Biomanufacturing Immersion Course Agenda

Biomanufacturing Immersion is a two-day course that examines all aspects of biomanufacturing. Learn about the equipment and facilities necessary to produce biologics; the regulatory oversite that assures the biologic's safety; and the science behind small- and large-scale production. Biomanufacturing Immersion is taught by an expert who offers practical insights into biologic-derived product production.

Five takeaways:

1. Equipment, controls, utilities and facilities needed to produce biologics
2. Typical procedures to prevent and address contamination
3. Master cell bank and working cell bank testing and handling requirements
4. Important consideration when scaling upstream, midstream and downstream
5. FDA guidance on process validation through the creation of a validation master plan

Course Agenda

Day One

Overview of a biomanufacturing Process *9:00-10:45*
History of biomanufacturing
Unit operations for upstream, midstream, downstream
Equipment functionality and requirements
Technology transfer considerations
(external to internal; R&D to manufacturing)

Break *10:45-11:00*

Cleanrooms and Facilities *11:00-12:30*
Required utilities to support biomanufacturing
Environmental classifications during production
Control of personnel, material, air, waste flows
Gowning requirements
Acceptable products produced in a biologic's facility

Lunch *12:30-1:30*

Definition of Biologic-Derived Products *1:30-2:15*
Biologic defined
Biologic vs small molecule drugs
Special biologics handling requirements

Importance of Monosepsis During Biologic Manufacturing *2:15-3:15*
Monospesis defined
Monospesis in the upstream manufacturing
Objectionable organisms
Typical procedures to investigate contamination events

Break *3:15-3:30*

The Cell Bank *3:30-4:15*
Cell bank establishment
Clonality and how is it assured
Master cell bank and working cell bank
Cell bank testing requirements
Phage concerns and practices

Q&A|Wrap-Up *4:15-4:30*

Day Two

Upstream Processes *9:00-10:00*
Preculture environmental requirements
Culture profile
Expectations around process repeatability
Tips and tricks for processing techniques

Soluble Versus Insoluble Products *10:00-10:45*
Solubility changes during midstream
Insoluble product considerations

Break *10:45-11:00*

Downstream Process *11:00-12:00*
Segregating live vs non-live operations
Large-scale processing considerations
Control measures for low bioburden/endotoxin
Sterility vs bioburden claim to bulk drug substance

Lunch *12:00-1:00*

Scale-Up Considerations *1:00-2:00*
Scaling a microbial process
-Upstream
-Midstream
-Downstream
Engineering (non-GMP) manufacturing runs

Quality Considerations for Biomanufacturing *2:00-3:00*
Good-better-best batch record formats
Raw material considerations
Clinical/commercial site
Equipment cleaning and change over requirements
Cleaning qualification vs validation

Break *3:00-3:15*

FDA Guidance on Process Validation *3:15-4:15*
Overview and Interpretation
Validation master plan strategy for a multi-product/multi-client facility

Q&A Evaluations *4:15-4:30*