

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:

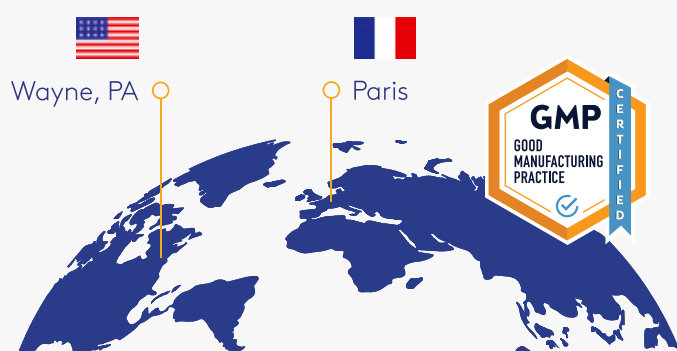
- High-resolution sequence verification
 - Broad genomic coverage
- Detection of complex mixed populations



Integration Site Analysis:

Better understanding of your clones

2 GMP MIRROR FACILITIES

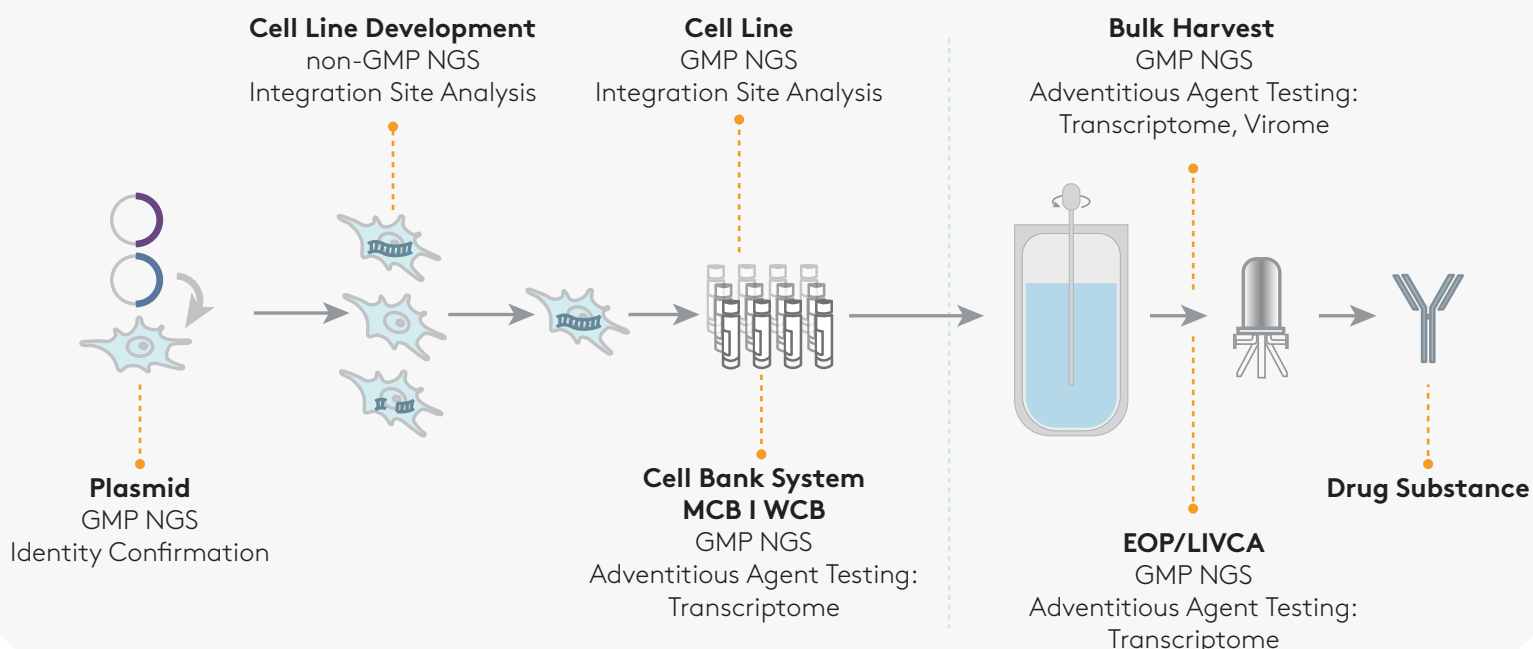


REGULATORY GUIDELINES

- 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 (Calendar Days)	Deliverables to Client
VIRAL SAFETY	iDTECT® Transcriptome For cell-based material	✓	Min. 3×10 ⁵ cells	28 days (Standard) 21 days (Fast Track)	- Certificate of Analysis - Expert virologist report - Raw data
	iDTECT® Virome For cell-free material	✓	2×5 mL	42 days (Standard) 35 days (Fast Track)	- Certificate of Analysis - Expert virologist report - Raw data
GENETIC CHARACTERIZATION	iDTECT® Identity	✓	Varies by sample type	21 days (Standard) 14 days (Fast Track)	Certificate of Analysis (% identity match to reference, presence and nature of variants)
	iDTECT® Integration Site Analysis		5×10 ⁶ cells (≥10 µg DNA per sample)	35 days (per round)	- Report - Raw data

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



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