Understanding Supplier Pipeline Through Elemental Impurities:

A New Perspective on Risk Assessment

The mindset of supplier qualification continues to change in accordance with increased knowledge of production variables and demand for proper change control protocols. Such is the case with research on the importance of micronutrients in the form of trace elements, and control of contamination. Everything that cell cultures (mammalian or plant) contact needs to be monitored for trace metals contamination. The difference between micronutrient levels and cytotoxicity of metals are miniscule and differ depending on the exact genetic make-up of the cell line. Control and monitoring of alkali earth and transition metals must be integrated into biopharmaceutical processes on a holistic perspective to ensure the long-term viability of production and R&D activities.

Confirming nutrient concentrations and levels of contaminants in chemically defined media plays the most vital role for both drug discovery and manufacturing. One can choose either a robust quality assurance program or luck to drive whether an OOS is encountered at the production phase at a CMO's facility. If luck, 'aka' reliance upon vendors' certificate of analyses, is driving quality then an OOS probability is no longer an "if" but a "when." Considering CMOs still invoice regardless of batch viability, the risk is solely on the pharmaceutical company. Integration of proactive monitoring programs not only mitigates risk but also ensures the pipeline of R&D is unfettered.

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The adoption of single-use technologies in the biopharmaceutical production cycle has presented a new array of variables. Of course, the flexibility, reduced capital costs, and reduced water usage can be very attractive in a competitive environment. However, integration of continual change necessitates a new approach to proactive screening and monitoring and adaptation of quality systems. Metals contamination in a single disposable storage container has the capacity to induce an OOS for a production batch that costs far more than just a monetary sum. Reduced availability of a life-saving drug for patients is a far costlier price to pay.

The importance of acid-cleaned, not just sanitized, sampling and archival labware is often overlooked due to the simplicity of the concept. Futility is performing an investigation on historical production batches or experiments and not knowing if your results are attributed to the actual sample or the sample vessel. That is why BAL places utmost importance on our cleaning process and provides certificates of analyses for every batch of labware released to our clients.

Our expertise in trace element analyses demands a detailed understanding of contamination sources and how to mitigate them. This translates to not just quality, but trust that our clients have in BAL for supporting all of their sampling and sample archival needs. Whether you are performing clinical trials, R&D for biopharmaceuticals, or supporting quality systems from industrial applications, it is within your best interest to contact us today to mitigate risk and maximize your potential for success.

For more information, please visit our website at www.brooksapplied.com or call 206-632-6206.