compounding Expert Committee

Biography

Mary Baker, B.S., M.B.A., Pharm.D., is currently Medical Manager and Clinical Fellow for Global Medical Affairs at Hospira, Inc. She is responsible for directing clinical programs in infusion therapy, parenteral nutrition, medication error reduction, labeling and label enhancement, promotional review, and the development of small and large volume parenterals. Dr. Baker has presented at meetings of the American Society of Health-System Pharmacists (ASHP), the American Society for Parenteral and Enteral Nutrition, and the European Society for Clinical Nutrition and Metabolism. Her publications include articles in the *Journal of Parenteral and Enteral Nutrition*, the *American Journal of Health System Pharmacy (AJHP)*, the *International Journal of Pharmaceutical Compounding (IJPC)*, and *Pharmacotherapy*. Dr. Baker holds an affiliate faculty appointment at Purdue University School of Pharmacy and has lectured at numerous pharmacy schools on sterile compounding and careers in industry. She was recognized as a Distinguished Alumna of the Purdue University School of Pharmacy in 2004.

Statement of Interest

Health care professionals are expected to be perfect, but are only human. Medication errors, whether through labeling, naming, system defects, or improper sterile compounding, have the potential to cause harm, including death. USP has the opportunity to set standards for these areas that can help reduce errors. USP standards can eliminate reliance on urban legends, “the way it has always been done,” and conflicting opinions among the various health professions. Expert Committee participation is a multidisciplinary, collaborative approach which is the most effective way to achieve optimal patient care goals. Though I work full time in the pharmaceutical industry, I still practice pharmacy, mainly in the intensive care setting, which is an area where an error could have a tragic outcome. At Hospira, I develop and review over 300 labels and label changes annually and am active in medication error reduction initiatives. Sterile compounding has been de-emphasized in pharmacy schools for over 25 years and few schools have the expertise to provide adequate training. Clinicians need clear and consistent standards, nomenclature, and monographs to guide them for dealing with the more complex patients that are found in hospitals today.



NOMENCLATURE, SAFETY, AND LABELING EXPERT COMMITTEE

THOMAS P. REINDERS, PHARM.D.



Education

1972: Pharm.D., University of Cincinnati College of Pharmacy
1970: B.S. (Pharmacy), University of Cincinnati College of Pharmacy

Professional Experience

1995 to Present Associate Dean, Virginia Commonwealth University (VCU) School of Pharmacy
1984 to 1996 Director of Pharmacy Services, VCU – Medical College of Virginia Hospitals
1974 to present Associate Professor of Pharmacy and Pharmaceutics, VCU, School of Pharmacy
1970 to 1974 Pharmacist, Cincinnati Children’s Hospital, U.S. Veteran’s Administration (VA) Hospital, and Appalachian Regional Hospitals

USP Experience

2005 to 2010 Chair, Nomenclature Expert Committee
1990 to 2005 Member, Drug Nomenclature and Labeling Committee
2000 to 2005 Member, Parenteral Products: Industrial Ad Hoc Advisory Panel
1985 to 2000 Chair, Pharmacy Practice Advisory Panel (1990-2000)
Member, Pharmacy Practice Advisory Panel
1995 and 2000 USP Convention Delegate representing the VCU School of Medicine

Other Relevant Experience

1980 to 1984 Member, FDA Cardiovascular and Renal Drugs Advisory Committee

Biography

Thomas P. Reinders, Pharm.D., is a tenured faculty member and Associate Dean of the VCU School of Pharmacy, having joined the faculty of the school in 1974. In addition to his faculty responsibilities, Dr. Reinders has held a variety of administrative positions, including twelve years as the Director of Pharmacy Services at the Medical College of Virginia Hospitals. He completed pharmacy residency programs at the Cincinnati Children’s Hospital and the U.S. VA Hospital in Cincinnati. He is a fellow of the APhA Academy of Pharmacy Practice and the recipient of several honors including the Bowl of Hygeia Award for Outstanding Community Service, the VCU Distinguished Faculty Award for Teaching, the ASHP Award for Achievement in the Practice of Hospital Pharmacy on two occasions and the APhA Distinguished Achievement Award in Administrative Practice. For twenty-five years, Dr. Reinders has served as a USP volunteer. He is chair of the 2005-2010 Nomenclature Expert Committee and has been a member or chair of the committee for twenty years. He was chair of the Pharmacy Practice Advisory Panel from 1990 to 2000 and served as the USP Convention Delegate representing the VCU School of Medicine at the 1995 and 2000 membership meetings.

Statement of Interest

My volunteer experience with USP has been personally and professionally rewarding. I fully appreciate and value the impact that USP’s Expert Committee on Nomenclature, Safety, and Labeling can have on patient safety and public health.



COMPOUNDING EXPERT COMMITTEE

LISA D. ASHWORTH, B.S., R.P.H.



Education

1987: B.S. Pharmacy; University of Oklahoma College of Pharmacy

Professional Experience

11/2007 to present Clinical Pharmacist, Center for Cancer and Blood Disorders Children's Medical Center Dallas
6/2000 to 7/2007 Assistant to the Editor-in-Chief, *IJPC*
6/1997 to 1/2006 Co-Owner, Pharmacist, DSA Group, Inc., Brown's Pharmacies
3/1993 to 3/2004 Staff Pharmacist, Supervisor and Manager of Purchasing, Texas Health Resources

USP Experience

2005 to 2010 Member, Pharmacy Compounding Expert Committee; Subcommittee Chair, *USP-NF* General Chapter <1163> Revision; Formula Monograph Redesign Participant; Subcommittee Chair, *USP-NF* All Chapters Review; Subcommittee Member, *Pharmacists' Pharmacopeia* 2nd Edition

Other Relevant Experience

2004 to present Member and Chair, Research and Education Committee; Chair, Publication Committee; Member and Chair, Grant Application Evaluation Committee; Board Member – International Academy of Compounding Pharmacists Foundation
1987 to present Member, Treasurer, and President, Kappa Epsilon Alumnae, Dallas/Fort Worth and National Chapter

Biography

Lisa D. Ashworth, B.S., R.Ph., has worked in the pharmaceutical field for over 30 years. She is a Clinical Pharmacist in the Center for Cancer and Blood Disorders at Children's Medical Center Dallas. Her career as a practicing pharmacist includes Contributing Editor and Content Manager positions for *IJPC*, Inc., co-ownership of Brown's Pharmacies, and positions at Texas Health Resources, Baylor Medical Center at Irving, and Kroger Pharmacy. As a pharmacy technician, her employment history includes Norman Regional Hospital and Reavis Drug. She is an Adjunct Faculty member and a Preceptor for the University of Texas College of Pharmacy and a Residency Preceptor for the ASHP. She is a peer-reviewer for the *AJHP*. Ms. Ashworth's research interests include the quality and stability of sterile and non-sterile compounded preparations, pharmacokinetics, and the clinical application of commercially manufactured products and compounded preparations in pediatric and young adult populations. She is also a member of ASHP, the American Society of Pharmacy Law, AAPS, the National Community Pharmacists Association, the American Society of Pediatric Hematology and Oncology, the Texas Pharmacists Association, the American Medical Writer's Association, and the International Pharmaceutical Federation (FIP).

Statement of Interest

I am on the front line and have the wonderful opportunity to be able to compound and supervise the compounding of sterile and nonsterile preparations regularly. The challenges we face are sometimes greater and sometimes smaller than other pharmacies and institutions who compound, and it gives me the opportunity to assess what we can and cannot do and should and should not do when compounding. The Compounding Pharmacy Expert Committee has reviewed and revised a lot of material over the last four and one half years, which has given me the privilege to see the overall picture and how streamlining and harmonizing *USP-NF* is so important. The dosages available in countries outside the U.S. make us realize we have to think internationally when setting standards in USP so that we can be moving towards the future of a global pharmacopeia. I have spoken internationally on compounding and to the National Association of Boards of Pharmacy (NABP), worked on the drug information side of compounding with *IJPC*, and communicate regularly with compounders around the world for work and have formed personal relationships with many. My organizational skills are very good and I believe that we need to develop a plan to review all compounding monographs in *USP-NF* and update them to the new nomenclature of General Chapter <1151> *Pharmaceutical Dosage Forms*, and review all compounding general chapters assigned to this Expert Committee (General Chapters <797>, <795>, <1163>, etc.).



COMPOUNDING EXPERT COMMITTEE

GIGI S. DAVIDSON, B.S., R.P.H., DICVP



Education

2001: DICVP (Veterinary Pharmacy), International College of Veterinary Pharmacy
1983: B.S. (Pharmacy), University of North Carolina, Chapel Hill

Professional Experience

1/1992 to present Director of Clinical Pharmacy Services, North Carolina (NC) State University
College of Veterinary Medicine
5/1983 to 1/1992 Veterinary Clinical Pharmacist, NC State University College of Veterinary
Medicine

USP Experience

2005 to 2010 Member, Veterinary Drugs Expert Committee
2005 to 2010 Member, Pharmacy Compounding Expert Committee
2000 to 2005 Member, Veterinary Drugs Expert Committee
2002 to /2005 Member, Pharmacy Compounding Expert Committee

Other Relevant Experience

1/2009 to present Member, Pharmacy Compounding Accreditation Board (PCAB) Standards Revision Committee
1/2009 to 1/2009 Guest Surveyor/Consultant, NABP, Vet-Verified Internet Pharmacy Practice (V-VIPPS)
2009 to present Guest Surveyor/Consultant, PCAB accreditation site surveys
2009 to present American Veterinary Medical Association (AVMA) Council on Biological and Therapeutic Agents
(COBTA) Working Group for revision of Animal Health Institute Compounding Brochure
2004 FDA/AVMA Ad Hoc Committee on Veterinary Compounding Compliance Policy Guide
2004 North Carolina Board of Pharmacy – Committee for Compounding Regulations
2001 to 2004 AVMA/Council on Biologic and Therapeutic Agents Subcommittee on Prescribing/Dispensing
1/2002 to present Guest Member, AVMA /COBTA Working Group on Compounding
1998 to present Advisory Council, Society of Veterinary Hospital Pharmacists (SVHP)
1998 to 2002 President, SVHP
1992 to 1993 FDA Task Force on Compounding in Veterinary Medicine

Biography

Gigi S. Davidson, B.S., DICVP, has been the Director of Clinical Pharmacy Services at NC State University College of Veterinary Medicine for the last 18 years. She is an active member in many professional societies, serving as a consultant for NABP and PCAB and as a member of the AVMA's Council on Veterinary Biologicals and Therapeutics. Ms. Davidson serves as Faculty Consultant to the American College of Veterinary Pharmacists and Professional Compounding Centers of America (1999 to present). She is a preceptor for pharmacy students (1989 to present) and veterinary students (1987 to present). Ms. Davidson received the Preceptor of the Year award from Campbell University (2002) and the UNC Eshelman School of Pharmacy (2010). Ms. Davidson has authored or contributed to over 100 publications, text books, and presentations.

Statement of Interest

It is my belief that no greater individual opportunity exists for effecting relevant change in the quality of pharmaceutical care than USP voluntarism. While pharmacy compounding regulations and mandatory standards of quality are difficult to enact and vary greatly from state to state, USP expert committees are able to accomplish universal standard setting with the stroke of a pen and without conflict of interest. It is because of this unique opportunity that I desire to be reappointed to the Pharmacy Compounding Expert Committee for the 2010-2015 cycle, and would be honored to serve as Chair. The complexity and breadth of compounding pharmacy practice are increasing at an astonishing pace, and national changes in health care will dramatically affect compounding pharmacy practice during the 2010-2015 Convention cycle. As I have been intimately associated with the development, revision and harmonization of USP general chapters, monographs, and standards for the last 10 years, as well as been an active participant of other compounding standards-setting teams, I feel I am qualified to continue in a position of leadership that will secure the best future for compounding practice in this rapidly changing environment. If selected for Chair of the Pharmacy Compounding Expert Committee I would begin the cycle with a State of the Industry overview featuring key issues and problems associated with each of the specialty areas of compounding practice (e.g. nuclear, veterinary, cosmeceutics, to name a few) and challenge the committee to develop strategies to best ensure that the multifaceted practice of compounding pharmacy is thoroughly supported by USP compendia guidelines, standards, and monographs.



REFERENCE STANDARDS EXPERT COMMITTEE

MATTHEW W. BORER, PH.D.



Education

1992: Ph.D. (Chemistry); Indiana University Bloomington
1987: B.S. (Chemistry); Bowling Green State University

Professional Experience

12/2002 to present Advisor, Eli Lilly and Company
12/1998 to 12/2002 Manager, Eli Lilly and Company
1/1997 to 12/1998 Research Scientist, Eli Lilly and Company
5/1992 to 1/1997 Senior Analytical Chemist, Eli Lilly and Company

USP Experience

2005 to present Member, Reference Standards Expert Committee (RSEC)
8/2009 to present RSEC Subcommittee Chair, The Future Role of the RSEC
4/2009 Moderator, USP Workshop on Metal Impurities
3/2008 to present Member, RSEC Subcommittee on Certified Reference Materials

Other Relevant Experience

12/2008 Invited Participant, Bureau International des Poids et Mesures/Consultative Committee for Amount of Substance – Metrology in Chemistry Workshop: Traceability for Pharmaceutical and Biopharmaceutical Measurements
1/2008 to 10/2008 Program Committee, EDQM Council of Europe: International Symposium on Pharmaceutical Reference Standards
7/2006, 10/2007 Invited Speaker, Management Forum Course on Reference Standards
5/2006 Organizer and Host, 8th Reference Standard Symposium

Biography

Matthew W. Borer, Ph.D., is the senior technical and strategic leader for the global reference standard program at Eli Lilly and Company, responsible for all corporate reference standard materials that support drug development and manufacturing. He is also the subject matter expert for the Lilly reference standard quality system. Dr. Borer obtained his Ph.D. in Analytical Chemistry from Indiana University, Bloomington and conducted dissertation research on novel plasma sources for atomic spectroscopy. Dr. Borer has dedicated his career to pharmaceutical analytical chemistry and has developed deep expertise in areas such as analytical method development, establishing pharmaceutical control strategies, statistical design of experiments, and technical leadership. His quality system expertise and influence spans cGMP, ICH, ISO, WHO, and other external standards relevant to the pharmaceutical industry and reference materials. In 2006, Dr. Borer was the host and organizer of the 8th Reference Standard Symposium, the largest scientific meeting series on compendial and pharmaceutical reference standards. He has continued to play an integral role in sustaining this important meeting, serving on the Program Committee for the 2008 International Symposium on Reference Standards, hosted by EDQM, and the 2010 symposium to be hosted by USP this fall. Dr. Borer has been invited to speak at numerous global venues on this and related analytical chemistry topics.

Statement of Interest

There are two primary reasons for my interest in serving as the Chair of the RSEC. First, I have a passion for this critically important field of pharmaceutical science. As a USP Expert Committee member and in my roles at Eli Lilly & Company, I have spent a significant portion of my professional career dedicated to defining and expanding the topic of pharmaceutical reference standards as a unique scientific discipline. A reliable supply of accurately defined reference materials is critical for ensuring the safety, identity, strength, purity, and overall quality of the pharmaceutical materials that we all rely upon. The science of reference standards is not only important, but also complex in that it intertwines with all other aspects of pharmaceutical development, manufacturing, and control. USP benefits greatly from engaging experts from one of its most important stakeholders, the pharmaceutical industry, to help ensure that the interplay between pharmaceutical manufacturing, reference standard science, and the compendial process is as effective as possible. As Chair of the RSEC, I feel that I can leverage my professional career to help propel the USP Reference Standards program to even greater quality and prominence. The other important reason for my interest is my firm belief in the mission of the USP Convention. Ensuring the quality, safety, and benefit of medicines and foods has a tremendous impact on the health of people around the world. Public standards, and specifically reference standards, are the foundation that defines quality and safety.



REFERENCE STANDARDS EXPERT COMMITTEE

ROBERT L. WATTERS, JR., PH.D.



Education

1976: Ph.D. (Analytical Chemistry), University of Wisconsin
1970: B.S. (Chemistry), University of Notre Dame

Professional Experience

Present Chief, Measurement Services Division, National Institute of Standards and Technology (NIST)
10/1976 to present Analytical Chemist, Group Leader for Atomic and Molecular Spectrometry, and Deputy Division Chief, NIST

USP Experience

4/2009 to present Member, Reference Standards Expert Committee
2005 to present Delegate to the USP Convention Representing NIST

Other Relevant Experience

12/2003 to present Task Group Chair, ISO REMCO
12/2003 to 12/2004 Member, U.S. CODATA Committee
10/1976 to 10/1995 ASTM E01

Biography

Robert L. Watters, Jr., Ph.D., has over 30 years of experience in the development of Standard Reference Materials (SRMs) and international metrology comparisons. He is the Chief of the Measurement Services Division at NIST, responsible for all business support and information technology resources for NIST's SRMs, calibration services, and Standard Reference Data. These programs represent over twenty million dollars in the transfer of NIST measurement services to public and governmental agencies around the world. Dr. Watters joined the National Bureau of Standards in 1976 and became Group Leader for Atomic and Molecular Spectrometry in 1987. He has participated in the analysis and certification of over 150 SRMs. He was a member of the NIST Ad Hoc Committee on Uncertainty Statements, which developed the NIST policy on implementing the ISO Guide to Uncertainty in Measurement. Dr. Watters has presented numerous workshops on applying the ISO principles to measurements in analytical chemistry. He also served as Senior Program Analyst for the NIST Director and as Deputy Chief in the Analytical Chemistry Division. Dr. Watters was a founding member of the Comité International des Poids et Mesures Consultative Committee on Amount of Substance. He led a team that developed an international database system for comparison measurements performed by the world's National Metrology Institutes. He is also responsible for maintaining the NIST Traceability web site, wherein the NIST policy on traceability is articulated, and through which many of NIST's customers obtain answers to their traceability questions.

Statement of Interest

I very much recognize and appreciate the complementary nature of the relationships between NIST SRMs and USP Certified Reference Materials (CRMs). I think NIST has some good experience to share with the USP effort and we undoubtedly have things to learn about the USP experience and about its stakeholders.

A major activity of the Reference Standards Expert Committee will be to provide process specifications and guidance to the Monograph Expert Committees on how to develop the best USP reference standards for their chapters. I believe my 30+ years of experience in the technical design of NIST SRM certification programs will benefit this new USP effort.



STATISTICS EXPERT COMMITTEE

TIMOTHY SCHOFIELD, M.A.



Education

1976: M.A. (Statistics & Operations Research), University of Pennsylvania
1973: B.S. (Mathematics), Lafayette College

Professional Experience

7/2009 to present Director, GSK
1/2009 to 6/2009 Senior Consultant, Biologics Consulting Group, Inc.
12/1976 to 12/2008 Senior Director, Merck Research Laboratories
9/1981 to 5/2002 Lecturer, Ursinus College

USP Experience

2005 to present Member, Development and Design of Biological Assays Ad Hoc Advisory Panel
2005 to present Member, Validation of Biological Assays Ad Hoc Advisory Panel
2005 to present Member, Biostatistical Analysis Ad Hoc Advisory Panel

Other Relevant Experience

Co-author, WHO Guidelines on Stability Evaluation of Vaccines
Co-editor, Special Issue of Biologicals, Stability Evaluation of Vaccines
Co-author, A Rational Approach to Setting and Maintaining Specifications for Biological and Biotechnology Derived Products

Biography

Timothy Schofield, M.A., is a Director in the U.S. Regulatory Affairs department of GSK, where he provides regulatory support to vaccines. Prior to joining GSK, Mr. Schofield was head of the Nonclinical Statistics Unit at Merck Research Laboratories, leading 18 full-time statisticians supporting the development and manufacture of pharmaceuticals, biologics, and vaccines. In addition to providing statistical design and analysis guidance in many areas of non-clinical development, Mr. Schofield also teaches courses in the design of experiments, assay development and validation, stability study design and analysis, technology transfer, and specifications. Mr. Schofield has been course director for several workshops on statistics in the pharmaceutical industry. For the past five years, he has served on three USP Ad Hoc Advisory Panels focusing on the biostatistical analysis and the development, design, and validation of biological assays.

Statement of Interest

I would like to continue and extend my collaboration with USP on initiatives related to the development and manufacture of biologics and vaccines. As Chair of the Statistics Expert Committee, I would work with other members and USP to identify opportunities to develop standards of practice in development and manufacturing, and where appropriate, collaborate with other Expert Committees on developing general chapters to address new paradigms.



STATISTICS EXPERT COMMITTEE

ROBERT SINGER, M.S.



Education

M.S. (Statistics), California State University
B.A. (Chemistry and Psychology), Florida Atlantic University

Professional Experience

8/2008 to present Founder, Principal Consultant, Biometry Associates LLC
6/1991 to 8/2008 Bioassay Group Senior Manager, Biostatistician, PDL BioPharma

USP Experience

2009 USP Pharmacopeial Education Bioassay Course; Course Organizer and Instructor (Statistics module)
2008 Co-author; In-Process Revision to USP General Chapter <111>, Design and Analysis of Biological Assays. USP Pharmacopeial Forum, Vol. 34(3) [May-June 2008]
2008 to 2010 USP Bioassay Workshops; Planning Committee, Session Chair, and Presenter
2007 Co-author; Hauck, W., Singer, R., Callahan, L. (2007) Summary of Planned Revisions to Chapter <111>, Design and Analysis of Biological Assays. USP Pharmacopeial Forum, Vol. 33(3) [May-June 2007]
2006 Co-author: Singer, R., Lansky D., Hauck, W. *Bioassay Glossary*. USP Pharmacopeial Forum, Vol. 32(4) [July-August 2006]
2005 to 2010 Vice Chair, Statistics Expert Committee
6/1991 to present Chair, Bioassay Chapters Ad Hoc Advisory Panels

Other Relevant Experience

2005 Co-author, Hauck, W., Singer, R., et al. *Assessing Parallelism Prior to Determining Relative Potency*. PDA Journal of Pharmaceutical Science and Technology, 59(2): 127-137.
2004 to 2010 Speaker on topic: "Status of USP Bioassay Chapters." Presented at conferences and symposia, including those held in Berlin, Rome, Arlington, Rockville, San Diego, and Washington, DC.

Biography

Robert Singer, M.S., has 25 years experience in industrial biotechnology (biologics). He established and managed bioassay development/service groups, and has diverse experience in biostatistics as well as a unique hybrid of biological, statistical, and clinical expertise. He has chaired three USP Bioassay Chapters Ad Hoc Advisory Panels over the course of nearly 20 years. Mr. Singer played a key role at USP in developing internationally recognized standards of practice in bioassay design, development, analysis, and validation.

Statement of Interest

I have been involved with the good work of the USP for some time. The unique structure of the USP allows the gathering of experienced and accomplished individuals in pursuit of the best contemporary thought. In the case of the bioassay chapters, much has been accomplished, and a tipping point – co-publication in summer of 2010 of three bioassay chapters in *Pharmacopeial Forum* – is upon us. Opportunities abound for continuing this work, work that identifies USP as a forward-looking resource in the field. As Chair of the Statistics Expert Committee, I would effectively contribute to USP's continuing to serve as a scientific beacon.



TOXICOLOGY EXPERT COMMITTEE

JOHN DOULL, M.D., PH.D.



Education

1953: M.D., University of Chicago School of Medicine
1950: Ph.D. (Pharmacology), University of Chicago
1944: B.S. (Chemistry), Montana State College

Professional Experience

1995 to present Professor Emeritus, University of Kansas
1967 to 1994 Professor, Director and other positions, University of Kansas
1951 to 1967 Research Associate to Associate Professor, University of Chicago Medical School

USP Experience

2009 to present Member, USP Council of Experts Nominating Committee
2008 Keynote Speaker, USP Annual Scientific Meeting, Kansas City, Kansas

Other Relevant Experience

6/2005 to present Board Member, Chair of Threshold Limit Value Committee, American Conference of Governmental Industrial Hygienists (ACGIH)
Federal Insecticide, Fungicide, and Rodenticide Act Advisory Panel, Science Advisory Board, Committees, Environmental Protection Agency (EPA)
Board, Committees etc., National Academy of Sciences (NAS), Institute of Medicine, National Research Council (NRC)
Working for Equality and Economic Liberation Committee, American Industrial Hygiene Association

Biography

John Doull, M.D., Ph.D., is Professor Emeritus of Pharmacology and Toxicology in the Department of Pharmacology, Toxicology and Therapeutics at the University of Kansas Medical School. Prior to coming to Kansas, he was the Assistant Director of the University of Chicago Toxicity Laboratory and Associate Professor in the Department of Pharmacology at the University of Chicago. He served on National Institutes of Health's (NIH) Toxicology Study Section and the council of the National Institute of Environmental Health Sciences (NIEHS). He is past president of the SOT and the American Board of Toxicology, has chaired ACGIH's Threshold Limit Value Committee, and served on International Life Sciences Institute Expert Panels, the Federal Emergency Management Agency, and DISCUS, and was a member of the Presidential/Congressional Risk Assessment and Management Commission and the MraK Commission. He has chaired the NRC's Committee on Toxicology and served on scientific advisory panels of the FDA, EPA, the National Institute for Occupational Safety and Health and others, and consults with many governmental, state, industrial, and private organizations. He received numerous awards from the Society of Toxicology (SOT) for his contributions to the discipline of toxicology, including the Kenneth DuBois Award (1981) from the Mid-America Chapter, the Toxicology Ambassador Award from the Mid Atlantic Chapter (1991), and the Merit award (1993). He was the first recipient of the John Doull Award, established by the Central States Chapter (1992) and the SOT Founders Award (2008). He also received the Samuel Kuna Award (1989, Rutgers University/Robert Wood Johnson Medical School), the International Achievement Award (1990, International Society for Regulatory Toxicology and Pharmacology), the Commanders Award for Public Service (U.S. Army, Armed Forces Epidemiological Board), the Distinguished Medical Alumnus Award (1991, University of Chicago), the Stockinger Award (ACGIH, 1992), and the Snider Award of the Arkansas Toxicology Symposium Series (1994). In 1996, he received the Founder's Award (Chemical Industry Institute of Toxicology), an honorary doctorate degree from the University of Kuopio in Finland, the Meritorious Service Award (ACGIH), and the Distinguished Service Award (American College of Toxicology). He received the Philippe Shubik Distinguished Scientist award from the Toxicology Forum in 2007.

Statement of Interest

Many areas of toxicology are becoming of increasing importance to USP and I would like to help USP address some of these issues.



TOXICOLOGY EXPERT COMMITTEE

ROBERT E. OSTERBERG, PH.D.



Education

1972: Ph.D. (Pharmacology), Georgetown University
1969: M.S. (Pharmacology), Georgetown University
1965: B.S. (Pharmacy), Long Island University/Brooklyn College of Pharmacy

Professional Experience

1989 to 1/2006 Supervisor-Pharmacology/Toxicology, Division of Anti-Infective Drug Products
1988 to 1989 Deputy Division Director, Antiviral Drug Products, FDA
2002 to 8/2004 Supervisor-Pharmacology/Toxicology, FDA Division of Anti-Infective Drug Products (DAIDP) and Division Anti-Inflammatory Drug Products
2/2002 to 4/2003 Acting Associate Director Pharmacology/Toxicology, FDA CDER
1/2000 to 2/2002 Associate Director, CDER Office of Drug Evaluation (ODE) IV
1989 to present Part-time Pharmacist, CVS Pharmacy

USP Experience

2009 Invited Speaker, USP: Drug Purity and Impurity Safety
2/2009 Invited Moderator, Discussion on problems with residual solvents in drug products
1/2007 Invited Speaker, USP meeting on residual solvents, Impurities: Residual Solvents ICH Q3C
4/2006 Member, Advisory Group for Verification and Qualification Program

Other Relevant Experience

2009 Chair, New Excipient Evaluation Committee, IPEC
2002 to 2007 Speaker/panelist on regulatory toxicology, CDER Pharmaceutical Education and Research Inst.
1993 Author/Presenter, Four-Day Workshop on FDA Drug Approval Process (Toxicology), P.R.China
2004 Speaker, Extractables and Leachables Course, Barnett International

Biography

Robert E. Osterberg, R.Ph., Ph.D. is a senior consultant in pharmacology and toxicology at Aclairo Pharmaceutical Development Group, having retired from the FDA after almost 34 years. He held numerous supervisory positions in FDA's Center for Veterinary Medicine and CDER in the Divisions of Anti-Infective and Ophthalmologic Products, Anti-Viral Products, Special Pathogens, and Anti-Inflammatory Products. As a toxicologist and a pharmacist, Dr. Osterberg conducted safety reviews of identified chemicals that could be used in pharmaceutical compounding. As a member of several ICH Safety Expert Working Groups for more than 10 years, he assisted in the development of many toxicological safety and quality guidelines including Q3A, B, and C. He was the co-chair of the CDER Inactive Ingredients Subcommittee for more than 12 years until his retirement in 2006. He also has been a member of several federal government committees to develop toxicology testing protocols for the Interagency Regulatory Liaison Group (IRLG), Organisation for Economic Co-operation and Development (OECD), Bureau of Foods' Red Book, and CDER toxicology guidances, including the Photosafety and Excipient guidances. He is a past president of the American College of Toxicology and the Society of Toxicology Regulatory and Safety Evaluation Specialty Section, and a Fellow of the Academy of Toxicological Sciences. He was recently awarded the first IPEC Foundation Marshall Steinberg Memorial Prize for contributions in excipient safety and has received several awards and recognition from CDER.

Statement of Interest

USP is the symbol of drug purity and quality with its genesis in 1820. Many activities in my career with CDER have involved drug quality as exemplified with the Quality Expert Committees of the ICH that involved discussions with representatives of the three major pharmacopeias. Several times, I have been asked to speak about drug impurities, extractables, and leachables regarding their potential toxicities. During my career at FDA, I was also asked to review and comment on many impurities and other chemicals from the FDA division that was involved with the USP and its quality standards and in vitro and in vivo biological tests. I believe that the latter biological tests and strategies can be improved to further define the safety of chemicals and impurities that the USP relies on for safety determinations.





PART V

APPENDICES

ADVANCING HEALTH THROUGH PUBLIC STANDARDS

**APPENDIX A. EXCERPTS PERTAINING TO THE
NOMINATING COMMITTEE FOR THE COUNCIL OF EXPERTS
FROM THE USP CONSTITUTION AND BYLAWS**

**Bylaws – Chapter X
The Nominating Committee for the Council of Experts**

Section 1—Appointment of Committee Members

The Nominating Committee for the Council of Experts, hereinafter referred to in this chapter as the Committee, shall consist of twenty persons, five of whom shall be members of the Pharmacopeial Convention, appointed by the President with the advice and consent of the Board of Trustees, together with ten members of the Council of Experts, appointed by the Executive Vice President-CEO taking into consideration the advice of the Executive Committee of the Council, and five other persons appointed by the Executive Vice President-CEO with the advice and consent of the Board of Trustees. Staff may participate in the Committee's deliberations but shall not be permitted to participate in Committee votes. The five members of the Convention, appointed by the President, who serve on the Nominating Committee for the Council of Experts may not be members of the Council of Experts, Expert Committees, the Board of Trustees, salaried employees, or officers of the Pharmacopeial Convention.

The President of the Pharmacopeial Convention shall serve as the chairperson of the Committee. The Executive Vice President-CEO shall be a member, *ex officio*, of the Committee. The Committee shall elect a Vice Chairperson. The Secretary of the Convention shall serve as Secretary of the Committee.

The Committee shall be organized at least six months after the stated meeting of the Pharmacopeial Convention, and shall continue until its successor committee is appointed.

Section 2

Not later than seven months prior to the stated meeting of the Pharmacopeial Convention, the Secretary of the Committee shall issue to all who are entitled to representation in the Pharmacopeial Convention, as provided in Article II, Section 1, of the Constitution, to all members of the Convention and to the members of the Council of Experts, its Expert Committees and its advisory panels, a request that they submit the names of persons whose qualifications entitle them to consideration as nominees for membership on the Council of Experts. Each name submitted shall be accompanied by a statement on an official form supplied by the Committee indicating affiliations, academic and professional backgrounds, and the qualifications for the specific classification or classifications of membership on the Council of Experts as set forth in the outline referred to in Chapter VII, Section 17, of these Bylaws. All recommendations shall be mailed to the Secretary of the Pharmacopeial Convention not later than one hundred and twenty days prior to the stated meeting.

All recommendations received by the Secretary shall be submitted to the Committee not later than ninety days prior to the stated meeting and shall be given primary consideration by the Committee in selecting nominees for membership for the Council of Experts.

Section 3

At the stated meeting of the Pharmacopeial Convention, the Committee shall submit, through the Secretary, to each member, a list of names of persons whom it deems qualified to serve on the Council of Experts, together with a statement covering the classification for which each nominee is deemed best qualified, and the affiliations, academic and professional backgrounds and specific qualifications of each nominee.



The Committee shall nominate, insofar as possible, twice the number of qualified persons to be elected to meet each need shown in the outline referred to in Chapter VII, Section 17, of these Bylaws.

Additional nominations may be made from the floor for membership on the Council of Experts and shall be seconded on the floor by at least ten members of the Pharmacopeial Convention. Each such nomination shall be submitted on the official form and presented at once to the Secretary of the Pharmacopeial Convention.

Section 4

Between meetings of the Convention, the Committee will operate on a continuing basis and will be the source of providing the names of nominees for election to the Council of Experts, if needed. The Committee shall also provide the names of qualified experts as potential nominees for election to Expert Committees, in accordance with Chapter VII, Section 5 of the Bylaws.

Section 5

The Committee shall provide advice and consent to the Executive Vice President-CEO prior to the appointment of individuals to advisory panels to the Council of Experts.



**APPENDIX B. 2010-2015 USP EXPERT COMMITTEES AND
THEIR FOCUS AREAS, ROLES, AND EXPERTISE REQUIRED**

The following information describes USP's 2010-2015 Expert Committees, their focus areas, roles and responsibilities, and the expertise required.

Expert Committee	Focus Areas	Expert Committee Roles and Responsibilities	Expertise Required
Monographs—Small Molecules 1	<ul style="list-style-type: none"> • Antibiotics • Antimicrobials • Antivirals 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference standards for drug substances and dosage forms 	<ul style="list-style-type: none"> • Expertise in analytical chemistry including wet chemistry techniques, compendial tests, chromatography, spectroscopy, dissolution testing and/or microbiological tests (e.g., microbial limits, bacterial endotoxins, sterility, etc.) • Expertise in antibiotics microbial assays • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials
Monographs—Small Molecules 2	<ul style="list-style-type: none"> • Cough, Cold • Analgesics • Cardiovascular 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference standards for drug substances and dosage forms 	<ul style="list-style-type: none"> • Expertise in analytical chemistry including wet chemistry techniques, compendial tests, chromatography, spectroscopy, dissolution testing and/or microbiological tests (e.g., microbial limits, bacterial endotoxins, sterility, etc.) • Expertise in non-prescription drugs • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials
Monographs—Small Molecules 3	<ul style="list-style-type: none"> • Gastrointestinal • Renal • Endocrine • Ophthalmology • Oncology • Dermatology • Veterinary 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference standards for drug substances and dosage forms 	<ul style="list-style-type: none"> • Expertise in analytical chemistry including wet chemistry techniques, compendial tests, chromatography, spectroscopy, dissolution testing and/or microbiological tests (e.g., microbial limits, bacterial endotoxins, sterility, etc.) • Expertise in development and/or testing of veterinary pharmaceuticals • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials

Expert Committee	Focus Areas	Expert Committee Roles and Responsibilities	Expertise Required
Monographs—Small Molecules 4	<ul style="list-style-type: none"> • Psychoactives • Psychiatric • Pulmonary/Aerosols • Steroids • Radiopharmaceuticals 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference standards for drug substances and dosage forms 	<ul style="list-style-type: none"> • Expertise in analytical chemistry including wet chemistry techniques, compendial tests, chromatography, spectroscopy, dissolution testing and/or microbiological tests (e.g., microbial limits, bacterial endotoxins, sterility, etc.) • Expertise in aerosol performance testing and container closure systems • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials
Monographs—Biologics and Biotechnology 1	<ul style="list-style-type: none"> • Glycosaminoglycans and Heparins • Peptides/Hormones • Enzymes • Therapeutic Proteins • Monoclonal Antibodies 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference materials for biological medicines 	<ul style="list-style-type: none"> • Expertise in analytical biochemistry, immunology and biological potency determination related to biological medicines • Expertise in pharmaceutical quality control, compliance, and analytical characterization testing. • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials.
Monographs—Biologics and Biotechnology 2	<ul style="list-style-type: none"> • Vaccines • Cell-based Therapies • Plasma Derivatives • Tissue Therapies Monographs • Gene Therapy • Potency Assays 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference materials for biological medicines. 	<ul style="list-style-type: none"> • Expertise in vaccine manufacturing and analysis, immunology, virology testing and biological potency determination related to the above biological medicines. • Expertise in pharmaceutical quality control, compliance, and analytical characterization testing. • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials • Expertise in raw, process, and ancillary materials qualification
Monographs—Excipients	<ul style="list-style-type: none"> • Excipients—Simple • Excipients—Complex 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference materials for simple and complex excipients 	<ul style="list-style-type: none"> • Expertise in the areas of analytical chemistry and manufacturing related to simple and macromolecular pharmaceutical ingredients. • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials

Expert Committee	Focus Areas	Expert Committee Roles and Responsibilities	Expertise Required
Monographs—Dietary Supplements	<ul style="list-style-type: none"> • Vitamins and Minerals • Botanical Drugs • Phytomedicines • Traditional Medicines • Aminoacids • Articles of Botanical Origin 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference materials for dietary supplement ingredients and products 	<ul style="list-style-type: none"> • Expertise in manufacturing, analytical chemistry, pharmacognosy, or toxicology related to dietary supplements and/or dietary ingredients and botanical drugs/traditional medicines • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials
Monographs—Food Ingredients	<ul style="list-style-type: none"> • Food Ingredients • Contaminants/Adulterants • Flavors and Extracts • Additives • Colorants 	<ul style="list-style-type: none"> • Develop new and revise existing monographs and their associated reference materials for food ingredients 	<ul style="list-style-type: none"> • Expertise in food chemistry, food technology, food toxicology, food manufacturing, food regulatory affairs or analytical chemistry • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials
General Chapters—Chemical Analysis	<ul style="list-style-type: none"> • Spectroscopy • Chromatography • Dietary Supplement Tests and Assays • Metal Analysis • Pharmaceutical Waters • Classical Wet-chemical Tests and Assays • Food Ingredients Tests and Assays 	<ul style="list-style-type: none"> • Develop new and revise existing General Chapters related to chemical analysis (e.g., chromatography, spectroscopy, metal or water analysis) • Develop new General Chapters to assure the compendia include technologies that will become accepted industry practice over the next several years 	<ul style="list-style-type: none"> • Expertise in spectroscopy (e.g., MS, NMR, IR, NIR, UV, Fluorescence, AA, ICP, XRF or hyphenated techniques), chromatography (e.g., HPLC, TLC, CE), thermal analysis, classical techniques for functional-group analysis, food analysis and dietary supplement analysis (e.g., vitamin, mineral or botanical supplement analysis) or experience in compendial issues related to water quality • Expertise in tests or methods of assay in settings involving the demonstration of compliance with FDA current Good Manufacturing Practices, (identity, strength, quality and purity)

Expert Committee	Focus Areas	Expert Committee Roles and Responsibilities	Expertise Required
General Chapters— Physical Analysis	<ul style="list-style-type: none"> • Tests related to excipient performance (e.g., density, rheology, flow characteristics) • Particle size determination • Classical Physical Measurement Tests • Industry Guidances (e.g., Manufacturing Practices, Bulk Excipients, Analytical Instrument Qualification, Validation, Verification, Stability, Harmonization) 	<ul style="list-style-type: none"> • Develop new and revise existing General Chapters related to excipient and API physical properties • Review and update current informational chapters that provide industry guidance and propose and write new documents as appropriate 	<ul style="list-style-type: none"> • Expertise in classical physical measurement techniques, excipient performance characteristics and their effects on manufacturing processes, Expertise in writing, review or implementation of regulatory guidances and an understanding of their genesis and impact • Expertise in demonstrating compliance with FDA current Good Manufacturing Practices, (identity, strength, quality and purity)
General Chapters— Biological Analysis	<ul style="list-style-type: none"> • Proteins • Glycoproteins • Polysaccharides • Blood Products • Cell, Gene and Tissue-Engineered Products • Vaccines and Virology • Bioassays • Immunoassays 	<ul style="list-style-type: none"> • Develop new and revise existing General Chapters related to biological molecules, ancillary materials and reagents, and product monographs • Develop technique-based General Chapters as needed to contain key technologies supporting multiple product monographs 	<ul style="list-style-type: none"> • Expertise in cell-based assays, immunochemistry, physicochemical characterization of proteins and natural products, virology, immunology, vaccines, or the development or manufacturing of biologics. • Expertise in tests or methods of assay in settings involving the demonstration of compliance with FDA current Good Manufacturing Practices, (identity, strength, quality and purity)
General Chapters— Dosage Forms	<ul style="list-style-type: none"> • Dosage forms by routes of Administration: <ul style="list-style-type: none"> ○ Oral ○ Parenteral ○ Inhalation ○ Transdermal/Topical ○ Mucosal 	<ul style="list-style-type: none"> • Develop new and revise existing General Chapters and default-monograph General Chapters related to pharmaceutical dosage forms 	<ul style="list-style-type: none"> • Expertise in the development and testing of drug products for quality and performance. Specific expertise includes BA/BE testing, dissolution testing, formulation design and testing, medical gas testing, and testing of performance of parenterals, aerosols, ophthalmic solutions, patches, topicals, as well as expertise in veterinary and radiochemical applications

Expert Committee	Focus Areas	Expert Committee Roles and Responsibilities	Expertise Required
General Chapters— Microbiology	<ul style="list-style-type: none"> • Microbiology • Rapid Microbiology • Sterility Assurance • Bacterial Endotoxins 	<ul style="list-style-type: none"> • Develop new and revise existing General Chapters and General Information Chapters related to Microbiology and Sterility Assurance • Evaluate Sterility assurance, Bacterial Endotoxins and Microbial Quality requirements, relative to new monograph development and revisions • Lead in the evaluation of rapid microbiological methodology and other upstream methodology as they relate to compendial activities 	<ul style="list-style-type: none"> • Expertise in relevant compendial areas such as, classical Microbiology, Sterility Assurance, and familiarity with current industrial and regulatory trends in these areas, including, automated / rapid technologies • Expertise in tests performed in settings involving the demonstration of compliance with FDA current Good Manufacturing Practices, (identity, strength, quality and purity)
General Chapters— Packaging, Storage, and Distribution	<ul style="list-style-type: none"> • Packaging (Anti-Counterfeiting, Extractables/ Leachables) • Storage and Stability • Distribution and Cold Chain Storage • Shipping Requirements • Temperature Control 	<ul style="list-style-type: none"> • Develop new and revise existing General Chapters related to packaging (container-closure systems), storage or distribution of pharmaceutical ingredients or dosage forms. • Develop new General Chapters in the areas of anti-counterfeiting, supply-chain management, packaging extractables and leachables, and storage temperature control 	<ul style="list-style-type: none"> • Expertise in packaging, storage or distribution of drug substances, drug products, excipients, dietary supplements or food ingredients • Expertise in the areas of anti-counterfeiting technologies, packaging, and analysis and control of extractables and leachables
Nomenclature, Safety, and Labeling	<ul style="list-style-type: none"> • Drug Product Nomenclature • Biologics/Biotechnology Nomenclature • Dietary Supplements Nomenclature • Food Ingredients and Excipients Nomenclature • Safe Medication Use standards • Labeling standards 	<ul style="list-style-type: none"> • Review and approve monograph titles for drug products, biologics and biotechnology products, excipients, dietary supplements, and food ingredients • Prospectively name drug products newly approved by the FDA • Implement/develop nomenclature policies • Consider patient safety aspects of drug labeling • Develop/revise standards for safe medication use 	<ul style="list-style-type: none"> • Familiarity with nomenclature issues, regulations, and policies • Familiarity with current marketplace products in respective focus areas • Expertise in healthcare fields related to patient safety, health literacy, and labeling

Expert Committee	Focus Areas	Expert Committee Roles and Responsibilities	Expertise Required
Compounding	<ul style="list-style-type: none"> • Human Drug Compounding (Sterile and Nonsterile) • Veterinary Drug Compounding • Radiopharmaceuticals Compounding • Compounding Flavorings 	<ul style="list-style-type: none"> • Develop new and revise existing human and veterinary compounded preparation monographs • Revise and update current and develop new General Chapters that pertain to the compounding of extemporaneous non-sterile and sterile preparations 	<ul style="list-style-type: none"> • Expertise in a) formulating and compounding sterile and non-sterile preparations b) evaluating process development and stability data related to compounded preparations • Expertise with regulatory requirements for compounding
Reference Standards	<ul style="list-style-type: none"> • Reference Standard decision-making framework and guideline development for small molecules, biologics and biotechnology, dietary supplements, excipients, and food ingredients 	<ul style="list-style-type: none"> • Develop guidelines that align with best practices for the development of reference materials • Periodically review guidelines to assure relevance and compliance to best practices. • Review complex Reference Standards referred from other Expert Committees • Periodically audit/review Reference Standard approvals 	<ul style="list-style-type: none"> • Expertise in analytical methods and data evaluation • Understanding of the regulatory aspects of reference materials and certified reference materials
Statistics	<ul style="list-style-type: none"> • General Statistics • Biostatistics • Chemometrics • Epidemiology 	<ul style="list-style-type: none"> • Develop new and revise existing <i>USP-NF</i> General Chapters requiring extensive statistical expertise • Develop and help implement statistical approaches for performance-based monographs and General Chapters and for demonstration of “equivalent or better” for alternative methods • Serve as a resource to other Expert Committees as required to assure the appropriate level of statistical rigor is maintained 	<ul style="list-style-type: none"> • Expertise in statistics and current industrial trends of packaging, quality assurance, chemometrics, microbiology, biostatistics, biological assays (immunochemistry or cell-based assays), epidemiology, manufacturing and CMC controls. • Expertise involving the demonstration of compliance with FDA current Good Manufacturing Practices, (identity, strength, quality and purity)

Expert Committee	Focus Areas	Expert Committee Roles and Responsibilities	Expertise Required
Toxicology	<ul style="list-style-type: none"> • Food, Dietary Supplements • Drugs and Excipients • Metals • Medical Device Biocompatibility • Nanotechnology 	<ul style="list-style-type: none"> • Develop new and revise existing <i>USP-NF</i> and <i>FCC</i> General Chapters related to toxicology and product safety testing. • Serve as a resource to other Expert Committees and Expert Panels requiring toxicology guidance 	<ul style="list-style-type: none"> • Expertise in the role of toxicology as it relates to drug development, drug testing both pre- and post-market as well as in the role of toxicology as it relates to food ingredients and dietary supplements • Expertise with small molecule and biologics and biotechnology drugs

APPENDIX C. ABBREVIATIONS

AAAS	American Association for the Advancement of Science
AACP	Association of Colleges of Pharmacy
AAPS	American Association of Pharmaceutical Scientists
ACGIH	American Conference of Governmental Industrial Hygienists
ACS	American Chemical Society
ADPC	Association of Deans of Pharmacy of Canada
AIChE	American Institute of Chemical Engineers
<i>AJHP</i>	<i>American Journal of Health System Pharmacy</i>
ANDA	Abbreviated New Drug Applications
APhA	American Pharmacists Association
APS	Academy of Pharmaceutical Sciences
ARS	Agricultural Research Service
ASHP	American Society of Health-System Pharmacists
ASN	American Society for Nutrition
ASPET	American Society for Pharmacology and Experimental Therapeutics
ASQ	American Society for Quality
AVMA	American Veterinary Medicine Association
BERM	Biological and Environmental Reference Materials
<i>BP</i>	<i>British Pharmacopoeia</i>
CBER	Center for Biologics Evaluation and Research (FDA)
CDER	Center for Drug Evaluation and Research (FDA)
cGMP	Current Good Manufacturing Practices
CMC	Chemistry, Manufacturing, and Control
CMCCC	Chemistry, Manufacturing and Control Coordinating Committee
CRM	Certified Reference Material
DP/TC/DTC	Dairy Products Technology Center/ Development Technical Committee
EDQM	European Department for Quality of Medicines
<i>EP</i>	<i>European Pharmacopoeia</i>
EPA	Environmental Protection Agency
FAO	Food and Agricultural Organization
<i>FCC</i>	<i>Food Chemicals Codex</i>
FDA	Food and Drug Administration



FIP	International Pharmaceutical Federation
GCSF	granulocyte colony-stimulating factor
GSK	GlaxoSmithKline
HPLC	High Performance Liquid Chromatography
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IFAC	International Food Additives Council
IFT	Institute of Food Technologists
IIR	Institute of International Research
<i>IJPC</i>	<i>International Journal of Pharmaceutical Compounding</i>
IND	Investigational New Drug
IPEC	International Pharmaceutical Excipients Council
ISO	International Organization for Standardization
ISPE	International Society for Pharmaceutical Engineering
<i>JP</i>	<i>Japanese Pharmacopoeia</i>
MIT	Massachusetts Institute of Technology
MWCDG	Mid-Western Compendial Discussion Group
NAS	National Academy of Sciences
NDA	New Drug Application
NIBSC	National Institute for Biological Standards and Control
NIEHS	National Institute of Environmental Health Sciences
NIST	National Institute Standards and Technology
NRC	National Research Council
OGD	Office of Generic Drugs (FDA)
PAT	Process Analytical Technology
PCAB	Pharmacy Compounding Accreditation Board
PDA	Parenteral Drug Association
PhRMA	Pharmaceutical and Research Manufacturers of America
PQRI	Product Quality Research Institute
PQRI	Product Quality Research Institute
QA	Quality Assurance
QbD	Quality by Design
QC	Quality Control
R&D	Research and Development
RA	Regulatory Affairs



rDNA	recombinant DNA
RSEC	Reference Standards Expert Committee
SOT	Society of Toxicology
SRM	Standard Reference Material
TDRM	Technical Division on Reference Materials
TOC	Total Organic Carbon
UK	United Kingdom
USDA	U.S. Department of Agriculture
USP-NF	<i>U.S. Pharmacopeia–National Formulary</i>
WFI	Water for Injection
WHO	World Health Organization

