

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

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)
- Performance Levers in Bioproduction: Lean, Maintenance, and Industry 4.0 (P1M6-1)
- Introduction to Fill&Finish (P3M2)
- Transportation and logistics management of bioproduction (P10M1)

■ 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)