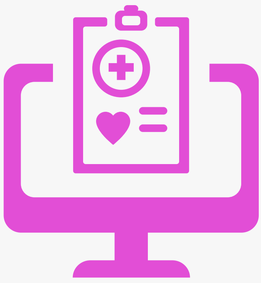
Accelerating Medical Device Approval:
Approvo.ai

Approvo.ai uses AI to help medical device companies identify and select these predicate devices, produce portions of the associated regulatory application, and conduct semantic summarization to help regulatory experts go through lengthy technical documents.

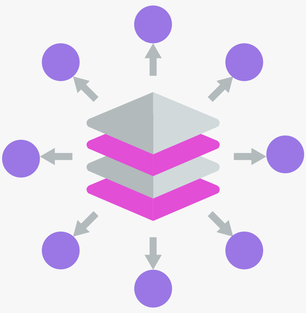


About Approvo.ai:

A startup in the regulatory compliance space, Approvo.ai deeply understands the value of taking a new medical device to market faster than competitors. But unlike most things you can buy from Amazon, these potentially life-sustaining machines must undergo rigorous testing, review, and clinical trials before they can be introduced.

The approval process of these medical devices can be long and arduous. In the US, the FDA has different standards for different classes of medical devices. A way to accelerate the process is to identify a “predicate” device that substantially overlaps the functionality and technological specifications of the subject device. This would greatly facilitate the review process and bypass certain testing / trials that would otherwise have to be conducted.

Its knowledge source comes from a self-hosted database containing all published records of FDA 510K summaries (regularly updated), official guidance documents, technical specifications of medical devices from select vendors, relevant market research reports, and expert advice.



The Challenge:
Standardizing Decades of Diverse Data

Approvo.ai has a massive dataset. The data spans decades and their formats are wildly inconsistent. This presents a unique challenge when standardizing information and indexing it for search. Furthermore, regulatory affairs require a high degree of accuracy, so any generative AI tool used must have minimal hallucinations.

The Solution

GPT-trainer’s unique approach to a low-code / no-code generative AI framework enabled Approvo.ai’s team to quickly extract and standardize its vast repository of data. Through its intuitive UI, GPT-trainer empowered Approvo.ai’s regulatory affairs consultants to rapidly iterate on an optimal LLM-configuration and prompt to clean up its data effectively. When the optimal setup has been decided, GPT-trainer’s team helped Approvo.ai design a custom workflow linked with GPT-trainer’s API that created summaries of 510K reports, identified key points from FDA guidance documents and commercial product technical specifications, and applied labels where appropriate to help classify the information.

The combined expertise of Approvo.ai and GPT-trainer teams enabled the former to develop a clean and scalable dataset within just 2 weeks.

Then, using GPT-trainer, Approvo.ai implemented an in-app “copilot” which assisted medical device experts to draft applications and 510K predicate summaries. The generative AI built into the app greatly accelerated the pace at which regulatory experts prepare FDA submissions.

Results

GPT-trainer’s technology brought about the creation of the world’s first “generative AI powered” medical device regulatory affairs platform.

The post-processed dataset enabled Approvo.ai to develop an algorithm that correctly identifies actual Predicates used within the top 20 results 80% of the time during internal benchmarks. More impressively, conditioned on the above, 92% of the time actual Predicates appear in the top 10, and 85% in the top 5.

The intelligent labeling of data also allowed Approvo.ai to implement Full Predicate lineage tracking and discovery of other products that use the same Predicates as the subject device, thereby providing clients with a degree of market surveillance.

By partnering with GPT-trainer, Approvo.ai was able to solidify its core competence within a matter of weeks. The platform offers unique generative-AI powered capabilities that no other competitor in the market brings.

In January 2024, Approvo.ai received a new round of VC funding with an undisclosed amount.