QC for biopharma:

Change control, compliance & collaboration

Biopharmaceuticals require some of the most stringent quality control protocols. Produced from living cells using cutting-edge biotechnology with exacting standards, any compromise in material or deviation in process could mean a significant financial loss, drug shortage and/or potential adverse patient outcomes.

As biopharmaceutical manufacturers evaluate alternative suppliers due to global supply chain disruptions, close collaboration between the manufacturer and supplier is critical to meet market requirements, minimise risk and ensure quality control.

Change control & consistency

Because the production of biopharmaceuticals such as vaccines, antibodies and recombinant proteins requires more stringently controlled processes and raw materials compared with traditional small molecule drugs, change control is particularly important. This ensures that no unnecessary changes are made and, if they are, they are thoroughly documented and communicated.

"Any unintended deviation can have a significant impact on a drug's performance," explains Jigisha Patel, VP of Quality and Regulatory Compliance for Spectrum Chemical. "That's why manufacturers should partner with suppliers that have adopted strict, fully functional quality management systems that help ensure change control and materials meet specifications and process needs with validated consistency."

Patel points to Spectrum Chemical's QC protocols, which encompass multiple processes, including change control and batch traceability, monograph compliance, lab testing certifications, scientific documentation, and packaging and labelling. Certifying that raw materials are free of contaminants or foreign particles is critical to bioprocessing.

Another example involves current good manufacturing practices (cGMP). Suppliers may differ in their application of GMPs and audit programmes can be difficult to develop and implement. Biopharmaceutical manufacturers should ensure that suppliers of raw materials can provide complete GMP audit reports, including documentation of non-compliance events, and corrective and preventive actions (CAPAs).

100% tested. 100% transparent. 100% trusted.

Spectrum Chemical's industry-leading bioCERTIFIED™ quality management system and chemicals are intended to help biopharmaceutical manufacturers deliver products with remarkable consistency quickly and efficiently.

With more than 50 years of expertise as a supplier to drug developers, Spectrum Chemical knows how to address current issues and challenges while facilitating faster processes and higher quality. For example, each bioCERTIFIED chemical undergoes complete testing including expanded analysis for bioburden, endotoxin and residual solvents to ensure it meets monograph requirements. Additional testing is also available to meet manufacturer specifications.

Collaborative confidence

Spectrum Chemical's bioCERTIFIED programme also provides complete traceability, including change control and batch tracing, a dossier of regulatory and scientific information, auditing and quality management. All products are packaged in ISO Class 8 cleanrooms with very specific protocols.

In addition to bioCERTIFIED materials, customers gain a best-in-class support team, robust scientific documentation, and strict quality and certification processes to ensure product consistency, predictability and performance.

"We can serve as an adjunct to the manufacturer's own QC team, providing supply chain transparency, standardised materials and confirmatory testing," says Patel. "Our collaboration definitely brings confidence and peace of mind while helping speed final product to market." ●

For more information, visit
SpectrumChemical.com/biocertified