

Bioproduction engineer

Operational skill #1

Prepare, coordinate and control production, ensuring compliance with quality, health, safety and environmental standards

Operational skill #2

Management of malfunctions and carrying out technical interventions with usual tools on controlled equipment

Operational skill #3

Work in a Controlled Atmosphere Zone

Bioproduction environment (DS-DP)

- Discovering biopharmaceuticals: key development stages, regulatory framework, and manufacturing processes (P1M1-1)
- Overview of Quality Control (P5M1)
- Performance Levers in Bioproduction: Lean, Maintenance, and Industry 4.0 (P1M6-1)
- Introduction to Fill&Finish (P3M2)
- Transportation and logistics management of bioproduction (P10M1)

Q-HSE investigation

- Case study applied to bioproduction facility operation (P7M7)

Work in a Controlled Atmosphere Zone

- Immersion in a controlled atmosphere area: preventing contamination and adopting best practices (P1M2-1)

Microbiological Controls

- Focus on microbiology (P5M2A) VR
- Applicative module: microbiological tests (P5M3A)

Operational skill #4

Monitoring, processing information and carrying out improvement actions

Quality by Design

- Introduction to the methodology of development for cell culture (USP) and purification (DSP) processes (P7M1)
- Case study applied to the development of an Upstream process (USP) (P7M2)
- Case study applied to the development of a Downstream Process (DSP) (P7M3)

Operational skill #5

Handling of biological manufacturing equipment according to quality, safety and environmental standards

Tech Transfer

- Introduction to Technology Transfer (P7M4)
- New technological trends in bioproduction (P7M5)
- Case study applied to bioprocess industrialization (P7M6) VR

Data integrity

- Data Quality and Integrity in Bioproduction: Principles and practical cases (P1M5-1)
- Integrity applied to product batch release (P6M5)

Data management

- Bioprodut life cycle data, from development to manufacturing (P12M1)
- Information system organization in the pharmaceutical industry (P12M2)
- Statistical tools to describe and analyse process operation (P12M5)

UpStream Processing

- Presentation of cGMPs and industrial environment – USP (P2M2)
- In-Process Controls (IPCs) for USP in cGMPs (P2M4)
- Practice USP in cGMPs (P2M6)

DownStream Processing

- DSP Process in cGMPs (P4M2)
- Viral Clearance (P4M4)
- Equipment Cleaning in DSP (P4M5)
- In-Process Controls (IPCs) for DSP in cGMPs (P4M6)
- DSP -Applicative module (P4M8)

ATMP

- Exploring the fundamentals of Advanced Therapy Medicinal Products (ATMPs): Specifics, Challenges and Applications (P13M1)
- RNA and gene editing: strategies based on non-viral vectors (P13M3)
- Scaling up: overcoming challenges in ATMP bioprocessing (P13M6)