

clean cells

SOLUTION FOR BIOLOGICS

VIRAL VACCINE FOR HUMAN USE:

A SAFETY WAY FROM RAW MATERIALS TO FINAL PRODUCT

Clean cells offers its expertise to support the development of your vaccine for human use, from raw materials to final products. Our extensive range of validated tests will ensure the safety of your bioproducts at each step of the production process according to regulatory requirements.

ONE STOP SHOP SOLUTION

GMP & non-GMP PRODUCTION

Master and Working cell banks, End Of Production Cells as well as Master and Working virus seed stocks

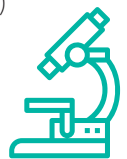
GMP & non-GMP QUALITY CONTROL TESTING

Biosafety, Identity & Purity testing from raw materials to the final product

ANALYTICAL TOOLS:

Development & validation for GMP routine testing

- Viral titration (TCID50, dPCR or qPCR)
- Specific viruses detection by PCR (cell origin dependent)
- Impurities (cell origin and process dependent)
- Release testing



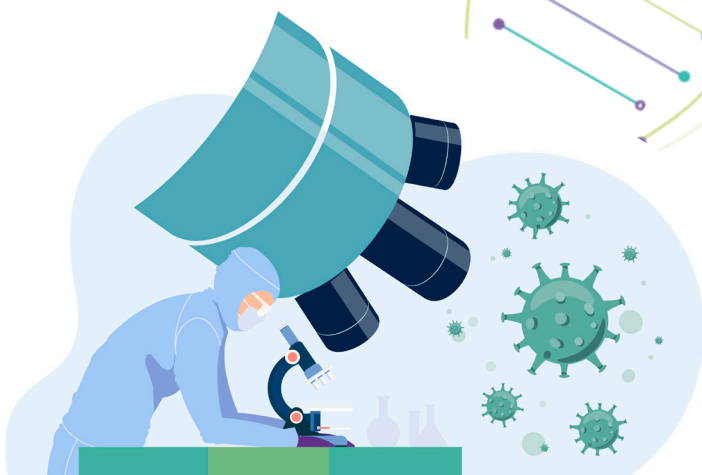
REGULATORY COMPLIANCE WITH:

- Eur. Ph §2.6.16, §5.2.3 and 0153
- PTC in the Characterization of Cell Lines Used to Produce Biologicals (1993, US FDA)
- Vaccine substrates (2010, US FDA)
- 9CFR 113.52
- ICH Q5A & ICH Q5D



KEY ADVANTAGES:

- Over 20 years
- Innovation
- Flexibility
- Qualified team
- Quality project management
- Traceability & Security
- End-to-end solution



QUALITY CONTROL SERVICES

In addition of GMP bank manufacturing services, we offer quality control on your biologics all along your vaccine production process. Our panel of testing is driven by appropriate regulatory requirement from Eur. Ph., U.S.Ph. and ICH guidelines.

	MCB	WCB	EOPC	Control cells	MVSS	WVSS	Unp BH	BH	DS	DP
Sterility	✓	✓	✓		✓	✓	✓	✓	✓	✓
Mycoplasma detection	✓	✓			✓	✓	✓			
Mycobacterium detection	✓	✓			✓	✓	✓			
Identification (qPCR/DNA fingerprinting / karyotyping)	✓	✓	✓							
Identity (qPCR/sequencing)					✓	✓	✓			
Tumorigenicity (Cell type dependent)			(✓)							
Adventitious agent detection (<i>in vitro</i> testing)	✓		✓	✓	✓	✓	✓			
Retrovirus detection ○ by direct Q-PERT ○ semi-quantification by TEM	✓ ✓		✓ ✓		✓		✓			
Adventitious agent detection (<i>in vivo</i> testing)		✓	✓		✓					
Specific virus detection by PCR (cell type dependent)	✓	✓	✓		✓	✓				
Bovine & porcine viruses detection (depending on raw materials and culture process)	(✓)		(✓)		(✓)	(✓)				
Endotoxins detection									✓	✓
Impurities (host-cell DNA & proteins, BSA, Benzonase)								✓	✓	
Physicochemical tests (pH, osmolality, visual aspect)									✓	✓

MCB: Master Cell Bank
WCB: Working Cell bank
EOPC: End Of Production Cell
MVSS: Master Virus Seed Stock
WVSS: Working Virus Seed Stock
Unp BH: Unprocessed Bulk Harvest
BH: Bulk Harvest
DS: Drug Substance
DP: Drug Product
 (✓): according to risk analysis

VACCINE MANUFACTURING NEEDS?

Our sister company **Naobios** (Clean Biologics group) offers a comprehensive set of services for process development and manufacturing of viral vaccines and viral vectors products.

This GMP certified CDMO could support you for the production of pre-clinical and clinical products assisted by Clean Cells for the quality control part.

www.naobios.com

