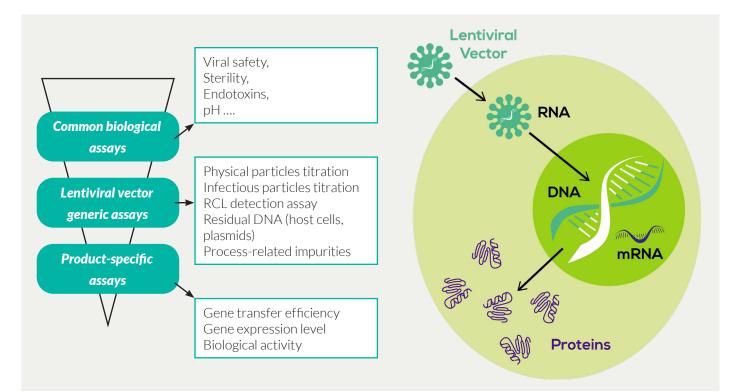
# clean cells SOLUTION FOR BIOLOGICS

# BIOLOGICAL CHARATERIZATION OF CLINICAL-GRADE LENTIVIRAL VECTORS

The manufacturing of lentiviral vectors incorporates multiple challenges, notably the development and validation of the appropriate quality controls (QC). To match the specific technical and regulatory requirements of each project, our gene therapy expert team has developed a full range of GMP QC dedicated to lentiviral vectors and routinely supports our clients from pre-clinical to commercial stage.



### **REGULATORY COMPLIANCE WITH**

- Assays according to FDA and EMA guidelines
- EP and USP dedicated chapters
  - (EP5.14, USP <1046> and <1047>)
- GMP guidelines
- ICH Q2(R1)-validated methods



## YOUR BENEFIT: -

#### • Combined expertise in:

- + Lentiviral vectors
- + Bioassay development
- + GMP-compliant quality controls
- Project follow-up & management

#### • Product-specific development &

validation according to the clinical stage

STAY FOCUS ON YOUR DEVELOPMENT TASKS



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