Now Virtual!

USP Workshop on Therapeutic Peptides and Oligonucleotides

Call for Abstracts

Deadline for Submission December 1, 2020

USP Biologics™

We are pleased to invite you to submit abstracts for oral presentations or posters at the USP Workshop on Therapeutic Peptides and Oligonucleotides: Regulations and Quality Standards to be held virtually on **March 1st, 3rd, and 5th , 2021**, from 10am – 1pm each day.

The Steering Committee is accepting abstracts for presentations on the following topics for either peptides or oligonucleotides:

- Raw materials for drug substance
  - Setting specifications
  - Identification and characterization of impurities in raw materials
  - Performance testing to demonstrate fit-for-purpose
  - Developing stability-indicating assays
  - Quality systems
  - Supplier risk management
  - Case studies sharing successes, failures and lessons learned due to raw material issues
- Drug products
  - Novel formulation approaches
  - Novel delivery systems

- Molecular design: improving stability, bioavailability, half-life extension
- Analytical development, characterization and validation
    - Modifying analytical techniques/sample preparation to support testing of complex drug products
    - Case studies demonstrating successful validation and use of sophisticated technologies for release testing (e.g., mass spectrometry, NMR, etc.)
    - Advanced orthogonal technologies for characterization
    - Bridging between old and new methods
    - Identifying and characterizing impurities in raw materials, drug substances and drug products
    - Bioassay development
- Green chemistry approaches for synthesis and/or analysis
- Advances in manufacturing and purification technologies: strategies and novel methods
- Control strategies
    - Setting specifications and acceptance criteria
    - Comparability between generics and innovator products, including special cases of recombinant to synthetic peptides
    - Peptide-related immunogenicity testing (in-silico, in-vitro, in-vivo)
    - Current and future documentary standards and reference standard materials to support peptides and oligonucleotides
- Regulatory aspects
    - Compliance
- CMC strategies
    - Case studies demonstrating successful regulatory submissions or addressing gaps following review
- Drug conjugates
- Personalized medicines
    - Peptide vaccines
    - Oligonucleotides

- Structure-function studies and new targets

Contributed abstract/poster submission timeline:

- **Submission deadline**: For oral presentations, please submit abstracts by December 1, 2020. For posters, we will continue to accept poster presentations on a rolling basis (priority review will be given for early submissions).
- **Notification of acceptance/denial**: Notification will be sent beginning in December 2020.

Submission instructions:

1. **Submit your abstract**
   Send your abstract submission to: Maura Kibbey at mck@usp.org **Your abstract must include your full contact information**: **presenter's name, title, company, email address, and telephone number**. If there are multiple authors on the abstract, please indicate one person who will be the presenter. Please also indicate if you are applying to be a speaker or poster presenter.
2. **Financial considerations for approved presenters**
   Complimentary workshop registration will be provided for all session speakers and graduate student poster presenters. A discounted registration fee will be offered for other poster presenters.
3. **Assistance**
   If you have any questions or are experiencing difficulties in the submission process, please contact:

   Maura Kibbey
   Senior Scientific Fellow, USP Global Biologics
   Email: mck@usp.org