Dietary Supplements & Herbal Medicines, Food Ingredients Chair; US Pharmacopeia

Hiring organization
US Pharmacopeia; https://www.usp.org/

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Description

Job Description – Who is USP? The U.S. Pharmacopeial Convention (USP) USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. USP's fundamental belief that Equity = Excellence manifests in our core value of Passion for Quality through our more than 1,100 talented professionals across five global locations to deliver the mission to strengthen the supply of safe, quality medicines and supplements worldwide.Who are our Expert Volunteers?A hallmark of USP's standards is that they are determined by independent scientific experts. USP Expert Volunteers are selected based on their individual expertise and experience and use their best personal, professional, and scientific judgment to work collaboratively on setting standards. USP Expert Volunteers must agree to disclose conflicts of interest and to uphold standards of conduct that preserve the integrity of the standard setting process. Chair ResponsibilitiesLeads, listens, and builds consensus among committee membersElects Expert Committee (EC) Members through their Council of Experts (CoE) roleChairs and leads an ECEnforces standards of conduct as expressed in USP's Bylaws, rules, and policies, including CoE Rules and the USP Code of Ethics Participates in Collaborative Group discussionsLeads Chair succession planning and develops "next generation" of volunteersServes as the face of the ECAdministers the EC's Work PlanReviews disclosure statements and manages conflicts of interestPrepares for meetings by working with USP staff to develop meeting agenda and briefing materials; manages meeting agenda, including meeting closure, facilitates EC meeting and discussion; and focuses on and summarizes outcomesAdopts the Rules and Procedures of the 2025-2030 Council of Experts (CoE Rules)Approves General Notices and General Chapter<11> USP Reference StandardsParticipates in the adjudication of appealsRecommends the number and types of ECs for the next cycleAppoints new/replacement EC Chairs through CoE roleConsiders long-term implications of activities on USPFulfills all duties of an EC MemberChair QualificationProven track record of effective leadership within the pharmaceutical / food / dietary supplement & herbal medicines industry or related fields, demonstrating the ability to guide and inspire diverse teams towards achieving common objectives.Strong communication and interpersonal skills, essential for fostering collaboration, facilitating discussions, and building consensus among committee members.Experience in strategic planning and decision-making, with the capability to navigate complex challenges and drive initiatives aligned with USP's mission and goals.Commitment to upholding the highest standards of integrity, ethics, and professionalism, serving as a role model for ethical conduct and accountability within the committee and broader community.Ability to represent the EC's interests and perspectives within USP's governance structure, advocating for the adoption of evidence-based standards and best practices.Capacity to effectively manage time

and resources, ensuring the efficient operation of the committee and timely completion of assigned tasks and deliverables.Dedication to ongoing learning and professional development, staying abreast of relevant industry trends, regulatory requirements, and emerging technologies to inform the committee's work and recommendations.

Responsibilities – Focus AreasBotanical Dietary Supplements and Herbal MedicinesDevelopment of quality standards for botanical dietary ingredients and supplements, and herbal medicine ingredients from the Americas, East Asia, South Asia, and possibly Africa. Adulteration and contamination of botanicals and phytochemicals. Types of ingredients may include plant parts, plant powders, plant extracts, fungi, algae and lichens; classes of compounds include a variety of natural product constituents, in particular cannabinoids, and complex macromolecules such as carbohydrates, procyanidins/condensed tannins. Contaminants analysis including methods and limits for aflatoxins, pesticide residues, and pyrrolizidine alkaloids. Dietary supplement dosage forms including tablets, capsules (hard-shell and soft gels), sachets, gummies, and their performance analysis such as dissolution and disintegration.Non-Botanical Dietary SupplementsDevelopment of quality standards for non-botanical dietary ingredients and supplements. Application of modern analytical methods for compendial use, oxidative oils analysis. Types of ingredients include amino acids, carbohydrates (simple and complex), mineral salts and complexes, oils, fatty acids and other lipids, probiotics and live biotherapeutic products, dietary proteins, small molecules, vitamins and preparations, nanomaterials. Dietary supplement dosage forms including tablets, capsules (hard-shell and soft gels), gummies, Manufacturing, and formulation; Performance testing (dissolution, disintegration), and their performance analysis such as dissolution and disintegration.Dietary Supplements Admission Evaluation & LabelingEvaluation of safety-based on human data (clinical studies and adverse events), toxicological data (in vivo/animal studies and in vitro studies), and potential interactions for a variety of dietary ingredients including plants, plant extracts, probiotics, proteins, amino acids, oils, and others to determine their admissibility into the USP compendia.Food IngredientsDevelopment of standards of food ingredients for the Food Chemicals Codex (FCC). Adulteration and contamination issues in food ingredients (elemental impurities, residual solvents, pesticides, mycotoxins, microbial), especially those consumed by vulnerable populations. Development of standards and solutions for priority ingredients for special nutrition needs. Development of advanced methods/ guidelines that support standards for prioritized novel and emerging ingredients. Advocacy for our work and collaboration with FDA and other regulatory agencies.Key Issues/GoalsBotanical Dietary Supplements and Herbal Medicines: botanical identification; adulteration and contamination; sampling; fungal and algal ingredients; botanical monograph modernization; cannabis and cannabinoids.Non-botanical Dietary Supplements: implementation of advanced analytical methodologies in the pharmacopeia, development of standards for challenging ingredients, adulteration of ingredients.Dietary Supplements Admission Evaluation & Labeling: safety of ashwagandha and other safety signals that may arise; Revising the approach to conducting safety evaluations.Food Ingredients: address adulteration and contamination issues in foods (elemental impurities,

pesticides, mycotoxins, microbial) and create tools and other solutions (guidelines, etc.), to address emerging contaminant issues; develop standards (identification standards) and other solutions for key quality attributes for priority ingredients for special nutrition needs, such as ingredients used in infant formula; develop advanced methods/ guidelines that support prioritized innovative ingredients

Qualifications – Required Qualifications / TechnicalThe successful candidate would benefit from expertise in the several following areas:Method development/method optimization/method validationReference standard evaluationPharmacognosyChemometricsChromatography: Liquid (H/UPLC), Gas, Planar (HPTLC)Analytical Spectroscopy: IR/Raman, NMR/qNMR, flame/plasma, Light Scattering, UV-Vis, NIR, XRF/XRDTitrimetry: Potentiometric including ISE, Karl FischerMass SpectrometryQuality by DesignMultivariate/chemometric analysisWet chemistryDNA analysis, PCR methodsNomenclature and labelingPlant taxonomyMicrobiologic analysisEnzyme activity methodsBiopolymer size and mass analysis (SEC-MALS)Contaminant analysisDetection of adulterationEvidence-based toxicology reviewingIn silico toxicology testsIntegrative medicineRegulatory risk assessmentSurveillance/adverse effect monitoringSpecial nutrition ingredients including dietary proteins, amino acids, HMO, etc.,Statistics background and experience with the design of experimentsUnderstanding of regulatory frameworks/programs for food ingredientsExperience with the testing of food ingredients for quality/authenticityAdditional Desired QualificationsBotanical Dietary Supplements and Herbal Medicines: practicing pharmacologists, pharmacognosists, herbalists, naturopathsNon-Botanical Dietary Supplements: clinical or clinical pharmacology experienceDietary Supplements Admission Evaluation & Labeling: Clinical research experience utilizing herbal medicines and dietary supplementsFood Ingredients: experience in next-generation sequencing, NMR; expertise in botanical ingredient analysis, especially focusing on authenticity and adulteration.Volunteer Time RequirementMust be able to contribute average of 5 hours per week with some variationMeetings: 1 to 2 face-to-face official meetings per fiscal yearTeleconferences held as needed for official meetings and working sessionsTravel RequirementMust be able to attend two (2) in-person collaborative meeting at USP Headquarters in Maryland, US, Brazil, China, or India per fiscal year; minimum of 3 in-person attendance per 5-year cycleLanguage ProficiencyWhile USP operates primarily in English, our Expert Volunteers come from all over the world and speak multiple languages. While most LIVE business meetings are conducted in English, much of the work for the Expert Scientist includes reading, reviewing, and writing in Technical English. Proficiency in written English is required. Effective verbal communication may be facilitated by technology and written pre-read materials. Encourage application even if English is not the native spoken language but are proficient in reading and writing in Technical English. For more information on English Proficiency requirements, please refer to this link.

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Post End Date – 12/31/2024

Contacts

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