

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

Monitoring, processing information and carrying out improvement actions

- **Data integrity**
 - Data Quality and Integrity in Bioproduction: Principles and practical cases (P1M5-1)
 - Validation des systèmes informatisés (P6M3)
- **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 #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 #3

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

- **Storage and Transportation**
 - Transport des bioproduits à température contrôlée (VR LE3) P10M2
 - Storage and handling of bioproducts (VR LE3)

- **UpStream Processing**
 - Presentation of cGMPsand industrial environment –USP (P2M2)
 - In-Process Controls (IPCs) for USP in cGMPs (P2M4)
- **DSP (Downsream Process) en cGMPs**
 - DSP Process in cGMPs(P4M2) (P4M2)
 - In-Process Controls (IPCs) for DSP in cGMPs (P4M6)

- **Quality control**
 - Focus on microbiology (LE3 enVR) (P5M2A)
 - Focus on Physicochemical and Immunology (LE3 enVR) (P5M2B)
 - Focus on viral safety and molecular biology tests (P5M2C)
 - Applicative module : Microbiological test (P5M3A)
 - Applicative module : physicochemical test and immunoassay (P5M3B)
 - Applicative module : Viral safety and molecular biology tests (P5M3C)
 - Validation analytical methods (P5M4)
 - In vitro, in vivo and ex vivo efficacy test (P5M5)
 - Analytical methods : use cases (P5M6)

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)