IMPLICATIONS OF THE CAACB VIRUS CONTAMINATION IN BIOMANUFACTURING PROJECT FOR CELL THERAPY MANUFACTURERS

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Adventitious agent contamination of cell culture-based biomanufacturing operations for the production of protein and monoclonal antibody biotherapeutics are infrequent, but when they do occur, they are very costly, impact manufacturing operations, and can potentially impact patient safety and product supply. In response to this need, the MIT Consortium on Adventitious Agent Contamination in Biomanufacturing (CAACB) began the confidential collection and analysis of industry-wide viral contamination data with an emphasis on “lessons learned”. This presentation will cover the learnings from this study, including identified industry risks and best practices to mitigate those risks. Some of the key findings which have significant implications to the emerging cell therapy industry are:

1) Raw materials, including non-animal-based raw materials, may be a potential source of viral contamination and stringent raw material testing and vendor selection and auditing programs are critical.
2) Traditional viral tests, including in vitro testing and PCR, have contributed to false-positive events, which may take extended times to resolve prior to release of raw materials, process intermediates, or final product.
3) The time frames needed for viral testing in general, and for investigation of positive viral tests, can range from weeks to months, and are not compatible with the requirements for near real-time release testing for some cell therapy products.
4) Viral testing programs, and potential investigations of positive results, are quite expensive, and application to the autologous cell therapy space will be challenging.