Overview

The U.S. Pharmacopeial Convention (USP) is pleased to invite you to submit abstracts for oral presentations and posters at the 4th Workshop on Synthetic Therapeutic Peptides to be held at the USP Headquarters Meetings Center on November 6–7, 2017.

After a successful program in 2016 focused on manufacturing considerations, impurities, specifications, novel peptide therapeutics and regulatory considerations, USP is bringing its Therapeutic Peptides Workshop back again in 2017 for a more in-depth program which will examine GMP manufacturing considerations, analytical characterizations, CMC and formulation for diverse delivery systems, and USP updates.

We are seeking presentations and posters on the following topics:

**Session I: GMP Manufacturing Considerations**
- a. Raw material control
- b. Control strategies for impurities in raw materials
- c. Regulatory change control requirements for peptide starting material
- d. Individual amino acid specifications
- e. Simple to complex peptides and conjugants
- f. Appropriate level of GMP for peptide synthesis during clinical development
- g. GMP requirements for lot release

**Session II: Analytical Characterizations and Impurities**
- a. Alternative analytical methods to quantify and report related substances
- b. Level of characterization of impurities at different phases
- c. Impurities under main peak
- d. Common degradation routes for peptides in aqueous solutions
- e. Stability indicating assays

**Session III: Drug Substance and Drug Product Specifications**
- a. Quality attributes
- b. Drug substance (DS)/Drug product (DP) specifications (with analytical methods, limits)
- c. Specifications where the US is different from the rest of world with regard to peptides
CALL FOR ABSTRACTS & POSTERS
As of April 24, 2017

Session IV: Formulation and Delivery Systems
a. Strategies for overcoming solubility limitations
b. Lyophilization and other long-term storage methodologies
c. Formulating for various delivery systems and routes of administration: microparticles, polymeric nanoparticles, liposomes and solid lipid nanoparticles
d. Characterization of complex peptide formulations (e.g., microspheres)
e. Requirements for functional excipients

Session VI: Regulatory
a. Implementation of appropriate levels of GMPs for peptide synthesis during clinical development thought commercialization
b. CMC strategies for peptides
c. Comparability between the generic and the innovator products
d. Regulatory characterization (non-routine) required for submission
e. Are bioassays only necessary for recombinant peptides?

Contributed Abstract/Poster Submission Timeline:

- Submission Deadline: Wednesday, May 31, 2017
- Notification of Acceptance/Denial: Friday, August 30, 2017

Submission Instructions:

A. FORMAT YOUR ABSTRACT
Please write your abstract in English using either Microsoft Word or PDF format.

B. PROOFREAD
Be sure to proofread your submission to confirm that it contains all the information you want to include before submitting your abstract.

C. PRESENTING AUTHOR AND ADDITIONAL AUTHORS
When listing your authors, you must designate a presenting author. It is recommended that the presenting author also be the submitter of the abstract. All correspondence will be sent to the submitter. The authors can be listed in any order you designate.

D. SUBMIT YOUR ABSTRACT
Send your abstract submission to Chantelle Murat at cqm@usp.org.
E. FINANCIAL CONSIDERATIONS FOR APPROVED PRESENTERS
A complimentary workshop registration will be provided for all session presenters. A discounted registration fee will be offered for poster presenters. All travel costs including airfare, hotel, ground transportation, food and beverage, and any other travel related incidentals/extras are the responsibility of the session or poster presenter.

F. ASSISTANCE
If you have any questions or are experiencing difficulties in the submission process, contact:

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For more information about the workshop including an overview of topics and registration, please visit www.usp.org/meetings-courses/workshops