

SOLUTION FOR BIOLOGICS

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

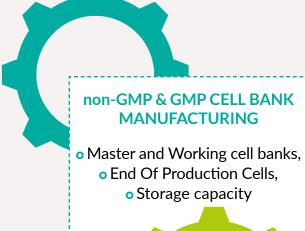
Clean Cells offers a full package of cGMP services in order to support the development of your ATMP. We bring you quality control for the safety and the characterization of your biologics from pre-clinical to commercial batches, according to the regulatory requirements.

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
- o ICH Q2
- ICH Q5B & Q6D, ICHQ5A
- Customized approach for other regulatory autority



ONE STOP SHOP SOLUTION



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.

	МСВ	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 (in vitro testing)	√	√	√	✓	✓		
Retrovirus detection • by direct Q-PERT • semi-quantification by TEM	✓ ✓		✓ ✓	✓	(√)		
Adventitious agent detection (in vivo 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, Benzonase, 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...





