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Heath Coats Highlights Evolving FDA Inspection Expectations At Charles River APAC Biomanufacturing Leadership Summit

10 March 2026 | News | By Ankit Kankar | ankit.kankar@mmactiv.com

Speaking at the Charles River APAC Biomanufacturing Leadership Summit, Heath Coats outlined how the March 2026 draft guidance from the U.S. Food and Drug Administration strengthens clarity around inspection observations and underscores the need for robust quality systems and continuous inspection readiness in biologics manufacturing.

In his keynote session, Heath Coats shared practical regulatory insights drawn from his experience both inside the U.S. Food and Drug Administration and now advising global biopharma companies on quality and compliance strategy. His presentation focused on the evolving expectations around manufacturing inspections and the implications of the newly released March 2026 draft guidance related to FDA Form 483 observations, which is currently open for industry comments.

Coats explained that FDA Form 483 remains one of the most critical regulatory signals during manufacturing inspections, particularly in clinical and commercial biologics production. The document is issued when investigators identify conditions that may indicate potential violations of Good Manufacturing Practice requirements. While it does not represent a final regulatory determination, it often signals areas where companies must take immediate corrective action to maintain regulatory confidence.

A central theme of the presentation was the growing regulatory scrutiny across both clinical manufacturing and commercial production environments. Coats noted that inspections today increasingly focus on data integrity, quality systems, process control, and documentation practices. With the complexity of biologics, cell therapies and advanced modalities increasing, regulators are placing greater emphasis on ensuring that manufacturing processes remain consistent, controlled, and fully traceable from development through commercial scale.

He also highlighted how the new draft guidance aims to clarify how FDA investigators document observations during inspections, including expectations for evidence, communication with companies, and timelines for responses. According to Coats, this effort reflects a broader move by regulators to enhance transparency and consistency in inspection outcomes while ensuring manufacturers clearly understand the severity and implications of each observation.

For companies operating in the global biomanufacturing ecosystem, Coats emphasised that inspection readiness must now be treated as a continuous operational discipline rather than an episodic compliance exercise. Organisations that embed quality culture across manufacturing, documentation, and supplier management will be better positioned to navigate inspections smoothly and avoid costly regulatory delays.

The keynote ultimately reinforced a broader message for the biomanufacturing sector: as production technologies advance and regulatory oversight becomes more sophisticated, quality systems and inspection preparedness will remain foundational to scaling biologics manufacturing globally.

About The Event

This session was part of the APAC Biomanufacturing Leadership Summit 2026 presented by Charles River, a leadership forum bringing together biopharmaceutical manufacturers, CDMOs, biotechnology innovators, investors, and regulatory experts from across the Asia Pacific region.

The summit focuses on advancing discussions around next generation biomanufacturing, regulatory readiness, advanced analytics, and global collaboration required to support the rapidly evolving biologics and advanced therapy landscape.

Through keynote presentations, expert panels, and technical sessions, the event highlights strategies that strengthen Asia Pacific's role as a critical node in the global biopharmaceutical manufacturing ecosystem.

For more information visit https://events.criver.com/event/APAC2026/summary.