

Quality technician

Operational skill #1

Préparer, coordonner et contrôler la production, en veillant au respect des normes de qualité, de santé, de sécurité et d'environnement

Operational skill #2

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

- **Bioproduction environment (DS-DP)**
 - Discovering biopharmaceuticals: key development stages, regulatory framework, and manufacturing processes (P1M1)
 - Overview of Quality Control (P5M1)
 - Introduction to Fill&Finish (P3M2)
 - Transportation and logistics management of bioproduction (P10M1)

- **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)
 - DSP -Applicative module (P4M8)

- **Fill & Finish**
 - Thawing / Formulation & Pooling / filtration (P3M4)
 - Aseptic Filling line: set up and filling into the primary packaging (P3M6)
 - Sampling and control in Fill & Finish (P3M7)
 - Packaging -labelling -Serialization (P3M8)

Operational skill #3

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)
 - Quality during storage and transportation (P10M5)

Operational skill #4

Monitoring, processing information and carrying out improvement actions

- **Data integrity**
 - Data Quality and Integrity in Bioproduction: Principles and practical cases (P1M5-1)

Operational skill #5

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)