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U.S. Pharmacopeial Convention

2015-2020 USP Expert Committees, Their Roles, and Expertise Required

February 20, 2015

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 2015-2020 Council of Experts includes 24 Expert Committees in areas described below, with each member of the Council of Experts chairing an Expert Committee. The following information describes the number of each type of Expert Committee for which USP is seeking candidates, their roles, and the expertise being sought for that Expert Committee.

Expert Committees	Role(s)	Expertise Required
Nomenclature and Labeling (1 Expert Committee)	Review and approve monograph titles using practices developed by the Expert Committee elaborated in the USP Nomenclature Guideline (go to www.usp.org and search on Compendial Nomenclature). Develop and revise general chapters that focus on nomenclature and labeling topics. Review labeling statements in individual monographs.	• Nomenclature regulations and policies • Current marketplace products in respective focus areas • Labeling requirements • Analytical chemistry • Drug formulation specialist • Regulatory requirements
Compounding (1 Expert Committee)	Develop new and revise existing compounding-related general chapters for human and veterinary patients as well as development of compounded preparation monographs.	• Pharmacist with expertise in formulating and compounding sterile and non-sterile preparations • Pharmacist/chemist with analytical experience in method development/validation/stability • Regulatory requirements for compounding • Clinical expertise (inpatient, outpatient, home health, and veterinary) • Environmental engineering • Microbiology/infection control
Healthcare Quality (1 Expert Committee)	Develop quality standards to support practitioners in the safe and effective implementation of other *USP-NF* standards; maintain quality standards of value to practitioners and the public supporting the US National Quality Strategy and current public health needs; and revise USP's Medicare Model Guidelines	• Therapeutic expertise (internal medicine, primary care, etc.) • Formulary expertise • Drug classification • Drug information • Health information technology • Patient advocacy • Safe medication use • Population health • Health literacy • Health Informatics

Expert Committees	Role(s)	Expertise Required
Chemical Medicines Monographs (6 Expert Committees)	Develop new and revise existing monographs and their associated reference standards for chemical drug substances and drug products. The work of the six Chemical Medicines Expert Committees will be organized by the chemical structure and associated chemical properties of monographed articles. Candidate experts will be assigned to the Expert Committees according to specific expertise and experience. The Committees will address global standards as well as standards for the US.	• Analytical chemistry • Synthetic organic chemistry • Drug performance characteristics • Impurities analysis • Validation • Microbiology • Qualification and use of reference materials
Biologic and Biotechnology Monographs (3 Expert Committees)	Develop new and revise existing monographs and their associated reference standards for biological medicines, including vaccines, therapeutic proteins, blood and blood products, and other biological products. The work of the three Biologic and Biotechnology Monographs Expert Committees will be organized by the product class of monographed articles. Candidate experts will be assigned to the Expert Committees according to specific expertise and experience. The Committees will address global standards as well as standards for the US.	• Immunology • Virology • Biological potency • Vaccine manufacturing and analysis • Biotherapeutic proteins • Monoclonal antibodies • Biosimilar characterization • Pharmaceutical quality control, compliance, and analytical characterization testing • Regulatory requirements • Qualification and use of reference materials
Excipient Monographs (2 Expert Committees)	Develop new and revise existing monographs and their associated reference standards for pharmaceutical excipients. The work of the two Excipients Expert Committees will be distributed across the Committees such that each will address a broad range of monographs. Candidate experts will be assigned to ensure broad expertise across both Expert Committees. The Committees will address global standards as well as standards for the US.	• Analytical chemistry • Synthetic organic chemistry • Excipient performance characteristics • Impurities analysis • Validation • Microbiology • Qualification and use of reference materials
Non-botanical Dietary Supplements (1 Expert Committee)	Develop new and revise existing monographs and their associated reference materials for non-botanical dietary supplement ingredients and products.	• Analytical chemistry • Toxicology related to dietary supplements/ingredients • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials

Expert Committees	Role(s)	Expertise Required
Botanical Dietary Supplements and Herbal Medicines (1 Expert Committee)	Develop new and revise existing monographs and their associated reference materials for botanical dietary supplements and herbal medicine ingredients. The Committees will address global standards as well as standards for the US.	• Traditional herbal medicine • Analytical chemistry • Pharmacognosy • Toxicology related to herbal medicines • Expertise with regulatory requirements • Expertise with the qualification and use of reference materials
Food Ingredients (1 Expert Committee)	Develop new and revise existing monographs and their associated reference materials for food ingredients. The standards appear in the *Food Chemicals Codex.*	• Food chemistry • Analytical chemistry • Food technology • Food toxicology • Food regulatory affairs • Qualification and use of reference materials
General Chapters—Chemical Analysis (1 Expert Committee)	Develop new and revise existing general chapters related to chemical analysis (e.g., chromatography, spectroscopy, metal or water analysis).	• 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 and dietary supplement analysis (e.g., vitamin, mineral, or botanical supplement analysis) • Compendial issues related to water quality. • Tests or methods of assay in settings involving the demonstration of compliance with FDA cGMPs (identity, strength, quality, and purity)
General Chapters—Physical Analysis (1 Expert Committee)	Develop new and revise existing general chapters related to physical analysis (e.g., particles, powders, rheology).	• Classical physical measurement techniques • Excipient performance characteristics and their effects on manufacturing processes • Demonstrating compliance with FDA cGMPs (identity, strength, quality, and purity)
General Chapters—Biological Analysis (1 Expert Committee)	Develop new and revise existing general chapters related to biological molecules, ancillary materials and reagents, and product monographs. Also to develop technique-based general chapters as needed to contain key technologies supporting multiple product monographs.	• Cell-based assays • Immunochemistry • Physicochemical characterization of proteins and natural products • Vaccines and virology • Immunology • Development or manufacturing of biologics • Demonstrating compliance with FDA cGMPs (identity, strength, quality, and purity)

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General Chapters—Dosage Forms (1 Expert Committee)	Develop new and revise existing general chapters related to pharmaceutical dosage forms.	• Development and testing of drug products for quality and performance • BA/BE and dissolution testing • Formulation design and testing • Medical gas testing • Performance testing of parenterals, aerosols, ophthalmic solutions, patches, topicals • Veterinary and radiochemical applications
General Chapters—Microbiology (1 Expert Committee)	Develop new and revise existing general chapters related to Microbiology and Sterility Assurance. Also to evaluate Sterility Assurance, Bacterial Endotoxins, and Microbial Quality requirements for particular monographs.	• Classical microbiology • Sterility Assurance • Familiarity with current industrial and regulatory trends in pharmaceutical microbiology, including automated/rapid technologies • Demonstrating compliance with FDA cGMPs (identity, strength, quality, and purity)
General Chapters—Packaging and Distribution (1 Expert Committee)	Develop new and revise existing general chapters related to packaging (container-closure systems), storage, and distribution of pharmaceutical ingredients or dosage forms.	• Packaging, storage and distribution of drug substances, drug products, excipients, dietary supplements or food ingredients. • Anti-counterfeiting technologies • Packaging extractables/leachables analysis and control • Storage/temperature control • Supply chain management
Statistics (1 Expert Committee)	Provide statistical and metrological support for other Expert Committees in their development and approval of monographs, general chapters, and reference materials.	• Statistics and current industrial trends in quality assurance, chemometrics, biostatistics, and biological assays • Statistics in manufacturing and CMC controls • Analytical methods and data evaluation • Metrology and measurement science (e.g., uncertainty assignments) • Statistical aspects of assay commutability and value assignment for reference materials