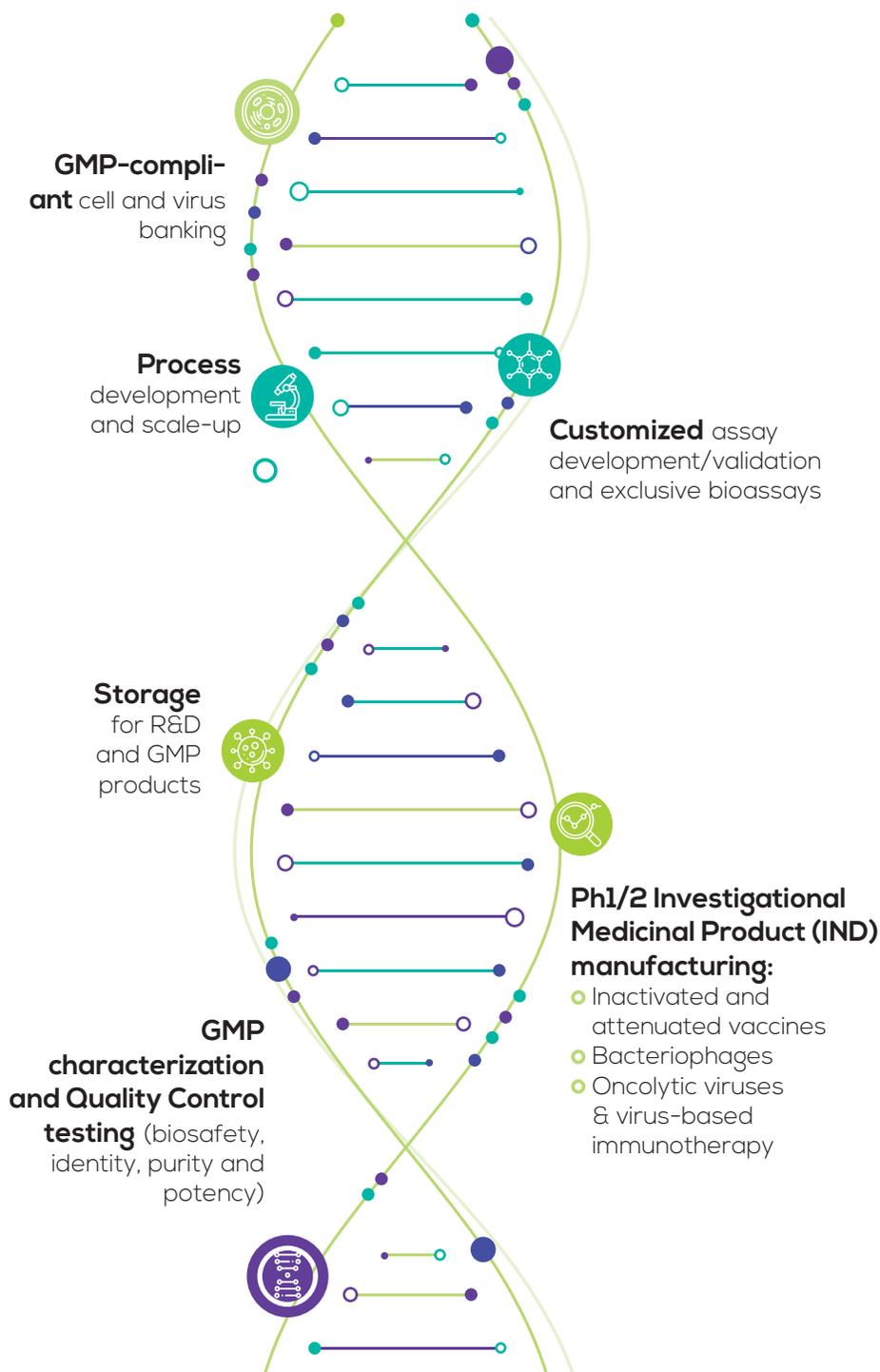


## GMP-compliant biomanufacturing and QC Services

**CLEAN CELLS & NAOBIOS are GMP-licensed service providers with main activities in:**



### Biomanufacturing capabilities

#### GMP-compliant cell & virus banking

- Microbial & eukaryotic cell banking
- BSL2/3 viral banking
- A-in-C grade

#### Process development and scale-up

- Production using adherent and suspension cells in roller bottles, cell stacks, single-use bioreactors (stirred tank or fixed bed) ranging from 2L to 200L working volume
- Process transfer

#### GMP biomanufacturing services

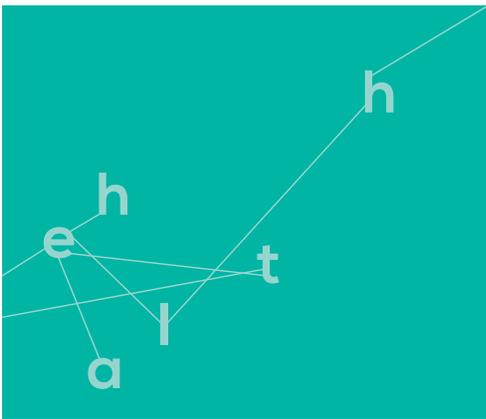
- GMP bulk drug substance production
- QC release testing, stability studies
- CMC support

### Quality Control: from R&D to GMP

#### Characterization and Quality Control testing – From raw materials to commercial products release

- Microbiological and viral testing
- Identity: karyotyping, FISH studies, RAPD testing
- Adventitious virus testing (in vitro/in vivo)
- Retrovirus detection
- Specific contaminants detection (PCR and RT-PCR)
- Genetic characterization: sequencing, gene & vector copy number, etc.
- Residual DNA/reagent/HCP detection and quantification
- Specific product characterization via physico-chemical tools
- Endotoxin testing
- Replication-competent virus detection (RCL, rcAAV)

**SECURED LONG TERM STORAGE**  
AT +5°C, -80°C and LN2



The Gene Therapy & Virology department and the Cytogenetics department from Clean Cells provides to gene therapy stakeholders a strong scientific and regulatory expertise and a personalized support for the QC of gene therapy vectors (notably for Lentivirus and AAV vectors), viruses and derived products (CAR-T cells, producer cells, etc.).



### Gene Therapy and Virology QC activities

The department provides regulatory tests for the characterization of vectors lots or vector-modified cells banks such as:

- Infectivity assays and infectious particles titration assays
- Physical particles titration assays
- Vector copy number determination assays
- Replication-competent virus detection assays (RCL and rcAAV) in vectors lots and cell banks
- Residual DNA quantification using qPCR techniques for a large panel of targets of interest (gag, pol, psi, VSV-G, kanamycin, E1A, T-SV40, AAV rep and AAV cap (serotypes 1-8, 10-13), HEK293, Sf sequences etc.)

The department also offers:

- Customized bioassays development and validation capabilities to answer specific needs
- Unique engineering, production and titration (TCID50 assays, focus-forming assays) capabilities for the generation and the characterization of innovative model viruses used for QC activities
- Bespoke assay development (cell-based, molecular, immunochemistry): full or partial development, integration and/or validation according to ICH Q2R1 guidelines

### INNOVATIVE VALIDATED CYTOTOXICITY METHODS FOR CAR-T CELLS EVALUATION



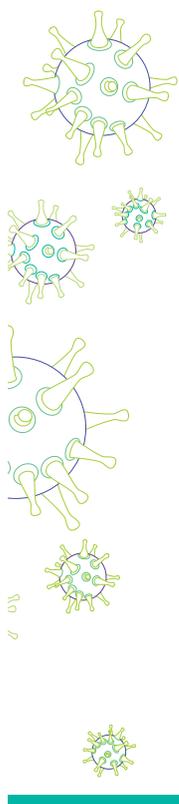
### Cytogenetics

Karyotype analysis for:

- Species identification
  - GTG banding profile
  - Cytogenetic marker identification
- Validation of diploid karyotypes
- Genetic stability
  - Aneuploidy detection (monosomies and trisomies)
  - Ploidy level abnormalities detection (haploidy, triploidy, polyploidy)
  - Modal chromosome number (MCN) determination
  - Gross structural aberrations detection (chromosome breaks and gaps, dicentrics etc.)
  - Specific structural aberrations detection: deletions, inversions, duplications, insertions and translocations (balanced and unbalanced)
  - Cytogenetic marker identification

FISH and M-FISH analyses - Standard and customized assays for the detection of:

- Trisomies and monosomies
- Balanced and unbalanced translocations
- Deletions and additions of whole chromosomes or specific genes
- Complex aberrations



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