TRANSPERFECT SUMMIT
CONVERSATIONS ON CLINICAL CONTENT

Adapting Regulatory Strategies for Tomorrow's Pharma Landscape

MODERATOR

Robyn Fairhurst

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THE PANEL

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Global Head of Compliance & Quality, DPO
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Jazz Pharmaceuticals

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In an evolving pharmaceutical landscape shaped by emerging technologies, compressed timelines, and rising regulatory complexity, the role of regulatory affairs is under more pressure than ever. This panel brought together leaders from Bayer, Jazz Pharmaceuticals, Eli Lilly, and Oracle Life Sciences to explore how regulatory strategies must adapt to remain proactive, scalable, and globally aligned.

The panel discussed the increasing integration of AI into regulatory workflows, including applications like automating document preparation, summarizing health authority feedback, and reusing responses. However, AI must be governed by clear accountability frameworks, as it still lacks consistency and contextual nuances.

A major theme of the discussion was the integration of AI into regulatory workflows. Panelists shared various use cases ranging from automating document creation and summarization to reusing responses to health authority queries. However, the session was equally focused on the pitfalls and limitations of AI, emphasizing its lack of accountability, inconsistent outputs, and user interface challenges. Both successes and failed experiments highlighted that AI is still maturing in this space and must be adopted with caution, keeping humans firmly in the loop.

Beyond technology, the panel discussed cross-functional alignment, workforce upskilling, and how digital transformation is reshaping regulatory submissions. A key focus was the evolving regulatory expectation to include patient perspectives: introducing a human-centered lens into compliance-heavy workflows.

KEY TAKEAWAYS

AI is a useful but limited tool:
It offers efficiency in repetitive regulatory tasks but lacks accountability and consistency, necessitating human oversight.

Digital transformation is ongoing:
Regulatory affairs is transitioning from document-based processes to data-driven, interoperable systems requiring new skill sets.

Patient involvement is non-negotiable:
Engaging patients early and consistently adds value, improves outcomes, and is becoming a regulatory expectation.

Global regulatory differences persist:
AI can help manage these variations by identifying patterns and optimizing compliance strategies.

The future is augmentation, not replacement:
AI should support, not supplant, regulatory professionals, preserving critical thinking at the heart of the discipline.

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