

clean cells

SOLUTION FOR BIOLOGICS

CELL & GENE THERAPY PRODUCT A SAFETY WAY FROM RAW MATERIALS TO FINAL PRODUCT

Clean Cells offers a full package of cGMP services in order to support the development of your **ATMP**. We bring you **quality control** for the **safety** and the **characterization** of your biologics from **pre-clinical** to **commercial batches**, according to the **regulatory requirements**.

OUR TRACK RECORD

- Assays according to FDA and EMA guidelines
- EP and USP dedicated chapters (EP 5.14, EP 5.2.3, USP <1032>, USP <1033>, USP <1034>, USP <1046> and USP <1047>)
- GMP guidelines
- ICH Q2
- ICH Q5B & Q6D, ICHQ5A
- Customized approach for other regulatory authority

ONE STOP SHOP SOLUTION

non-GMP & GMP CELL BANK MANUFACTURING

- Master and Working cell banks,
 - End Of Production Cells,
 - Storage capacity

VALIDATION

- Matrix-specific validation for your product based on your requirement,
- Potency assay development up to GMP validation

non-GMP & GMP QUALITY CONTROL

- Biosafety, Identity & Purity testing,
- Potency assay for further batch release of your product



QUALITY CONTROL SERVICES

In addition of GMP bank manufacturing services, we offer quality control on your biologics all along your production process. The following panel of testing is driven by appropriate regulatory requirement from Eur. Ph., U.SPh. and ICH guidelines, but is at the end under the client responsibility according to its internal risk assessment.

	MCB	WCB	EOPC	Virus seed	Unp BH	DS	DP
Sterility	✓	✓			✓	✓	✓
Mycoplasma detection	✓	✓			✓		
Mycobacterium detection	✓	✓			✓		
Identity (qPCR / DNA fingerprinting / Karyotyping / Barcoding)	✓	✓	✓				
Transgene identity / Integrity by sequencing (qPCR/sequencing)	(✓)	(✓)	(✓)		✓		
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)	✓		✓				
Tumorigenicity (Cell type dependent)	(✓)		(✓)				
Specific virus detection by PCR (cell type dependent)	✓	✓	✓				
Bovine & porcine viruses detection (depending on raw materials and culture process)	(✓)	(✓)	(✓)				
Lentivirus & AAV specific testing ○ Physical particles titer ○ Vector genome titer ○ Replication-competent virus detection (RCL, rcAAV) ○ Infectious particles titer				✓	✓	✓	(✓)
Endotoxins detection						✓	✓
Impurities (host-cell DNA & proteins, BSA, Benzoylase, residual sequences...)					✓	✓	(✓)
Physicochemical tests (pH, osmolality, visual aspect)						✓	✓

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

OTHER TRANSDUCED CELLS

Clean Cells is able to support you with the full GMP quality control of your transduced cells such as CAR-T cells...