# 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

> Address defciency letters, RFIs, or inspection findings promptly.



Stay audit ready with CAPA,

SOP updates, and regulatory intelligencee tracking. Receive Regulatory Decision

Await approval, complete any final steps, or resolve conditions for launch.

Submit Through Electronic Gateway

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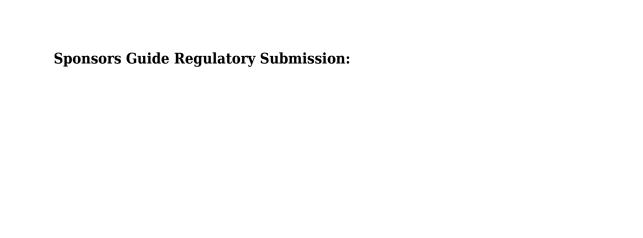
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