USP Workshop on Therapeutic Peptides and Oligonucleotides:
Regulations and Quality Standards
April 9 and 10, 2024

Call For Abstracts
Deadline: November 3, 2023

We are pleased to invite you to submit abstracts for oral presentations at the USP Workshop on Therapeutic Peptides and Oligonucleotides: Regulations and Quality Standards to be held on April 9 and 10, 2024.

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

- Drug products
  - Novel formulation approaches
  - Novel delivery systems
  - Drug conjugates
  - Personalized medicines
    - Peptide vaccines
    - Oligonucleotides
  - Molecular design: improving stability, bioavailability, half-life extension
  - Structure-function studies and new targets
- Manufacturing technologies
  - Green chemistry approaches for synthesis and/or analysis
  - Advances in manufacturing and purification technologies: strategies and novel methods
- 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., ID by MS and purity/related impurities by LC-MS, NMR, etc.)
    - Advanced orthogonal technologies for characterization
    - Bridging between old and new methods
    - Identifying and characterizing impurities in drug substances and drug products
    - Bioassays
- Control strategies
    - Setting specifications and acceptance criteria (e.g., for early vs. late development stages)
    - Comparability between generics and innovator products (e.g. special cases of recombinant to synthetic peptides, comparability of potential generic oligonucleotides at the level of phosphorothioate stereoisomers ratio)
    - Peptide aggregation and immunogenicity testing (in-silico, in-vitro, in-vivo)
    - Current and future documentary standards and reference standard materials to support peptides and oligonucleotides
    - Case studies demonstrating successful regulatory submissions or addressing gaps following review
- Regulatory aspects
    - Compliance
    - Strategies to meet global regulatory requirements
    - Post-approval change management
- 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 and Supplier risk management
    - Case studies sharing successes, failures, and lessons learned due to raw material issues

Contributed abstract submission timeline:

- **Submission deadline:** Please submit abstracts by November 3, 2023.

Submission instructions:

1. **Submit your abstract**
   Send your abstract submission to: Bruno.decarvalho@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 presenter.

   *Complimentary workshop registration will be provided for all session speakers.

2. **Assistance**

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

   Bruno De Carvalho
   Stakeholder Engagement Manager, USP Global Biologics
   Email: Bruno.decarvalho@usp.org