

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

Gene Therapies

## COMPLIANT, FASTER, ANIMAL-FREE



Adventitious Agent Testing | Identity Confirmation

### SIMPLIFIED VIRAL SAFETY TESTING



#### No neutralization needed:

Consistent and reproducible results that work the first time



#### Faster:

Comprehensive adventitious viral agent detection and identification in a single assay step



#### 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

### 2 GMP MIRROR FACILITIES



Wayne, PA



Paris

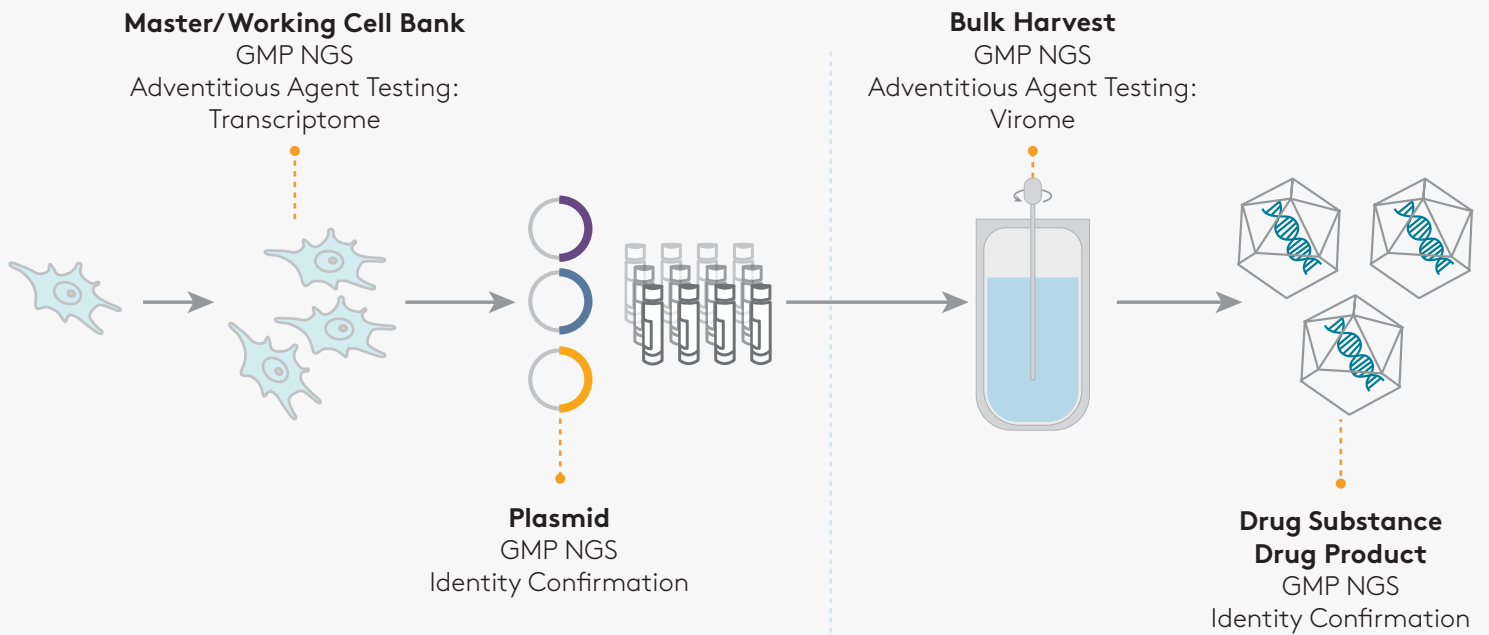


### REGULATORY GUIDELINES

- ICH Q5A(R2) – Viral safety (2023 revision)
- ICH Q5D – Derivation and characterization of cell substrates
- EMA Guideline: EMA/CHMP/BWP/457920/2012 Rev.1
- EMA Guideline: EMA/CAT/80183/2014
- 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
- 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	<b>iDTECT® Transcriptome</b> For cell-based material	✓	Min. 3×10 <sup>5</sup> cells	28 days (Standard) 21 days (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	42 days (Standard) 35 days (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	21 days (Standard) 14 days (Fast Track)	<ul style="list-style-type: none"> <li>Certificate of Analysis (% identity match to reference, presence and nature of variants)</li> </ul>

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



### CONTACT OUR EXPERTS

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