

# Quality 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)
  - Lean/Technologies Digitales pour l'industrie 4.0 (P1M6)
  - Overview of Quality Control (P5M1)
  - 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

- **UpStream Processing**
  - Presentation of cGMPsand industrial environment –USP (P2M2)
  - In-Process Controls (IPCs) for USP in cGMPs (P2M4)
  - Practice USP in cGMPs (P2M6)
- **DownStreamProcessing**
  - 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)
- **Tech Transfer**
  - Introduction to Technology Transfer (P7M4)
  - Case study applied to bioprocess industrialization (P7M6) VR

## 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

- **Quality by Design**
  - Introduction à la méthodologie de développement des procédés de culture cellulaire (USP) et de purification (P7M1)
  - Etude de cas associée au développement d'un procédé de culture cellulaire (USP) (P7M2)
  - Etude de cas associée au développement d'un procédé de purification cellulaire (DSP) (P7M3)
- **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)
  - Infrastructure and regulatory requirement supporting data management (P12M3)
  - 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)