



2010-2015 USP Expert Committees and Their Focus Areas, Roles, and Expertise Required
 Revised January 2010

USP invites qualified candidates – pharmaceutical scientists, academicians, regulatory professionals, healthcare professionals, and others – to apply to serve as scientific decision makers on the Council of Experts and its Expert Committees. The 2010-2015 Council of Experts includes 20 Expert Committees in the areas of Nomenclature, Small Molecules, Biologics and Biotechnology, Excipients, General Chapters, Reference Standards, Compounding, Food Ingredients, and Dietary Supplements, with each member of the Council of Experts chairing an Expert Committee.

The following information describes the Expert Committees for which USP is seeking candidates, its focus areas, its roles and responsibilities, and the expertise required of potential applicants.

Expert Committee	Focus Areas	Expert Committee Roles	Expertise Required
01. 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.
02. 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.
03. 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.



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04. 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.
05. 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.
06. 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
07. 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.



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08. 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.
09. Compounding	<ul style="list-style-type: none"> • Human Drug Compounding • 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 General Chapters that pertain to the compounding of extemporaneous non-sterile and sterile preparations. • Develop and approve additional content for the <i>USP Pharmacists' Pharmacopeia</i>. 	<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 • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials.
10. 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.
11. 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).



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12. 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 physical analysis. • 	<ul style="list-style-type: none"> • Expertise in classical physical measurement techniques, excipient performance characteristics and their effects on manufacturing processes, pharmaceutical compounding, writing, or 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).
13. 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).
14. General Chapters—Dosage Forms	<ul style="list-style-type: none"> • 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.



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15. 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).
16. 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 and packaging.extractables/leachables analysis and control.
17. Nomenclature, Safety, and Labeling	<ul style="list-style-type: none"> • Drug Product Nomenclature • Food and Excipients Nomenclature • Dietary Supplements Nomenclature • Biologics/Biotechnology Nomenclature • Safe Medication Use • Prescription Labeling 	<ul style="list-style-type: none"> • Review and approve monograph titles • Review new dosage forms appearing on the market • Implement/develop nomenclature policies • Develop and approve content for USP Dictionary • Patient safety aspects of drug labeling 	<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.
18. 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 	<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.



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19. 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 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).
20. 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