

HUMAN VIRAL CHALLENGE AGENTS



Naobios, your partner in the production of Human Viral Challenge Agents

Human Viral Challenge Agent (HVCA) is a new modality which is used in a strictly controlled clinical trial to test prophylactic vaccines or curative treatments.

Controlled Human Infection Models (CHIM) are already used in several countries such as the USA, the UK or Belgium.

ABOUT NAOBIOS

Naobios is a CDMO with **15 years experience** in bioprocess development and manufacturing of **BSL2/BSL3** viral vectors for clinical use in modalities such as viral vaccines, gene therapy and oncolytic virus therapy.

REGULATIONS

Naobios extends its current service portfolio and proudly offers **HVCA manufacturing** to the biotech and pharmaceutical industry as well as to academic institutions and agencies like Bill and Melinda Gates Foundation, CEPI, WHO, and others.

We can meet the expectations of the most **stringent regulations.**

Naobios regulatory approach is to manufacture of HVCA following as close as possible the **GMP requirements** - performing risk-analysis for any technical gap identified.



GMP MANUFACTURING

Naobios is uniquely suited for the manufacturing of **Human Viral Challenge Agents** :

• **GMP-certified** as a Pharmaceutical Establishment by the French Regulatory Agency ANSM,

• BSL2 and BSL3 manufacturing suites,

• broad experience in bioprocess development and clinical manufacturing of a wide range of viral vectors on many cell lines.

• full range of **analytical testing in-house** and with the support of Clean Cells. www.clean-cells.com

Naobios is producing Human Viral Challenge Agents for a third party, which is a world leader in Controlled Human Infection Models (CHIM).



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