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Strengthening Quality Culture Is Critical For Scaling Advanced Biomanufacturing

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Heath Coats discusses regulatory alignment, quality by design, and the evolving compliance landscape for advanced therapies across the Asia Pacific region.

At the **APAC Biomanufacturing Leadership Summit 2026 in Singapore, organised by Charles River, BioSpectrum Asia spoke with Heath Coats, MS, Senior Principal and Head of Quality and Compliance at Dark Horse Consulting, and former FDA DMPQ official.** With extensive experience in regulatory oversight and quality systems, Coats offers a perspective on how quality culture, procedural alignment, and regulatory preparedness will shape the next phase of advanced biomanufacturing. In this conversation, he discusses opportunities for improving compliance practices in APAC, the evolving regulatory pathways for cell and gene therapies, and the importance of leveraging established biologics manufacturing expertise to support emerging modalities.

Q: As advanced therapies continue to expand, how important is organisational quality culture in supporting reliable manufacturing?

A strong quality culture is foundational for any successful biomanufacturing organisation. Quality cannot simply be the responsibility of a single department. It must be embedded across the entire organisation.

Companies should adopt quality by design principles and ensure that every employee understands their role in maintaining product quality and patient safety. A healthy quality culture empowers employees to identify potential issues and intervene early when necessary.

This approach also supports continuous improvement. Organisations should constantly identify opportunities for improvement, investigate root causes, implement corrective actions, and evaluate the effectiveness of those changes. When quality culture becomes truly embedded, it creates a positive energy across the organisation and strengthens overall operational performance.

Q: From your experience, what are some areas where APAC biomanufacturing organisations can further strengthen regulatory compliance?

One area of improvement relates to alignment of procedures and documentation practices.

For example, the FDA requires regulatory submissions and supporting documentation to be provided in English. In some organisations across the APAC region, operational documentation may initially be written in local languages and later translated into English.

During this translation process, discrepancies can occasionally arise. Individual standard operating procedures may appear sound when reviewed independently, but when examined together they can sometimes present contradictory information. Ensuring consistency across procedures and documentation is therefore essential.

Another challenge is that many companies developing advanced therapies have not yet gone through full regulatory approval processes such as FDA pre licence inspections. As a result, there may be limited experience with the depth of compliance expectations required for commercial approvals.

Q: Automation and digital manufacturing are often discussed as the future of advanced therapies. What challenges do companies face when implementing these technologies?

Digitisation and automation can significantly improve efficiency and product consistency, but implementing these systems often requires substantial investment.

Many cell and gene therapy products developed to date have been small scale autologous therapies. In those cases, the cost benefit analysis for large scale automation may not yet justify the investment.

However, the landscape is evolving. Recent developments in Japan involving induced pluripotent stem cell based allogeneic therapies have the potential to treat much larger patient populations. As production scales increase, companies will have stronger incentives to adopt automation and advanced manufacturing tools to improve efficiency and reliability.

Q: You mentioned emerging clinical research models such as investigator initiated trials. How do you see these evolving globally?

Investigator initiated trials in regions such as China are gaining attention because they can sometimes be conducted with greater regulatory flexibility and at a lower cost compared with similar trials in the United States.

However, the key challenge will be ensuring consistent levels of quality compliance. Some IITs may be designed purely as exploratory proof of concept studies, while others may aim to support future regulatory submissions.

Establishing clear standards for quality and data integrity will therefore be important if these trials are to play a meaningful role in global drug development pathways.

Q: What value do international industry forums such as the APAC Biomanufacturing Leadership Summit bring to the sector?

Networking and knowledge exchange are extremely valuable.

The APAC region has decades of experience in manufacturing biologics and monoclonal antibodies. There is an opportunity to leverage those lessons and apply them to emerging modalities such as cell and gene therapies, lipid nanoparticles, and mRNA based products.

Regulatory frameworks such as the U.S. Code of Federal Regulations have remained largely stable for many years. This means many of the core manufacturing and quality principles developed for earlier biologics remain highly relevant for new technologies.

Events like this summit allow stakeholders to share insights, build partnerships, and adapt established best practices to support the next generation of advanced biomanufacturing.