

# SIMPLIFY AND SECURE YOUR BIOSAFETY QUALITY CONTROL WITH **NEXT GENERATION SEQUENCING (NGS)**



Biologics (mAbs, Recombinant Proteins)

## COMPLIANT, FASTER, ANIMAL-FREE



Adventitious Agent Testing | Plasmid Identity | Integration Site Analysis

### SIMPLIFIED VIRAL SAFETY TESTING



#### Faster:

One assay replaces *In Vivo* Adventitious Agent Testing, MAP HAP RAP, *In Vitro* tests



#### Safer:

Comprehensive viral breadth of detection



#### Animal-Free:

3Rs compliant

### UNMATCHED PRECISION FOR GENETIC CHARACTERIZATION



#### Identity:

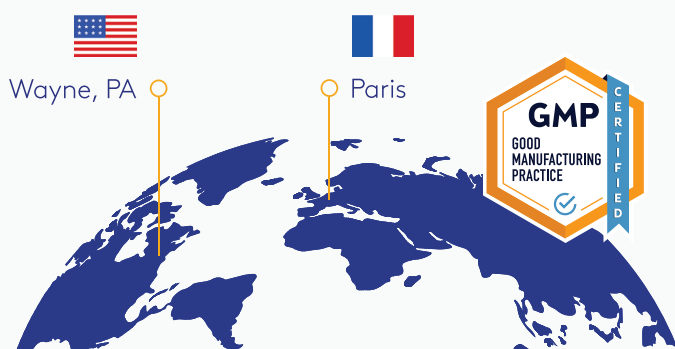
- High-resolution sequence verification
  - Broad genomic coverage
- Detection of complex mixed populations



#### Integration Site Analysis:

Better understanding of your clones

### 2 GMP MIRROR FACILITIES

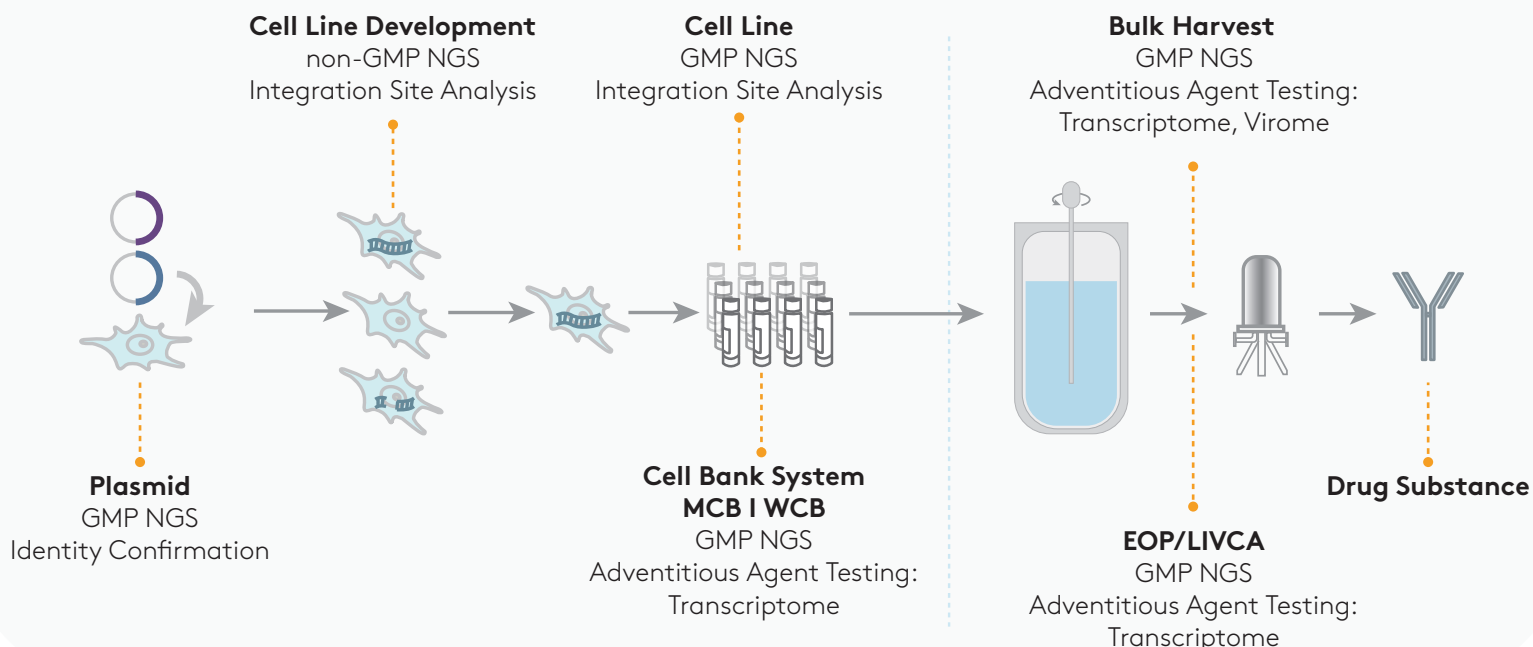


### REGULATORY GUIDELINES

- ICH Q5A(R2) – Viral safety (2023 revision)
- ICH Q5B – Expression construct analysis for production of r-DNA derived protein products
- ICH Q5D – Derivation and characterization of cell substrates
- EMA Guideline: EMA/CHMP/BWP/457920/2012 Rev.1
- FDA Guidance for the Industry: Points to consider in the characterization of cell lines (1993)
- USP <1050> – Viral safety from cell lines of human and animal origin
- WHO TRS 987 Annex 4 – Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology
- Ph. Eur. 5.2.3/5.1.7 – Cell substrates for the production of vaccines and biologicals and viral safety
- Ph. Eur. 2.6.41 – High-throughput sequencing for the detection of viral extraneous agents: New chapter adopted in March 2025

## UPSTREAM PROCESSING (USP)

## DOWNSTREAM PROCESSING (DSP)



## ASSAY SPECIFICATIONS

	Assay	GMP	Sample Requirements	Turnaround Time	Deliverables to Client
VIRAL SAFETY	<b>iDTECT® Transcriptome</b> For cell-based material	✓	Min. 3×10 <sup>5</sup> cells	5 weeks (Standard) 4 weeks (Fast Track)	<ul style="list-style-type: none"> <li>Certificate of Analysis</li> <li>Expert virologist report</li> <li>Raw data</li> </ul>
	<b>iDTECT® Virome</b> For cell-free material	✓	2×5 mL	6 weeks (Standard) 5 weeks (Fast Track)	<ul style="list-style-type: none"> <li>Certificate of Analysis</li> <li>Expert virologist report</li> <li>Raw data</li> </ul>
GENETIC CHARACTERIZATION	<b>iDTECT® Identity</b>	✓	Varies by sample type	3 weeks (Standard) 2 weeks (Fast Track)	<ul style="list-style-type: none"> <li>Certificate of Analysis (% identity match to reference, presence and nature of variants)</li> </ul>
	<b>iDTECT® Integration Site Analysis</b>		5×10 <sup>6</sup> cells (≥10 µg DNA per sample)	5 weeks (per round)	<ul style="list-style-type: none"> <li>Report</li> <li>Raw data</li> </ul>

Back up samples required. BSL1 and BSL2 samples accepted. | Shipment & storage: - 80°C / Dry Ice



### CONTACT OUR EXPERTS

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