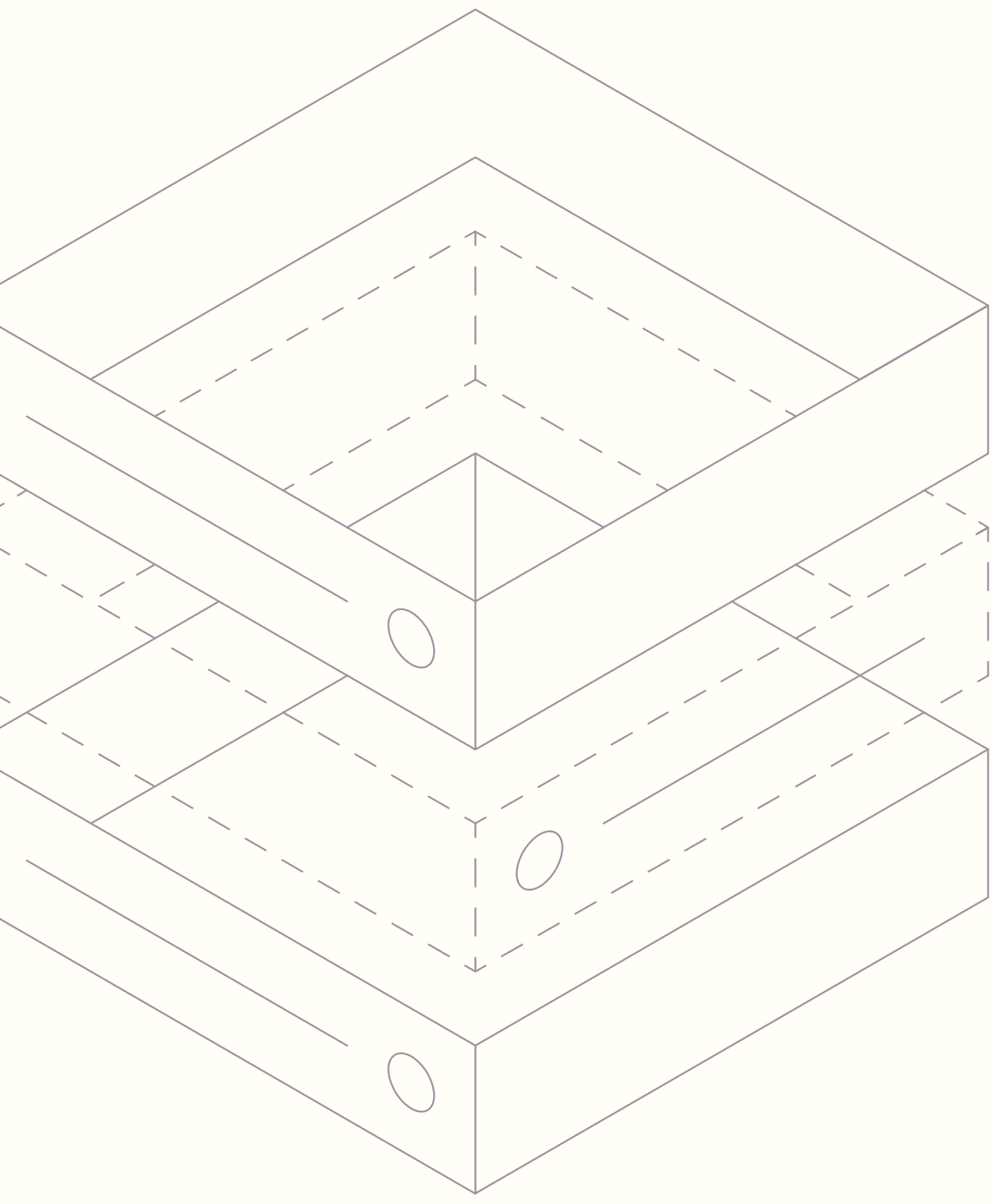
CASE STUDY

Streamline Pharmaceutical Regulatory Submission with *Generative AI*



Challenge

A global pharmaceutical company set out to streamline one of its most time-consuming and high-stakes processes: regulatory submissions for new medications. These efforts required extensive manual coordination between the R&D and Commercial teams, leaving little room for error. Leaders saw an opportunity to apply generative AI, but needed a solution that could leverage historical data, generate high-quality submission content, and ensure full compliance with evolving regulatory requirements.

Solution

SEI partnered with the client to design and implement a solution that accelerates regulatory submission workflows. Our approach combined strategic oversight with technical precision, including:

- Data discovery and analysis to structure historical submission content for reuse
- LLM identification and prompt design tailored to regulatory context and document types
- Rapid testing and tuning to validate results and improve response accuracy
- Proof-of-concept development to prototype end-to-end functionality
- Full solution delivery, with automated generation and validation of submission content

Results

By replacing manual tasks with intelligent automation, the organization achieved faster and more compliant submissions. Together, we:

- Boosted workforce productivity by reducing manual effort across submission cycles
- Generated first-draft submission recommendations grounded in historical context and current standards
- Validated key submission sections to ensure alignment with regulatory expectations
- Flagged missing or incomplete criteria, improving submission quality and reducing risk