Call for Candidates: Biologics Monographs—4 Antibiotics Expert Committee

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Closing Date: Extended 9–June–2017

Expert Committee: Council of Experts

In accordance with Section 4.01 of the Rules and Procedures of the 205-2020 Council of Experts, USP invites qualified candidates to apply to serve as scientific experts on the recently established Biologics Monographs 4—Antibiotics Expert Committee. This new Expert Committee will guide USP's ongoing scientific efforts to update monograph requirements and associated reference standards for antibiotics that are currently still assessed and potency-assigned by antimicrobial activity. These substances are currently assessed by assays that are described in General Chapter <81> Antibiotics—Microbial Assays.

The main goal for the work of the committee will be to advance the transition of additional antibiotics to physicochemical methods for *Assay* and value assignment. As part of this charge, the expert committee will also be asked to review and revise, as necessary, General Chapter <81> *Antibiotics—Microbial Assays* and <1223.1> *Validation of Alternative Methods to Antibiotic Microbial Assays*. As the relative potency assignment for these antibiotics is critically linked to the availability of appropriate reference standards. The EC will also oversee the development and approval of USP Reference Standards for antibiotics that support this portfolio, and make recommendations, as needed, for the updating of USP's approach to developing and maintaining these materials in alignment with available international standards.

Specific expertise sought for this group includes a deep understanding of the analytical and quality control assays currently applied to the antibiotics currently referenced in General Chapter <81> –both physicochemical characterization expertise for content and composition as well as microbial assay expertise in the currently official turbidimetric and cylinder-plate assays. Experience with assay transition from a microbial potency test to HPLC will also be considered highly desirable. Additionally, USP seeks expertise in the development, evaluation, establishment and maintenance of reference standards for these products.

To apply please submit an application at <u>http://callforcandidates.usp.org</u> highlighting relevant experience prior to consideration. Applications and inquiries will be accepted through April 10, 2017.

For more information, please contact Fouad Atouf, Vice President, Global Biologics Science at <u>fa@usp.org</u> or 301-816-8365.