



mini-BIOMAN: Quality in Biomanufacturing
July 16, 17 & 18 2019, Montgomery County Community College, Blue Bell, PA
Registration Application

As described in the Quality Assurance unit of the Introduction to Biomanufacturing textbook, “The primary customers for biopharmaceuticals include medical practitioners, regulators, and the patients who receive the biopharmaceutical products. All are concerned with the safety and effectiveness (efficacy) of the product.” With this in mind, Quality Assurance (QA) is the ability to manufacture a product with a predetermined set of criteria that insure the safety, efficacy and potency of the product, for every vial produced. Within the QA department are the Quality Control (QC) units, which perform biochemical and microbiological tests to ensure product quality throughout the manufacturing process. Measuring and testing functions are performed regularly during the process, including sampling final and packaged vials of product before it is shipped to the physician’s office, hospital or pharmacy.

In this workshop, participants will be introduced to experiments and techniques used in the biopharmaceutical industry to prevent microbial contamination of products, and biochemical assays that test for identity, purity and potency of the drug substance and product. Microbiological QC activities will include endotoxin testing, molecular and biochemical approaches to microbe detection and identification, and environmental monitoring. Biochemical QC techniques will focus on monoclonal antibody drug substance analysis and include aggregate testing by HPLC analysis, identity and concentration determination by ELISA and purity determination by SDS PAGE. In both the microbiological and biochemical sessions, techniques ranging from basic activities through advanced laboratory exercises will be performed in order to accommodate all levels of course and program development of the participating instructors. QA activities will include an easy to implement popcorn GMP lab exercise, an equipment operational qualification exercise, online classroom activities, case studies, and industry guest speakers.

At the conclusion of the mini-BIOMAN, participants will have a comprehensive, ready-to-insert curriculum module to utilize in their own classrooms. Curricular materials include PowerPoint slides, links to relevant resources, and all standard operating procedures. Breakfast and lunch will be provided each day of the conference, and transportation to off-site venues is included.

** Travel stipends are available for out-of-town participants.*

** Registration will remain open until all participant positions are filled.*

To register, complete this form and return to Matt Marshall, NBC2 Program Manager, at mmarshall@mc3.edu. Registrations will be accepted on a first-come, first-served basis, contingent on review by NBC2 leadership.

First Name _____

Last Name _____

Email Address _____

Phone Number _____

Job Title _____

College/Organization _____



Street Address _____

City _____

State _____

Zip _____

Have you previously attended a professional development event hosted by NBC2?

Do you currently have a biotechnology/biomanufacturing program at your institution? If so, which relevant courses do you currently teach or have you taught in the past?

For reporting purposes, NBC2 will issue an evaluation survey immediately following the conference and 6 months after the conference. Are you willing to complete these surveys?

NBC2 has a limited number of stipends to cover the cost of your travel. Would you like to be considered for a travel stipend from NBC2?

YES

NO