



CDMO FOR VACCINES AND VIRAL VECTORS MANUFACTURING

Fully integrated for process development and GMP manufacturing for Bulk Drug Substance:

- Wide experience of process development and GMP manufacturing for:
 - Cell banks
 - Virus seeds
 - IMP Bulk Drug Substance of live and inactivated virus and viral vectors
- Facility designed for BSL2 biocontainment for cells and virus (natural pathogens and GMOs)
- Grade B, C and D manufacturing areas
- GMP operations certified according to EU-GMP

As a CMO in virus manufacturing,

- **Upstream and Downstream** Process Development
- Process Scale-up
- Production using adherent and suspension cells in Roller Bottles, Cell Stacks, Singleuse Bioreactors (stirred tank or fixed bed) ranging from 2L – 200L working volume
- Experience with Vero, MRC5, BHK21, EB66 and CAP cells
- Process transfer
- GMP Bulk Drug Substance (BDS) production
- Analytical Development and Assay Qualification
- Biosafety Testing performed at Clean Cells www.clean-cells.com
- QC Release Testing, Stability Studies
- CMC support
- o Comprehensive Program Management





