

Bioprocess Training Academy Schedule at a Glance

(students will register for one course topic, but may move freely among classes)

	Introduction to Biopharmaceutical Manufacturing	Basics of Protein Formulation Development	Design and Validation of Immunoassays	Protein Characterization
Day One				
Morning	<ul style="list-style-type: none"> Introduction to the biopharmaceutical manufacturing industry Protein basics and analytical methods for characterization Expression systems: microbial and mammalian Cell banking: master and working cell banks 	<ul style="list-style-type: none"> Protein chemistry and biophysics as they relate to protein structure and stability Maintenance of protein conformation for optimal stability and biological activity Physical and chemical stability of proteins Degradation pathways relevant to proteins and shelf life 	<ul style="list-style-type: none"> Immunoassay general principles Antibody structure Antibody specificity and affinity Immunoassay formats Immunochemical reagent preparation and characterization 	<ul style="list-style-type: none"> Introduction to protein structure and post-translational modifications Protein Chemistry Techniques: <ul style="list-style-type: none"> capillary electrophoresis and HPLC enzymatic methods and peptide mapping sample treatment, preparation & work flow
<i>Networking Lunch with Students from All 4 Courses</i>				
Afternoon	<ul style="list-style-type: none"> Fermentation: culture methods and key process parameters Cell culture: culture methods and key process parameters Recovery methods: centrifugation and cell breakage Filtration: microfiltration, ultrafiltration and diafiltration 	<ul style="list-style-type: none"> Biophysical and analytical techniques for proteins Buffers and excipients relevant to protein formulation Route of administration concerns Typical workflow for formulation development projects 	<ul style="list-style-type: none"> Labeling and detection systems including biosensors and integrated devices Multiplex, microarray, and nano-technologies Immunoassay development Design goals and assay characteristics for intended use Immunoassay formats and conditions including Design of Experiments 	Protein Chemistry Techniques (Continued) <ul style="list-style-type: none"> mass spectrometry amino acid analysis protein sequencing • Biophysical characterization: spectral methods
Day Two				
Morning	<ul style="list-style-type: none"> Purification: fundamentals of chromatography Ion exchange, reversed phase, hydrophobic interaction and affinity Formulation, aseptic filling and lyophilization Process development and scale up, with large scale examples 	<ul style="list-style-type: none"> Strategic selection of formulation components for baseline screening Design of preformulation programs for liquid and lyophilized products Statistical design of experiments to identify effects and interactions Interpretation of both biophysical and analytical data Lyophilization process development for proteins 	<ul style="list-style-type: none"> Immunoassay optimization for detection limit, LLOQ, ULOQ, curve fitting and statistical analysis Method development with considerations for sample, assay, detection, data analysis, and report Method validation considerations for system suitability and regulatory guidelines Method revalidation, transfer, and verification Quality control with review of control charts and Westgard Rules 	<ul style="list-style-type: none"> Quality control of biotechnology products: guidance documents Activity assays Glycosylation analysis Biophysical characterization: light scattering, calorimetry, analytical ultracentrifugation, and field flow fractionation; aggregation and particle analysis
<i>Lunch on Your Own</i>				
Afternoon <i>(courses end at 5:00 on Day Two)</i>	<ul style="list-style-type: none"> Facility design and monitoring Current Good Manufacturing Practice (cGMP) Inspections and working with the FDA Validation: equipment, facility, process, viral clearance 	<ul style="list-style-type: none"> Forced degradation studies to support formulation selection Optimization of final formulation properties Container-closure and delivery systems Case studies and real-world examples 	<ul style="list-style-type: none"> Assay validation considerations for repeatability and reproducibility Robustness and effects of sample matrix, dilution, interferants Studies for analytical specificity, reference method and clinical correlation, and stability testing Immunoassay troubleshooting Applications in drug development and biologicals, bioprocessing, vaccines, environmental analysis, and point-of-care testing 	<ul style="list-style-type: none"> Characterization of recombinant protein products Monoclonal antibody structure and subclasses, heterogeneity analysis Bioprocess impact on product quality <ul style="list-style-type: none"> cell line selection, upstream process variables downstream process impact, formulation and storage Selecting characterization methods to support various stages of product development

"This course was spot on for me and my career. It gave me an overall understanding of biopharmaceutical manufacturing and gave me the knowledge to move forward in my career."

Basics of Protein Formulation Development attendee, D. Matsumoto, Validation Specialist, Baxter BioScience

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