Steps in the Regulatory Submission Lifecycle

Define Regulatory Pathway

> Choose between NDA, ANDA, BLA, MAA, or 510(k), based on product type.

Pre-Submisionn Meetings

Align with FDA or EMA expectations early to reduce rework. Gather Technical Documentation

Collect clinical. man-clinical, and manufacturing data to support your submission. Validate Submission Files

Use publishing tools to ensure formatting, metadata, and PDF links are correct. Respond to Agency Questions

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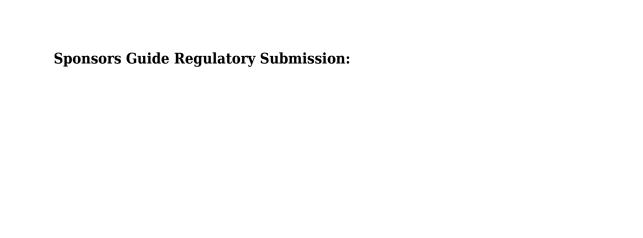
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