

Fill & Finish engineer

Operational skill #1

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

- **Bioproduction environment (DS-DP)**
 - Discovering biopharmaceuticals: key development stages, regulatory framework, and manufacturing processes(P1M1)
 - 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

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

- **Fill & Finish**
 - Material reception and handling (P3M3)
 - Thawing / Formulation & Pooling / filtration (P3M4)
 - Aseptic Filling line specific conditions (P3M5)
 - Aseptic Filling line: set up and filling into the primary packaging (P3M6)
 - Sampling and control in Fill & Finish (P3M7)
 - Packaging -labelling -Serialization (P3M8)
 - cGMP in Fill & Finish (P3M9)

- **Tech Transfer**
 - Introduction to Technology Transfer (P7M4)

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)

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)
 - 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)

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)

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