

## USP Workshop on Raw Materials for Manufacturing of Biologics

# Best Practices and Quality Standards

April 13-14, 2021 | Rockville, MD

**Call for Abstracts**  
Deadline October 1, 2020



We are pleased to invite you to submit abstracts for oral presentations or posters at the USP Workshop on Raw Materials for Manufacturing of Biologics to be held at the USP Meetings Center in Rockville, MD on **April 13-14, 2021**.

**The Steering Committee is accepting abstracts for presentations on the following topics:**

- Setting specifications for raw or ancillary materials
  - Identification and characterization of impurities in raw materials
  - Performance testing to demonstrate fit-for-purpose
  - Developing stability-indicating assays
- Quality systems for raw materials
- Case studies sharing successes, failures, and lessons learned due to raw material issues
- Cell and gene therapy (advanced therapy medicinal products) raw material qualification and differentiation with starting materials
- Safety and qualification of biologically derived/complex materials

- Supplier risk management
  - Setting expectations based on raw material attributes and process impact
- Analytical strategies to tie raw material quality attributes to process performance
- Existing and future documentary standards and reference standard materials to support raw materials

### **Contributed abstract/poster submission timeline:**

- **Submission Deadline:** For oral presentations, by **October 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 **mid-October 2020**

### **Submission Instructions:**

#### **1. Submit your abstract**

Send your abstract submission to: Maura Kibbey at [mck@usp.org](mailto: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. All travel costs including airfare, hotel, ground transportation, food and beverage, and any

other travel related incidentals/extras are the responsibility of the session speaker or poster presenter.

### 3. **Assistance**

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

Maura Kibbey, Ph.D.

Senior Scientific Fellow, Global Biologics

Email: [mck@usp.org](mailto:mck@usp.org)