Biopharmaceutical Manufacturing Curriculum

General and Support Cell Culture **Downstream** Formulation. **Upstream Harvest** Fill Finish & Lyophilisation Lectures Lectures **Lectures Lectures Lectures** Cell Culture Start Up Bioreactor Control Centrifugation Introduction to Bioprocessing Downstream Processing Bioreactor Design & Cell Culture Scale Up Introduction to ADCs for Biologics Filtration **Lectures** Bulk Filling Operations Facility Design & Classification Harvest Introduction to Fill Finish Chromatography Scale Up Upstream Processing Technologies Operations Chromatography Types Introduction to **Practicals** Microfiltration Latest Trends in Biomanufacturing Introduction to Fill Finish **Ventilation Cabinets** Column Packing for ADCs Plant and Process Contamination BSC Set-up Filtration Control Barrier Systems Working in a BSC Introduction to Regulatory Overview **Practicals** Overview for ADCs **Practicals** BSC Cleanup Chromatography Decontamination Harvest Aseptic Process Protein Structure & Stability Freezing and Thawing P&ID Review Validation Technologies Simulations including filtration Start Up Deviation Handling Bioreactor Set Up & Filling System Design troubleshooting Operation (SIP) Viral Clearance Technologies Scale Up Commissioning, Qualification, and Filling Process Overview Depth Filtration Validation Bioreactor Operation and Formulation Cell Viability Overview of Troubleshooting Buffers and their Application in Microfiltration Lyophilisation Metabolite Analysis Bioprocessing Single Use Bioreactor Disc Stack Formulation Media Prep (CHO media) Set Up & Operation Disposable Technologies Centrifugation **Practicals** Introduction to Aseptic Transfer Small Scale Autoclavable • FIT Lyophilisation for ADCs Formulation & Bulk Filling Bioreactor (7L Manufacturing Analytical Techniques Bioreactor) Manufacturing Gowning Analytical Techniques (pH. Intro to Microbiology conductivity, UV, SoloVPE) **Practicals** Environmental Monitoring Protein Stability Triple Bucket System (Sanitisation) • Filling Line Overview & Single Use Small scale UF/DF Cleanroom Disciplines & Gowning Large scale UF/DF Aseptic Set-up Column Efficiency Testing Process and Troubleshooting Lectures Simulations **Practicals** • Column Packing (Flow-Pack Single-use Overview Filling Line / Pack-in-Place) Utilities and Plant Tour Clean Utilities Troubleshooting Single-use Upstream Small/large scale • Validation of VHP Cycles Single-use Downstream Chromatography · Commissioning, Qualification, and Lyophilisation Chromatogram Validation Weigh and Dispense **Equipment Overview** Interpretation Contamination Control Vial Inspection Viral Clearance **Practicals** Buffer Preparation • Single Use in Fill Finish • In-line Dilution Equipment Preparation Single-use Overview Single-use Wave Bioreactors Parts Washer & Autoclave Differential Pressures & Air Quality • Single-use 200L BR Setup Studies • Single-use Large Scale Culture COP/SOP Single-use Chromatography • Single Use Technologies Single-use UF/DF • Gowning (Grades B and C) • 3-Bucket Sanitisaton System Process Automation - DeltaV **Digitalisation**