

## PRODUCTS DERIVED FROM CHO CELLS: SAFETY TO ENSURE QUALITY

As a CRO/CMO, Clean Cells supports your **therapeutic antibodies** and **recombinant proteins** development and manufacturing.

Our extensive range of GMP services covers **each step** of your products development from raw materials to final products. In order to accelerate your projects, Clean Cells is able to produce and perform **full characterization** of cell banks.

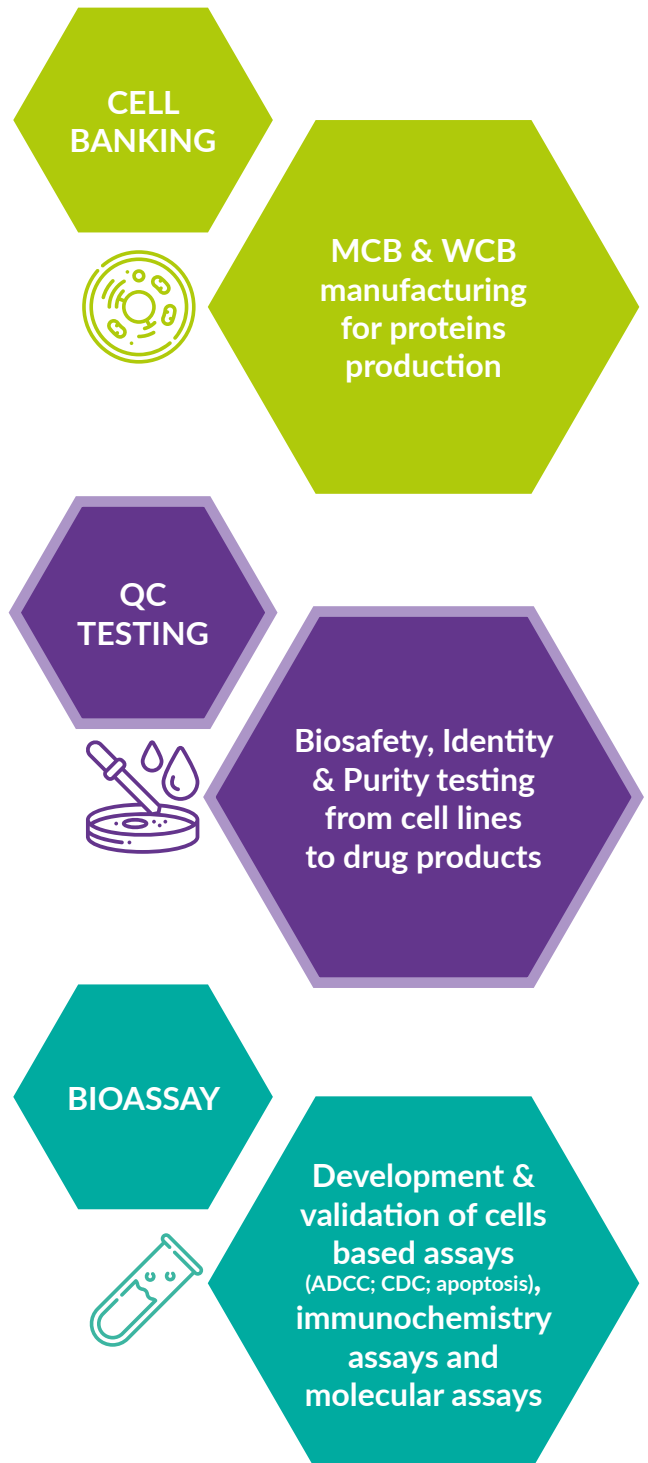
Proteins    Productivity    Identity  
Viral safety    mAbs    BSL2 labs  
MCB characterization  
Purity    Product validation  
Genetic stability  
In vivo/vitro testing    ADCC

### REGULATORY COMPLIANCE WITH:

- Eur. Ph 2.6.16 & 5.2.3
- PTC in the Characterization of Cell Lines Used to Produce Biologicals (1993, US FDA)
- PTC in the Manufacture and Testing of Monoclonal Antibody Products for Human Use (1997, US FDA)
- 9CFR 113.52
- ICH Q5A & ICH Q5D



QC ONE STOP SHOP SOLUTION





**Biosafety, Identity & Purity testing from cell lines to drug products**

**CLEAN CELLS QC SERVICES**

	Raw materials	MCB	WCB	PPCB*	UnpB*	DS	DP
<b>Genetic Identity</b>		✓	✓	✓			
<b>Genetic Stability</b> (i.e. Gene Copy Number)		✓	✓	✓			
<b>Sterility/Bioburden</b>	✓	✓	✓	✓	✓ <sup>2</sup>	✓	✓
<b>Mycoplasma detection</b>	✓	✓	✓	✓	✓		
<b>Endotoxins detection</b>	✓						✓
<b>Adventitious agent detection</b> (in vivo & in vitro testing)	✓	✓	✓	✓	✓		
<b>Bovine &amp; Porcine in vitro virus testing</b> (depending of raw materials)	✓ 9CFR	✓		✓			
<b>Retrovirus detection</b>		✓		✓	✓		
<b>Virus detection by Transmission Electron Microscopy</b>		✓		✓	✓		
<b>Species-specific<sup>1</sup> virus detection</b>		✓		✓	✓		
<b>MAP</b> (Mouse Antibody Production) <b>HAP</b> (Hamster Antibody Production)		✓		✓	✓		
<b>Impurities: host-cell proteins &amp; host-cell and vector DNA</b>						✓	✓

\*PPCB (Post Production Cell Banks)

\*UnpB (Unprocessed Bulk lots)

<sup>1</sup> Tests for rodent, primate, or human viruses (other than retroviruses), as appropriate

<sup>2</sup> Bioburden testing with acceptable limits is sufficient at this stage

**PROTEIN MANUFACTURING NEEDS?**

Our GMP certified sister company Biodextris (Clean Biologics Group) can support you in process development, clinical batch manufacturing & characterization of your therapeutic antibodies & recombinant proteins.

[www.biodextris.com](http://www.biodextris.com)

