Quality by Design (QbD) and Process Analytical Technology (PAT) for Biopharmaceuticals

Concepts and Applications in Development and Commercialization

Boston, Massachusetts

Course Description:

- This course aims to clarify the key concepts that interplay in defining and implementing QbD and PAT towards development and manufacturing of biotech products. This will be achieved via a sequence of lectures and group work. Concepts discussed include: Critical Quality Attributes (CQA), Design Space, Risk Assessment, Process Characterization, Process Analytical Technology, Scale-up, and Technology Transfer. At the end of the course, the audience will be able to explain what these concepts mean, the role they play in QbD/PAT implementation and the interplays amongst them.

Instructors:

- Anurag Rathore (IIT, India), Seongkyu Yoon (UMass Lowell)

Date & Location:

- Date: Monday May 6 - Tuesday, May 7, 2024 from 9 a.m. - 5:30 p.m.
- Location: University of Massachusetts Club (1 Beacon Street #32nd floor Boston, MA 02108)

TARGET AUDIENCE:

- Scientist, Senior Research Scientist, Bioprocess Engineer, or equivalent, involved in product and process development, regulatory, quality assurance/control, and manufacturing of biotech therapeutics.
- Attendees from academia and regulatory agencies may also benefit depending on their areas of interest and level of experience.

COURSE OBJECTIVES:

- Define CQAs and explain the link between CQAs and Design Space
- Understand what needs to be done differently in your current job in the QbD paradigm
- Understand the role of PAT in QbD paradigm and the challenges of implementing QbD for the commercialization of biotech products
- Explain the role of Risk Assessment and where to go to find the appropriate tool

Registration:

- Register using the QR code
- Cost of attendance:
  - $1800 for Industry
  - $1,440 for academia/government employees
  - $180 for students

- For questions please email: bpqc@uml.edu or Maurizio_Cattaneo@uml.edu.