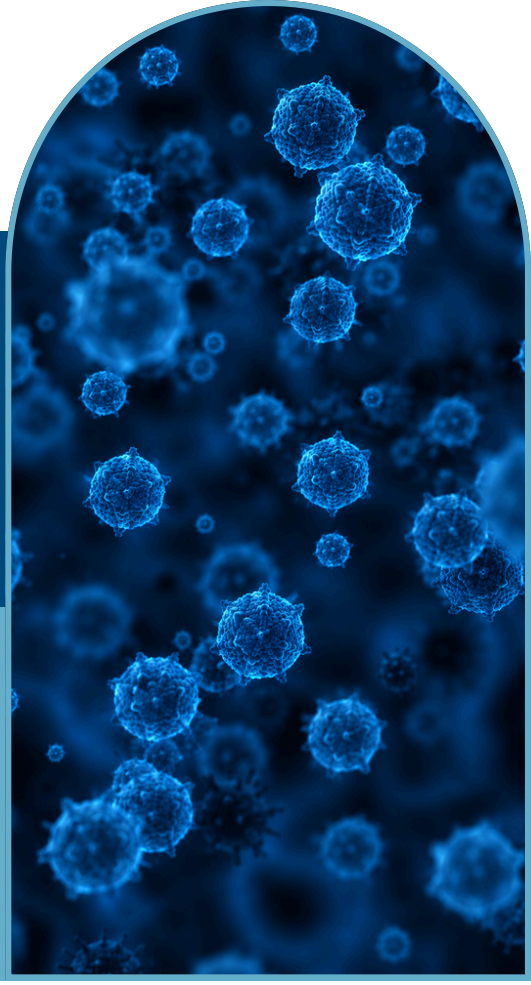
solvias



Seeing the Unseen:

INVESTIGATING SUSPECTED VIRAL CONTAMINATION IN CHO CELL CULTURES USING NGS

A commercial biopharmaceutical manufacturing facility observed unexpected cell culture performance changes during production of a recombinant monoclonal antibody (mAb) expressed in Chinese Hamster Ovary (CHO) cells. Traditional viral detection assays suggested the presence of an adventitious viral contaminant but were unable to rapidly identify the causative agent. Identifying the potential contaminant was essential to understanding the extent of the problem, investigating its origin, and determining the appropriate next steps. The company partnered with Solvias to investigate the suspected contamination.

THE CHALLENGES

Limitations of Conventional Testing
Traditional in vivo and in vitro assays can be labor-intensive and time-consuming, often requiring additional techniques to identify a detected virus.

The Need for Timely, Reliable Answers
The suspected contamination created uncertainty around manufacturing operations and product quality, making rapid identification critical to support informed decisions.

An Unknown Source of Contamination
Without knowing whether the virus originated from raw materials, cell substrates, or another stage of manufacturing, selecting an appropriate targeted testing strategy was difficult.

OUR COLLABORATIVE APPROACH

Step 1: Understanding the Contamination Event
Solvias worked closely with the manufacturer to understand the circumstances surrounding the suspected contamination. Was there a reason to suspect a specific virus or group of viruses? Could the potential source of contamination be traced to a particular stage of the manufacturing process? Was the product expected to contain naturally occurring viruses or endogenous viral signatures? Addressing these questions helped define the appropriate testing strategy and establish the context needed to distinguish expected viral signatures from potential contaminants during data analysis and reporting.

Step 2: Selecting the Appropriate Viral Detection Panel
With neither the viral agent nor the stage of manufacturing at which contamination may have occurred identified, Solvias recommended its comprehensive next-generation sequencing (NGS) viral detection panel rather than an organism-specific panel (e.g., bovine- or porcine-specific virus testing). This broader approach maximizes the likelihood of detecting potential contaminating viruses from a wide range of sources and provides a more thorough investigation when the origin of the contamination event is unknown.

Step 3: NGS Sequencing and Bioinformatics Analysis
We processed the client sample using our validated NGS workflow and analyzed the resulting data according to established acceptance criteria. Leveraging our robust bioinformatics pipeline, we successfully identified the contaminating virus as Minute Virus of Mice (MVM).

Step 4: Reporting
Solvias reported the identified virus in the Certificate of Analysis (CoA), together with supporting analytical data. The results provided the manufacturer with evidence to inform its internal contamination assessment and root cause investigation.

THE RESULTS

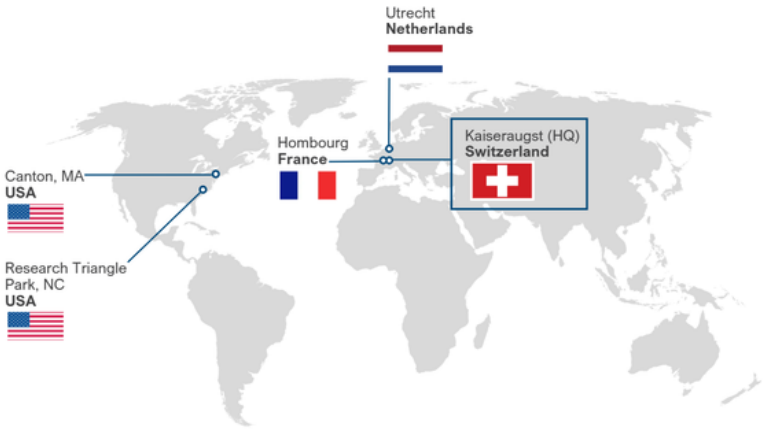
- Enabled broad viral screening without requiring prior knowledge of the contaminating agent or its source.
- Identified the contaminating virus as MVM.
- Supported timely manufacturing decisions, allowing the manufacturer to address the contamination before product release, avoiding patient risks, costly recalls, and reputational damage.

CONCLUSION

This case demonstrates how comprehensive viral screening can provide timely, actionable insights when the source of contamination is unknown. Recognized by regulatory authorities such as the FDA and EMA, NGS enables the detection and identification of a broad range of viral contaminants in a single, animal-free test. By reducing the need for multiple targeted assays, NGS can accelerate contamination investigations and support informed decisions on product quality, manufacturing, and release, helping manufacturers address potential risks before products reach patients.

WHY PARTNER WITH US?

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- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m^2 of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



Contact us to speak with an expert: info@solvias.com

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