

Multi-Shore Delivery Model for Regulatory Writing

Dedicated Center for Authoring
of CERs and CEPs for Medical Devices for Top
5 Global Medical Devices Major

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US-based Global Medical Devices Major

Business Need

- The company needed to outsource its regulatory writing activities for cost-effectiveness a headcount freeze. It needed a partner with a strong understanding of the local regulatory environment and a low-cost delivery model.

Our Solution

- Indegene was selected as the strategic partner for regulatory writing due to its multi-shore delivery model.
- Regulatory experts with expertise in medical devices were deployed in the United States; medical writing was managed by a team of medical writers in Indegene's India-based operations.

Outcome

The team developed high-quality submission documents, and the engagement expanded to include providing publication support



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