| FEATURING |

GMP BIOMANUFACTURING IN A BSL-3 SUITE

A GMP biomanufacturing expert, Naobios has worked with numerous viruses requiring specific biocontainment procedures. Our state-of-the-art BSL-3 suite welcomes hazardous microbes used for the generation of virus-based therapeutic products.

When working with pathogenic biological substances, specific precautions and environmental design features need to be taken into consideration to ensure safety all along the steps of generating medicinal products. Biosafety levels ranging from 1 (low risk) to 4 (highest risk) thus define containment groups and establish requirements when working with hazardous agents. Several criteria (such as agent transmissibility, level of characterization, microbe origin, induced disease severity, etc.) are considered to assign a biosafety level to an agent.

According to the CDC, BSL-3 agents "cause serious or potentially lethal disease through respiratory transmission"[1] and thus require specific **BSL-3 suites to perform biomanufacturing in addition to GMP requirements.** Such organisms include HIV, Polio, COVID, Hantaviruses, Influenza, SARS, West Nile Virus, Rabies, etc.

Naobios, a long-standing GMP biomanufacturing expert, has worked with dozens of biological substances including hazardous material belonging to the BSL-2+ or BSL-3 risk groups to generate vaccines **(live and inactivated), oncolytic viruses and viral vectors for other applications.**

A strictly designed and monitored BSL-3 suite

Our BSL-3 biomanufacturing suite is **a flexible 110 m2 (1184ft²) space** with a spacious class D room and a segregated class C room. This suite can be used for any standard virus manufacturing process **both upstream and downstream.**

Both suspension-and adherent based processes may be accommodated for **manufacturing scales up to 200L and 200m2, respectively.**

Equipment

In the BSL-3 suite, Naobios can perform upstream process manufacturing for both adherent or suspension cells – we have single use STRs up to 200L scale and we have experience with **iCELLis** in GMP which we can run up to 200m2.

In terms of downstream processes, we are equipped with mechanical lysis equipment and can perform any type of required filtration, standard clarification and ultrafiltration/diafiltration setups.

Chromatography systems are available and **suitable for all scales of manufacturing performed at Naobios.**

BSL-3 unit design

Our BSL-3 suite has been designed to meet all regulatory guidelines outlining expectations when working with BSL-3 agents. Specifications include:

- Structural (environment) and procedural (practises) setting, meeting BSL-3 standards for risk management
- **Dedicated double-door autoclave for waste decontamination**
- Continuous liquid waste decontamination with dedicated station
- Strict 24/7 monitoring of critical environmental parameters with EMS
- Segregation of people, material and waste flows to meet GMP standards

Naobios manufacturing suites and capabilities

Naobios has gathered substantial experience and offers GMP biomanufacturing services at various stages of production through a manufacturing-by-campaign system:

- **Cell banks** (Master Cell Banks, Working Cell Banks, End-of-process Cell Banks) and Viral seed banks (Master Virus
- Seed Stocks, Working Virus Seed Stocks)
- **Drug Substances** for Clinical Phase 1 to Phase 3
- Process validation (inactivation, aseptic processing, cleaning)

[1] https://www.cdc.gov/training/quicklearns/biosafety/