Case Study

Non-Clinical Regulatory Document Development

Regional Hub for Product Label Management

Non-Clinical Regulatory Document Development

Multinational Pharmaceutical Company

Business Need

Updating non-clinical sections of IB, quality checking non-clinical study report, authoring non-clinical overview to support label changes, authoring CTD 2.4 and 2.6, and compiling CMC documents to support post-approval changes. Identifying gaps in M3 documentation, obtaining information/documents to plug the gaps, assessing post-approval changes for the reporting category.

Our Solution

An offshore model consisting of scientific and technical writers, QC personnel, and a copy editor was deployed.

Outcome

Creation of efficient and high-quality non-clinical documents for regulatory submission.
The client has now contracted more work related to non-clinical regulatory documents to Indegene on an ongoing basis.

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