

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)
- 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)

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 #4

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)