Alternative Microbiological Methods:
A Workshop on Current Status and Future Directions of Compendial Standards
March 16–17, 2015
USP Headquarters, Rockville, Maryland

Agenda

Monday, March 16, 2014 (Day 1)

8:00 a.m. **Registration and Coffee**

9:00 a.m. **Welcome, Opening Remarks, and Workshop Overview**
James Akers, Ph.D., Chair, USP General Chapters–Microbiology Expert Committee

9:30 a.m. **Plenary Session I: Alternate Methods**
Moderator: David Hussong, Ph.D., ConcordiaValSource, LLC

a. Current USP Perspectives
James Akers, Ph.D., Chair, USP General Chapters–Microbiology Expert Committee
b. Current FDA Perspectives
Erika Pfeiler, Ph.D., U.S. Food and Drug Administration (FDA) CDER/OPQ/OPF/Division of Microbiology Assessment

10:10 a.m. **Discussion / Q&A**

10:30 a.m. **Plenary Session II: Status of Current Chapters**
Moderator: Karen McCullough, M.S.
Member, USP General Chapters–Microbiology Expert Committee
This session will highlight current status of the chapters on Alternative Microbiological Methods in U.S. and European Pharmacopoeias.

a. New Draft <1223.1>: Alternate Procedures to Antibiotic Microbial Assays
James Akers, Ph.D., Chair, USP General Chapters–Microbiology Expert Committee

10:50 a.m. **Break**

11:20 a.m. **Plenary Session II: Status of Current Chapters (Continued)**

b. <1223> Revisions
Edward Tidswell, Ph.D.
Member, USP General Chapters–Microbiology Expert Committee
c. EP 5.1.6. Alternative Methods for Control of Microbiological Quality: Current Status of Revisions
Stephen Wicks, Ph.D., European Directorate for the Quality of Medicines (EDQM), France

12:00 p.m. **Discussion / Q&A**

12:45 p.m. **Lunch**

1:45 p.m. **Plenary Session III: Equivalence Approaches**
This session will include presentations on equivalence approaches to alternative microbiological methods and statistical tools for validation of alternative microbiological methods.
Moderator: Scott Sutton, Ph.D.,
Member, USP General Chapters–Microbiology Expert Committee

a. Equivalence Determination
Anthony Cundell, Ph.D.
Vice Chair, USP General Chapters–Microbiology Expert Committee
b. Equivalence of Microbiological Methods: a Statistical View
Edwin van den Heuvel, Ph.D., Eindhoven University of Technology (TU/e), Eindhoven, Netherlands

3:05 p.m. **Break**

3:30 p.m. **Discussion / Q&A**

5:00 p.m. **Reception in Corridor of Volunteers**

6:00 p.m. **Adjourn for the day**

Tuesday, March 17, 2014 (Day 2)

8:00 a.m. **Registration and Coffee**

9:00 a.m. **Overview of Days Topics**
Radhakrishna Tirumalai, Ph.D., USP Principal Scientific Liaison, General Chapters

Plenary Session IV: Modern Microbiological Methods
Moderator: Donald Singer, M.S.
Member, USP General Chapters–Microbiology Expert Committee
Speakers representing the USP General Chapters–Microbiology Expert Committee, Japanese Pharmacopoeia (JP), Industry, and U.S. Food and Drug Administration (FDA) will present on current perspectives on Modern Microbiological Methods (MMM)

a. Current USP Perspectives on a Compendial MMM Sterility Test
James Akers, Ph.D., Chair, USP Microbiology Expert Committee
b. Current FDA perspectives on Biologics Sterility Tests FDA/ CBER
Simleen Kaur, M.S., U.S. Food and Drug Administration (FDA)/ CBER, Office of Compliance and Biologics Quality
c. Industry Perspective
David Roesti, Ph.D., Novartis, Switzerland

10:30 a.m. **Break**

11:00 a.m. **Plenary Session IV: Modern Microbiological Methods (Continued)**

d. Current JP Perspectives
Nobuyasu Yamaguchi, Ph.D., Osaka University, Japan
e. Current Status of Proposed USP Chapter <71.1>
Anthony Cundell, Ph.D., Vice Chair, USP Microbiology Expert Committee

12:00 p.m. **Lunch**

1:00 p.m. **Round Table Discussion / Q&A**

2:30 p.m. **Summary of Discussions: What Was Said, What Was Heard, Next Steps**
Moderator: Radhakrishna Tirumalai, Ph.D., USP Principal Scientific Liaison, General Chapters

3:00 p.m. **Break**

3:30 p.m. **Final Remarks / Conclusions**
James Akers, Ph.D., Chair, USP Microbiology Expert Committee

4:00 p.m. **Workshop Adjourns**

Abstracts & Biographies
In Order of Appearance

James Akers, Ph.D.
USP Affiliation:
Chair, USP General Chapters–Microbiology Expert Committee

President
Akers Kennedy & Associates
Leawood, Kansas

Presentations
Welcome, Opening Remarks, and Workshop Overview
March 16, 2015, 9:00 a.m. – 9:30 a.m.

Plenary Session I: Alternate Methods
USP Perspectives
March 16, 2015, 9:30 a.m. – 9:50 a.m.

Plenary Session II: Status of Current Chapters
New Draft <1223.1>: Alternate Procedures to Antibiotic Microbial Assays
March 16, 2015, 10:30 a.m. – 10:50 a.m.

Plenary Session IV: Modern Microbiological Methods
Current USP Perspectives on a Compendial MMM Sterility Test
March 17, 2015, 9:00 a.m. – 9:30 a.m.

Final Remarks / Conclusions
March 17, 2015, 3:30 a.m. – 4:00 p.m.

David Hussong, Ph.D.
Senior Consultant
ConcordiaValSource, LLC
Kensington, Maryland

David Hussong is a Senior Consultant with ConcordiaValsource, LLC, and is 30-year veteran of the Food and Drug Administration (FDA), and a retired Commissioned Officer of the US Public Health Service. While at FDA, David served 4 years in the Center for Biologics Evaluation and Research, and 26 years in the microbiology review program of the Center for Drug Evaluation and Review (CDER), where he led the development of the regulatory microbiology program. Dr. Hussong was an architect of the product quality microbiology review program in CDER, which he supervised for over 10 years. David has been affiliated with the USP Microbiology Committee of experts as either an FDA liaison or an elected member for 15 years. David earned his Ph.D. in microbiology from the University of Maryland and served as a laboratory researcher at the US Department of Agriculture, and the Office of Naval Research. He has published several papers on microbial populations in the natural environment, and published focused studies of *Salmonella* and *Legionella* that included development of new methods for their detection. He also performed research at FDA's Center for Biologics, studying antigens of pertussis and mycobacteria species. Overall, he has 40-years of professional microbiology experience.

Moderator
Plenary Session I: Alternate Methods
March 16, 2015, 9:30 a.m. – 10:30 a.m.

Erika Pfeiler, Ph.D.
USP Affiliation:
Member, USP Compounding Expert Committee

Microbiologist
U.S. Food and Drug Administration (FDA)
CDER/OPQ/OPF/Division of Microbiology Assessment
Silver Spring, Maryland

Erika Pfeiler is a microbiologist in FDA's Center for Drug Evaluation and Research. She holds a Bachelor of Science degree from the University of Tennessee and a doctorate from North Carolina State University. After an FDA Commissioner's Fellowship, Dr. Pfeiler began working with CDER since 2012, and has participated in review and inspection aspects of the new drug approval process. She is particularly interested in the regulatory and scientific aspects of alternative microbiological methods and pharmacy compounding. Aside from her FDA duties, Dr. Pfeiler also teaches an introductory microbiology class at Howard Community College.

Presentation
Plenary Session I: Alternate Methods
Current FDA perspectives
March 16, 2015, 9:50 a.m. – 10:10 a.m.

Regulatory approval is an important consideration in the process of adopting an alternative microbiological method in a pharmaceutical manufacturing setting. The variety of methods available in the marketplace makes the adoption of rigid standards for regulatory review of method validation impractical; however, microbiology reviewers in CDER have adopted a policy of open communication with industry stakeholders as a means to provide guidance in this area. This presentation will address FDA's general policies towards the use of alternative microbiological methods, will discuss some general approaches to method validation from the perspective of a microbiology reviewer, and will present an overview of the various administrative pathways that applicants can use to seek approval of their alternative microbiological methods. At the conclusion of this presentation, participants will have an improved understanding of CDER's policies and expectations regarding alternative microbiological methods.

Karen McCullough, M.S.
USP Affiliation:
Member, USP General Chapters–Microbiology Expert Committee

Vice President, Quality Operations
Dendreon
Bridgewater, New Jersey

Moderator
Plenary Session II: Status of Current Chapters
March 16, 2015, 10:30 a.m. – 12:00 pm.

Edward Tidswell, Ph.D.
USP Affiliation:
Member, USP General Chapters–Microbiology Expert Committee

Senior Director, Research
Baxter Healthcare
Round Lake, Illinois

Dr. Tidswell is a Quality Director for Baxter Healthcare; located north of Chicago, IL (USA). Within his role he supports more than 40 facilities setting strategy and tactical activities across the entire breadth of microbiological control, cleanroom control and sterility assurance. More specifically assuring process and product control through implementation of new systems-based process for sterile and aseptic manufacture for parenterals and medical devices. He has worked within bulk active pharmaceutical ingredient, vaccine and parenteral manufacturing operations for human health and animal health products in both technical and validation roles for the likes of Eli Lilly and Evans Vaccines. Dr Tidswell continues to actively publish and is a leading authority on risk, aseptic and sterile manufacture. In 2004 he received the Parenteral Society's George Sykes Memorial Award for his contribution to pharmaceutical risk assessment. As a microbial physiologist Dr Tidswell retains an active interest in several areas of microbiology, which include: bacterial adhesion, quorum sensing, viability, anaerobes, and rapid microbial technologies. From 1995-2010 he has served on the Editorial Boards of *Letters in Applied Microbiology* and *The Journal of Applied Microbiology*. In June 2010 Dr Tidswell joined the USP expert committee on Microbiology & Sterility Assurance. In 2013 Dr Tidswell joined the PDA's Science Advisory Board.

Presentation
Plenary Session II: Status of Current Chapters
<1223> Revisions
March 16, 2015, 11:20 a.m. – 11:40 a.m.

During the 2010-2015 cycle USP <1223> has been one of the many focuses of revision, improvement and enhancement. The proposed revisions to <1223> were published in the PF in August 2014 receiving positive comments. This presentation will compare and contrast the current to proposed versions of <1223> illustrating the substantial and creative changes. This chapter revision aligns this general guidance to the current and future anticipated state of alternative microbiological methods and provides new and expedient pathways for method validation.

Stephen Wicks, Ph.D.
Regulatory Policy and Intelligence Officer
European Directorate for the Quality of Medicines & HealthCare (EDQM),
Council of Europe
Strasbourg, France

Dr. Stephen Wicks is a Scientific Officer responsible for Scientific Regulatory Policy and Intelligence at the European Directorate for the Quality of Medicines and HealthCare (EDQM), at the Council of Europe. It is a leading organisation that protects public health by: enabling the development, supporting the implementation, and monitoring the application of quality standards for safe medicines and their safe use.

Dr. Wicks previously had responsibility for a number of Groups and Working Parties in the European Pharmacopoeia Department including the Microbiology groups, Blood and blood products group, Cell therapy products working party and, the Raw materials for the production of cell-based and gene therapy products working party.

Dr. Wicks holds a Doctorate in Cancer Cell Biology from Imperial College, London. Following post-doctoral research in Cell Biology at the University of East Anglia, Norwich, he joined the Drug Development Office of Cancer Research UK where he was responsible for the project management of the preclinical development and first in-patient clinical studies of novel cancer diagnostic and therapeutic agents. Dr. Wicks joined the Human Tissue Authority, a UK competent authority under the EU Tissue and Cells Directives as a Regulation Manager and Inspector and went on to become Head of Regulation with responsibility for Licensing and Inspection. Dr Wicks joined the EDQM in November 2011.

Presentation
Plenary Session I: Alternate Methods
Current FDA perspectives
March 16, 2015, 9:50 a.m. – 10:10 a.m.

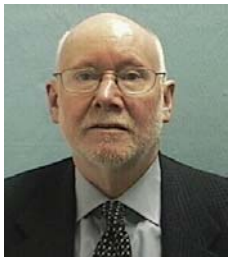
The European Pharmacopoeia (Ph. Eur.) has undertaken a revision of the chapter for Alternative Methods for Control of Microbiological Quality (5.1.6). The talk will outline the changes made during the revision and how comments can be made on the revised chapter.

Scott Sutton, Ph.D.
USP Affiliation:
Member, USP General Chapters–Microbiology Expert Committee

Principal
Microbiology Network
North Chili, New York

Scott Sutton is the Principal of Microbiology Network, Inc (microbiologynetwork.com) a company he started in 1996 as a means to encourage training and communications within the microbiological community. The Microbiology Network operates two Email discussion groups – the PMFList (for pharmaceutical microbiology) and the PSGDList (for stability issues). With over 90 publications and hundreds of presentations, Scott is a recognized consultant and trainer with emphasis in CGMP, investigations, Environmental Monitoring and contamination as well as microbiology laboratory audits and Quality operations. Scott has helped companies in pharma, compounding pharmacies, personal care products with questions and product development issues in both sterile and non-sterile production. Dr. Sutton is an adjunct faculty member of the Wegman's School of Pharmacy at St. John Fisher University (Rochester, NY) and is a long-time USP volunteer, having served as an elected member of the USP Microbiology Committee of Experts since 1995.

Moderator
Plenary Session III: Equivalence Approaches
March 16, 2015, 1:45 p.m. – 5:00 p.m.



Anthony Cundell, Ph.D.
USP Affiliation:
Vice Chair, USP General Chapters–Microbiology Expert Committee
Scarsdale, New York

Dr. Tony Cundell works as an independent consulting microbiologist supporting the pharmaceutical industry, sterile compounding pharmacies, suppliers of microbiological testing equipment and contract testing laboratories. Prior to December 2013 he worked for Merck Research Laboratories in Summit, New Jersey as the Senior Principal Scientist, Analytical Sciences - Microbiology in early phase drug development. In this role he advised product development teams on microbiological issues related to formulation, process development, specification setting and product testing and consulted on CMC sections, responses to regulatory filings and external inspections. Also he was a Senior Technical Advisor to the Merck Manufacturing Division Microbiology Center for Excellence working on the implementation of state-of-art regional microbial identification centers and investigating microbial contamination incidents.

Earlier in his career, Tony Cundell worked as a Director in Quality Control and Product Development organizations at the New York Blood Center, Lederle Laboratories, Wyeth Pharmaceuticals and Schering Plough.

Among his many accomplishments as a pharmaceutical microbiologist, Tony Cundell was Chair of 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*. He is the Vice-Chair of the 2010-2015 U.S. Pharmacopeia Microbiology Committee of Experts responsible for standard setting for the pharmaceutical industry. More recently, he was co-chair of the PDA Task Force on the exclusion of objectionable microorganisms from pharmaceutical drug products, medical devices, consumer health products and cosmetics responsible for the publication of PDA Technical Report #67. He has published extensively in the areas of rapid microbial methods, water activity determination, tribromoanisole taint mitigation, biotechnology, sterilization processes, microbial identification and risk assessment.

In June, 2009, he co-edited with Anthony Fontana a book entitled “Water Activity Applications in the Pharmaceutical Industry” and contributed two chapters to the book.

Tony Cundell has a Ph.D. in Microbiology from the Lincoln University, New Zealand as well as both a M.Sc.(Hons) degree in Biochemistry, and a B.Sc. degree in Biochemistry and Chemistry, Victoria University of Wellington, New Zealand. He did postdoctoral work in marine boring and fouling at Harvard University. Tony Cundell lives with his wife Roz who is an advertising copy writer in Scarsdale, New York.

Anthony Cundell, Ph.D. (continued)

Presentations

Plenary Session III: Equivalence Approaches
Equivalence Determination
March 16, 2015, 1:45 p.m. – 2:25 p.m.

Plenary Session IV: Modern Microbiological Methods
Current Status of Proposed USP Chapter <71.1>
March 17, 2015, 11:30 a.m. – 12:00 p.m.

Edwin van den Heuvel, Ph.D.
Professor
Eindhoven University of Technology (TU/e)
Eindhoven, Netherlands

After finishing his Ph.D. in mathematical statistics at the University of Amsterdam in 1996, he became a statistics consultant at the Institute of Business and Industrial Statistics (IBIS UvA). In this role he supported industry on process improvement and quality and process control. He became interested in measurement system analysis for engineering problems and published several articles. In 2002, he became manager of a statistical department of MSD (formerly known as Organon), where he was introduced to validation issues related to analytical, biological, and microbiological methods. He published many papers in this field and he generalized the method of most probable number. In 2010 he returned to the academy and became a full professor of medical statistics at the University Medical Center Groningen. Since 2014, he is a full professor in statistics at the Eindhoven University of Technology working on statistical methods for data science problems.

Presentation
Plenary Session I: Alternate Methods
Current FDA perspectives
March 16, 2015, 9:50 a.m. – 10:10 a.m.

The proposed revision of the USP <1223> guideline has changed its focus to equivalence of alternative and compendial methods, compared to current official guideline. Four types of equivalences are being suggested: “acceptable procedures”, “performance equivalence”, “results equivalence”, and “decision equivalence”. It will be argued that equivalence should be performed on validation parameters (i.e. performance equivalence) in the form of non-inferiority (one-directional equivalence). Furthermore, it will be demonstrated that non-inferiority should be formulated on parameters of the **detection probability**, a function that is not directly observable but most relevant for validation since it specifies the likeliness of a test outcome given a certain number of micro-organisms present in the test sample. Finally, it is illustrated that the number of test samples should be increased substantially with respect to the advice in the current and revised USP guideline when a statistically confident and reliable statement about the performance of alternative methods is considered important. Ignoring this advice, could possibly lead to the implementation of a seriously inferior alternative method compared to the compendial.

Donald Singer, Ph.D.
USP Affiliation:
Member, USP General Chapters–Microbiology Expert Committee
Chair, USP Governance Committee

Global Lead Quality Manager, Micxrobiology R&D
GlaxoSmithKline
Collegeville, Pennsylvania

Donald C. Singer is Global Lead Quality Manager, Microbiology R&D for GlaxoSmithKine. Don has been a member of the USP Microbiology Expert Committee since 2000, is a Certified Specialist Microbiologist (NRCM) and Certified Pharmaceutical GMP Professional (ASQ), He has been a Malcolm Baldrige Award Examiner, a National Director and Senior member of the American Society for Quality (ASQ). Don's career spans over 35 years of research, quality control, quality assurance and quality auditing experience including over 25 years in the pharmaceutical industry. He is currently an adjunct instructor in the Biopharmaceutical Quality program at University of Maryland Baltimore Campus, an author, and an invited instructor to numerous global educational conferences and workshops.

Moderator
Plenary Session IV: Modern Microbiological Methods
March 17, 2015, 9:00 a.m. – 12:00 p.m.

LCDR Simleen Kaur, M.S.
USPHS, Senior Regulatory Review Officer
U.S. Food and Drug Administration (FDA),
CBER/Office of Compliance and Biologics Quality
Silver Spring, Maryland

Simleen Kaur is a Senior Regulatory Review Officer with CBER's Office of Compliance and Biologics Quality. She has been evaluating and reviewing Rapid Microbiological Methods for sterility testing for the past six years. Her team has completed evaluation of seven platforms for alternate testing and is currently working on re-initiating the project at the new White Oak facility.

Presentation
Plenary Session IV: Modern Microbiological Methods
Current FDA perspectives on Biologics Sterility Tests FDA/ CBER
March 17, 2015, 9:30 a.m. – 10:00 a.m.

Rapid Alternate methods are highly sought after due to the shorter shelf life of certain biological products and the need to make products rapidly available during emergencies, such as pandemic outbreaks and bioterrorism attacks. Extensive study was performed by the CBER's Office of Compliance and Biologics Quality where several growth and non-growth based rapid microbiological methods were evaluated for their suitability for sterility testing of biological products. The presentation covers the data collected through the study and future plans for the project at the new White Oak facility.

David Roesti, Ph.D.
USP Affiliation:
Team Leader
Novartis Pharma Stein AG
Stein, Switzerland

David is a global expert in microbiology for Novartis Pharmaceuticals and is currently leading the microbiology network of Novartis Pharma and the Rapid Microbiological Methods team at Novartis Pharma AG in Stein Switzerland. Prior to this assignment, David was the laboratory supervisor for the microbiological testing of non-sterile drug products at Novartis Pharma Stein AG and during this time was the local project leader for the implementation of the harmonized Pharmacopoeial methods for non-sterile product testing.
David holds a PhD in microbial ecology from the University of Neuchâtel, Switzerland and has 15 years of experience in the field of microbiology within various domains (drug product manufacturing, food microbiology, biogaz production, microbial interactions in the rhizosphere).

Presentation
Plenary Session IV: Modern Microbiological Methods
Industry Perspective
March 17, 2015, 10:00 a.m. – 10:30 a.m.

Modern Microbiological Methods (MMMs) are now recognized for their many advantages over conventional methods such as for instance a reduction of throughput time or an earlier and more precise identification of product contaminants. They may actually become essential for assuring patient safety of novel product types with very low shelf life (e.g. cell therapy products). Yet, there still exists many hurdles even within the pharmaceutical industry to use MMMs in routine quality control and monitoring. This presentation will discuss pathways for successful implementation of MMMs and sharing the experience gathered over the years from a team specialized in MMMs within a major pharmaceutical company.

Nobuyasu Yamaguchi, Ph.D.
Associate Professor
Osaka University (Osaka, Japan)

Dr. Nobuyasu YAMAGUCHI, graduated in 1993 from Osaka University and received his Ph. D. in 1999 from Osaka University. From 1993 to 2006, he was assistant professor, and associate professor from 2006 at Graduate School of Pharmaceutical Sciences, Osaka University.

He has interest in relationship among human, environment and microbes. He has been contributing to establish new methods to detect and analyze microbes, especially in the environment.

His research fields are as follows:

- Real-time and on-site monitoring of microorganisms using fluorescent staining techniques and microfluidic devices
- Application of new methods to monitor and analyze microbes
- Ecology of harmful microorganisms, especially in aquatic environments
- Microbial dynamics in crewed habitat in space, such as International Space Station-KIBO, as a basic research program of human long-duration space habitation in the future as lunar habitat and Mars exploration

He is an editorial board member of Scientific Reports (Nature Publishing Group) in microbiology (www.nature.com/srep/eap-ebm/index.html#microbiology).

Presentation
Plenary Session IV: Modern Microbiological Methods
Rapid Biological Methods – Perspective of Japanese Pharmacopoeia
March 17, 2015, 11:00 a.m. – 11:30 a.m.

Rapid microbiological methods, newly developed to enumerate and identify microbes, revealed that most microbes in environments hardly form colonies under conventional culture conditions and the number of bacteria had been underestimated. To understand the nature of microbes, new methods have been applied in environmental microbiology, become essential for precise analysis, and are now widely used. In addition, interests on new methods are increasing in the fields where strict microbial control is required, such as pharmaceutical manufacturing.

In JP, fluorescent vital staining and microcolony method were introduced in the information chapter of supplement II of 15th edition (September 2009) as “Rapid Counting of Microbes using Fluorescent Staining”. Identification of bacteria and

Nobuyasu Yamaguchi, Ph.D. (continued)

fungi based on DNA sequence was introduced in the information chapter of supplement II of 14th edition (December 2004) as "Rapid Identification of Microorganisms Based on Molecular Biological Method" and was updated in the 16th edition (March 2011).

Total direct counting method using fluorescence microscopy has been widely acknowledged to be one of the useful techniques to determine true value of microbes and enumerate viable microbes based on their enzyme activity, respiration activity, membrane integrity, and so on. Results can be obtained within one working day.

Identification of microbes has shifted from phenotypic analysis to genotypic one, and gene sequencing has become popular to identify isolated microbes based on their DNA sequences. By direct extraction of microbial DNA in pharmaceutical samples and sequencing of microbial rRNA gene, we do not have to culture and isolate contaminated microbes to identify them, and we can determine dominant microbes even if they do not form colonies. This approach will provide early warning of an impending problem and lead us to take corrective actions.
In September 2014, JP introduced draft of new information chapter "Rapid Microbiological Methods" for the 17th edition as public comments, and the following methods were listed in the draft:

> Direct method: solid-phase cytometry, flow cytometry
>
> Indirect method: immunological methods, nucleic acid amplification techniques, bioluminescence, microcolony method, impedance method, measurement of consumption or production of gas, fatty acid analysis, infrared absorption spectrometry, mass spectrometry, genetic fingerprinting, high-throughput sequencing

In the next edition of JP, one novel method, "high-throughput sequencing", is introduced. The techniques for high-throughput sequencing are actively developed in recent years and we can read more than 100,000 sequences of microbial DNA in parallel by a high-throughput sequencer. Phylogenetic analysis based on gene sequences has become popular, and one can analyze the composition of microbial community in a short time. By high-throughput sequencing, we can obtain information on real microbial world.

Radhakrishna Tirumalai, Ph.D.
Principal Scientific Liaison, General Chapters
USP
Rockville, Maryland

Radhakrishna Tirumalai, Ph.D., is a Principal Scientific Liaison in the USP, Rockville, MD, Department of General Chapters

He is the Staff Liaison to the USP Expert Committees on Microbiology, and, Toxicology. He works with the industry/ academia/ regulators and the USP Expert Committee in the development and revision of General Chapters in these areas. He represents USP on various external task forces and committees (AAMI and PDA) related to Sterilization, Sterility Assurance and Biocompatibility.
He has been with the USP since 2003. Prior industry experience encompasses process and product research &development, transfer and product manufacturing.

He is an author of several review articles in the area of Pharmaceutical Microbiology. He is also a frequent speaker at conferences and has taught Pharmacopeial Microbiology courses at numerous locations globally.

Presentations
Overview of Day's Topics
March 17, 2015, 9:00 a.m. – 9:10 a.m.

Summary of Discussions: What Was Said, What Was Heard, Next Steps
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