CUSTOMER SUCCESS STORY

Regulatory Submissions / Medical Devices

IN PARTNERSHIP WITH Complyze • POWERED BY APEX

Three Health Canada submissions. Three first-pass acceptances.

Ailethea's **APEX** engine, deployed through **Complyze**, cleared three medical device submissions to Health Canada on the first attempt, removing the rejection and resubmission cycles that normally add months and cost to regulatory approval.

3 of 3
Submissions accepted on first pass

$2M
Saved per submission

$6M
Total savings across the engagement

THE CHALLENGE

Medical device submissions to Health Canada follow standardized eCTD documentation and folder structures. Missing or contextually required documents trigger rejection and resubmission, adding time and cost to every cycle. Some requirements are context dependent: a regulator may not always request a given document, yet a specific submission still requires it. Those omissions are difficult to catch through manual review.

THE SOLUTION

APEX is Ailethea's regulatory submission engine, built on the TRIAD-AI foundation. It evaluates draft packets against the frameworks that govern medical device filings, then checks the full context of the submission, not only its structure.

- FDA Title 21 CFR, including Part 11
- ISO 13485 and QMSR quality standards
- eCTD standards for FDA and Health Canada
- Folder structure and document completeness

WHAT APEX CAUGHT

In one submission, APEX flagged clinical data that human reviewers had left out. Health Canada does not always request clinical data for that device type, so the gap passed manual review. APEX evaluated the full context of the submission, determined the data was required, and kept the packet on a first-pass path.

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