

# Viral Clearance Market to Touch \$977.8 Million by 2031, Accelerating at 8.6% CAGR

PORTLAND, OR, UNITED STATES, July 4, 2025 /EINPresswire.com/ --

Biologic-based therapeutics are thriving, but their success hinges on an invisible safety net: viral clearance. This set of validated removal and inactivation steps keeps monoclonal antibodies, recombinant proteins, blood products, vaccines, and novel cell and gene therapy candidates free of viral contaminants. The global [viral clearance market](#), valued at \$425.9 million in 2021, is forecast to more than double to \$977.8 million by 2031—a trajectory powered by tightening regulatory scrutiny, surging biologics pipelines, and a wave of strategic partnerships.



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## 1. Why Viral Clearance Is Non-Negotiable

Unchecked viral contamination can halt an entire bioproduction campaign—causing multimillion-dollar losses and supply shortages.

No single assay catches every virus; therefore, a multilayered strategy combining viral inactivation (e.g., low-pH, solvent-detergent, heat pasteurization) and viral removal (e.g., nanofiltration, chromatography) is mandated.

Regulatory guidelines (ICH Q5A, EMA, US FDA) increasingly require process-specific viral clearance validation, pushing demand for both in-house systems and outsourced services.

## 2. Market Catalysts & Headwinds

Growth Drivers Potential Constraints

Boom in monoclonal antibodies & advanced therapies—over 1,200 biologics now in clinical

pipelines Market consolidation limits vendor choice and pricing flexibility  
Rising investments in Asia-Pacific biomanufacturing hubs High capital cost of state-of-the-art filter skids and pathogen-reduction equipment  
Accelerated approvals for orphan & breakthrough drugs Complexity of validating clearance for novel viral vectors  
High-profile contamination events (e.g., BAVENCIO® case study) sharpening industry vigilance  
Skilled-labor shortages in viral safety labs

### 3. Segment Snapshot

#### By Method

Viral Removal (~55% share, fastest-growing)—Nanofiltration membranes as low as 15 nm now trap parvoviruses without sacrificing protein yield.

Viral Inactivation—Low-pH holds remain a mainstay for IgG, while solvent-detergent cocktails are preferred for plasma proteins.

#### By Application

Recombinant Proteins (largest, chronic-disease demand)

Cellular & Gene Therapy (CAGR >10%)—driven by ~3,000 active regenerative-medicine trials.

#### By End User

Pharma & Biotech Firms (dominant)—building internal “virus suites” to shorten tech-transfer timelines.

Contract Research Organizations (CROs) —gaining momentum as small biotechs outsource expensive biosafety studies.

### 4. Regional Outlook

Region 2021 Share 2022-2031 Focus

North America ~40% Continuous-processing adoption, Phase-III gene-therapy boom

Europe ~30% EMA's Advanced Therapy Medicinal Products (ATMP) framework driving audits

Asia-Pacific Fastest CAGR China, India, and South Korea scaling GMP biologics parks; local regulators aligning with ICH-Q5A

LAMEA Niche Investment incentives for vaccine manufacturing (e.g., Gulf Cooperation Council funds)

### 5. Competitive Landscape

Key players—including Merck KGaA (MilliporeSigma), Sartorius Stedim Biotech, Charles River Laboratories, Wuxi Biologics, and Eurofins Scientific—are expanding viral safety offerings via:

Targeted M&A (e.g., Clean Cells + NAOBiOS, 2019) to integrate vaccine challenge–study capacity.

Single–use, closed–system skids that bundle depth filtration, nanofiltration, and inline virus sensors.

AI–assisted virome analytics to cut assay time from weeks to days.

## 6. What Lies Ahead (2025–2031)

Advent of continuous viral clearance modules enabling 24/7 production lines.

Broader use of next–generation sequencing for untargeted viral detection in real time.

Regulatory movement toward platform viral clearance claims—letting manufacturers reuse validated steps across molecule families.

Sustained outsourcing wave as emerging biotechs prioritize speed–to–IND over building internal biosafety labs.

### Key Takeaways

Market Momentum: Revenues set to more than double, reaching \$977.8–million by 2031 at an 8.6% CAGR.

Dominant Method: Viral removal—especially nanofiltration—remains the front–runner, owning >50% share.

Hotspot: Asia–Pacific will log the steepest growth, buoyed by government R&D grants and fresh GMP plants.

Opportunity Nexus: Cell & gene therapy pipelines and continuous–manufacturing initiatives represent the next big lift for viral clearance vendors.

Strategic Imperative: Partnerships and technology integration—from AI–powered analytics to single–use systems—will decide who captures the lion’s share of this expanding market.

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