

Bioproduction engineer

Operational skill #1

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

- **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)

Operational skill #2

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

- **Q-HSE investigation**
 - Case study applied to bioproduction facility operation (P7M7)

Operational skill #3

Work in a Controlled Atmosphere Zone

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

- **UpStream Processing**
 - Presentation of cGMPsand 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 bioprocessingP13M6)