

## **Upstream Processing Lab**

BSL2 suite for microbial and mammalian cell expression from benchtop to pilot scales including rocking bag and stirred tank bioreactors in single-use and reusable varieties

## Downstream Processing Lab

BSL2 suite for product clarification, normal flow filtration, tangential flow filtration, chromatographic methods, formulation and lyophilization

### Product Analysis Lab

BSL2 suite supporting various analytical assays used in both quantifying and analyzing biomolecules and potential contaminants



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NCTM training equips your biomanufacturing workforce with on-the-job skills needed to reduce operator error, increase productivity, and improve your company's bottom line.



The amount of time it takes for a biomanufacturing hire to be self-sufficient (Door-to-Floor) is 1 year.

On average, recruiting and training expenses for a new employee costs 9 months' salary.

- Society for Human Resource Management

# NCTM Training Core Competencies

## Cell Culture and Upstream Processes

- · Bioreactor assembly, sterilization, operation
- · Microbial and mammalian cell cultivation
- Harvest and storage of biomass
- Single-use options for unit operations
- · Process optimization and scale-up

### Recovery and Downstream Processes

- · Cell lysis, centrifugation, clarification, and TFF
- · Sterile filtration and membrane integrity testing
- UNICORN chromatography software
- Column packing and evaluation
- Ion exchange/hydrophobic interaction chromatography and single-use alternatives

### Quality Systems and Analytical Techniques

- Documentation practices
- · Aseptic technique, sterile operations
- Bacterial endotoxin testing, SDS-PAGE assay, total protein assay, TOC analysis, and HPLC
- Gowning, environmental monitoring
- Cleaning, sterilization, CIP/SIP
- Equipment calibration, validation (IQ/OQ/PQ)

## cGMP Principles and Regulatory Matters

- Product development cycle and creating a design space
- Biopharmaceutical facility operations/safety
- · Process documentation, control, and pathway
- · Regulatory compliance, FDA interactions
- · Corrective and preventative actions
- Quality Risk Management, science and risk-based approaches

