

clean cells

SOLUTION FOR BIOLOGICS

PRODUCTS DERIVED FROM CHO CELLS: SAFETY TO ENSURE QUALITY

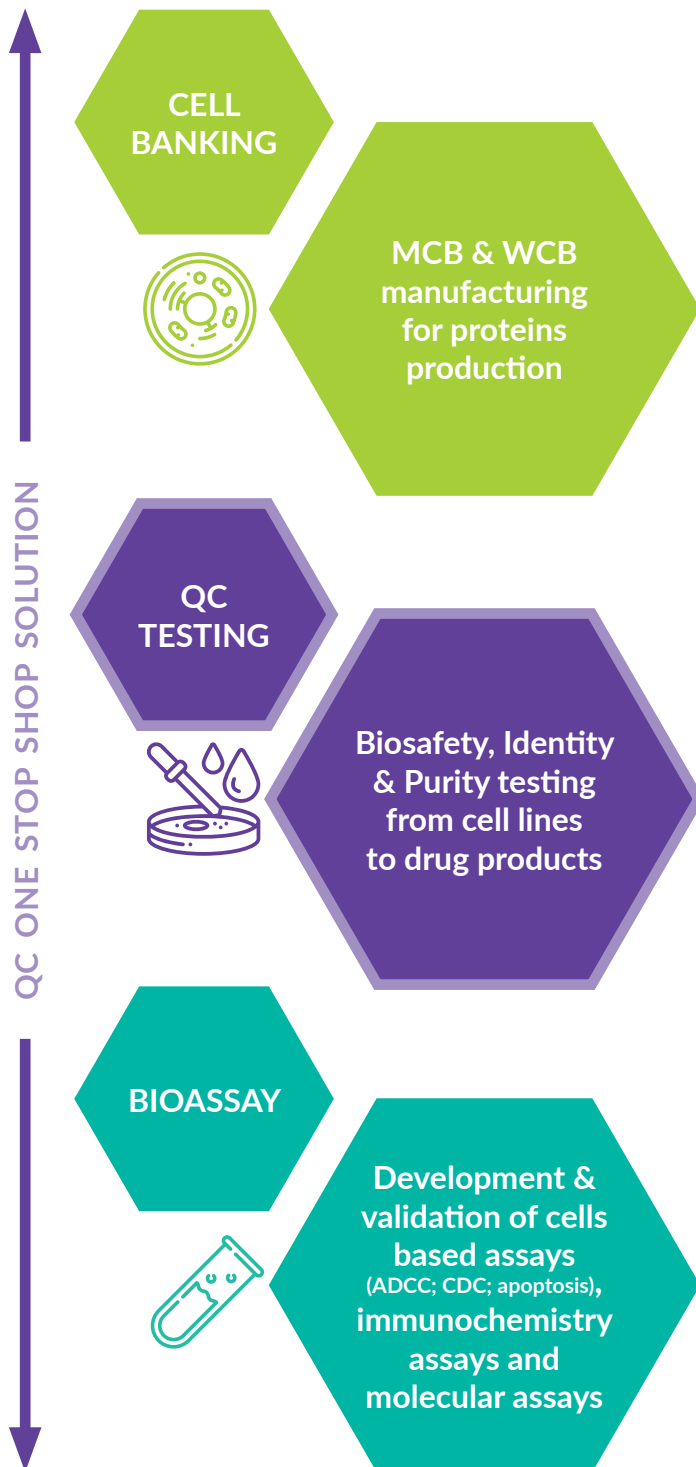
As a CRO/CMO, Clean Cells supports your **therapeutic antibodies** and **recombinant proteins** development and manufacturing.

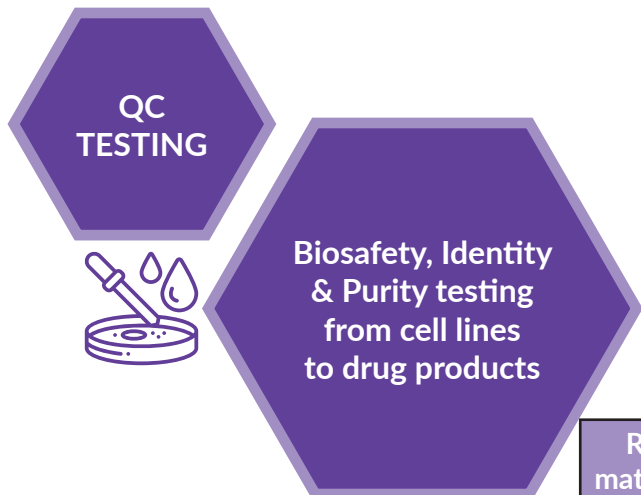
Our extensive range of GMP services covers **each step** of your products development from raw materials to final products. In order to accelerate your projects, Clean Cells is able to produce and perform **full characterization** of cell banks.

Proteins Productivity Identity
Viral safety mAbs BSL2 labs
MCB characterization
Product validation
Purity 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





CLEAN CELLS QC SERVICES

	Raw materials	MCB	WCB	PPCB*	UnpB*	DS	DP
Genetic Identity		✓	✓	✓			
Genetic Stability (i.e. Gene Copy Number)		✓	✓	✓			
Sterility/Bioburden	✓	✓		✓	✓ ²	✓	✓
Mycoplasma detection	✓	✓	✓	✓	✓		
Endotoxins detection	✓						✓
Adventitious agent detection (in vivo & in vitro testing)	✓	✓	✓	✓	✓		
Bovine & Porcine in vitro virus testing (depending of raw materials)	✓ 9CFR	✓					
Retrovirus detection		✓		✓	✓		
Virus detection by Transmission Electron Microscopy		✓		✓	✓		
Species-specific¹ virus detection		✓		✓	✓		
MAP (Mouse Antibody Production) HAP (Hamster Antibody Production)		✓		✓	✓		
Impurities: host-cell proteins & host-cell and vector DNA						✓	✓

*PPCB (Post Production Cell Banks)

*UnpB (Unprocessed Bulk lots)

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

² 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

