GLOBAL
REGULATORY WRITING & CONSULTING

CASE STUDY

Restoring Compliance in Electronic Document Signing

Therapeutic Area: Infectious Disease

Product Type: Vaccine

Document: IB, Interim Analysis Report, Protocol, and ICFs

We support Medtech and Biopharma innovators with strong, collaborative partnerships, tailored regulatory consulting and writing services, and deep strategic expertise.

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GLOBAL'S DOCUMENT PRODUCTION CAPABILITIES

- Experienced writers with regulatory and therapeutic knowledge
- Flexible project management approach with customized solutions
- High quality deliverables with consistent client satisfaction
- Focus on efficient practices and streamlined workflows
- Integrative partnership versus provider-client relationship

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ABOUT THE CLIENT

The sponsor – a mid-size, clinical-stage synthetic biology company developing vaccine platforms for infectious disease and oncology – was supported by a lean but capable team.

While advancing innovative live-attenuated viral therapies, the group faced operational and compliance challenges typical of rapidly growing biotech organizations preparing documents for FDA submission.

ABOUT THE PROJECT

The sponsor's team generated PDF submission documents that had been processed through electronic signing software. However, during this process, key functionalities—such as internal hyperlinks—were lost, creating a compliance risk. Without restoration of these features, the documents would not have been suitable for FDA review or submission.

Although technically correct in appearance, the corrupted PDFs introduced instability and risk of rejection, requiring specialized intervention to ensure the documents met regulatory standards.

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GLOBAL SOLUTIONS

GLOBAL's document production specialists, with deep expertise in MS Word and Adobe PDF functionalities, rapidly identified the root cause of the compliance issue. Rather than requiring the sponsor to redo and re-sign the affected documents—a process that would have delayed submission—GLOBAL worked within the existing signed PDFs to restore hyperlink functionality.

This pragmatic approach ensured the documents were technically compliant, functional, and suitable for regulatory publishing and submission.

OUTCOME

By diagnosing the issue early, GLOBAL was able to safeguard the remainder of the submission package. All subsequent documents were converted and processed correctly, retaining internal links even after passing through the sponsor's signing software. This proactive intervention prevented further document failures, saving both the sponsor and GLOBAL significant time on a tight submission schedule.

CONCLUSIONS

Technical issues in document production can create serious risks to submission readiness, particularly under deadline pressure. GLOBAL's combination of regulatory expertise and technical proficiency enabled the sponsor to deliver compliant, functional documents without disruption to timelines.

This case demonstrates how GLOBAL can provide rapid, reliable solutions to complex technical challenges, supporting sponsors in achieving successful and efficient regulatory submissions.

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info@globalrwc.com GlobalRWC www.globalrwc.com