AI Platform to Revolutionize Regulatory Documentation in Pharma and FMCG Sectors

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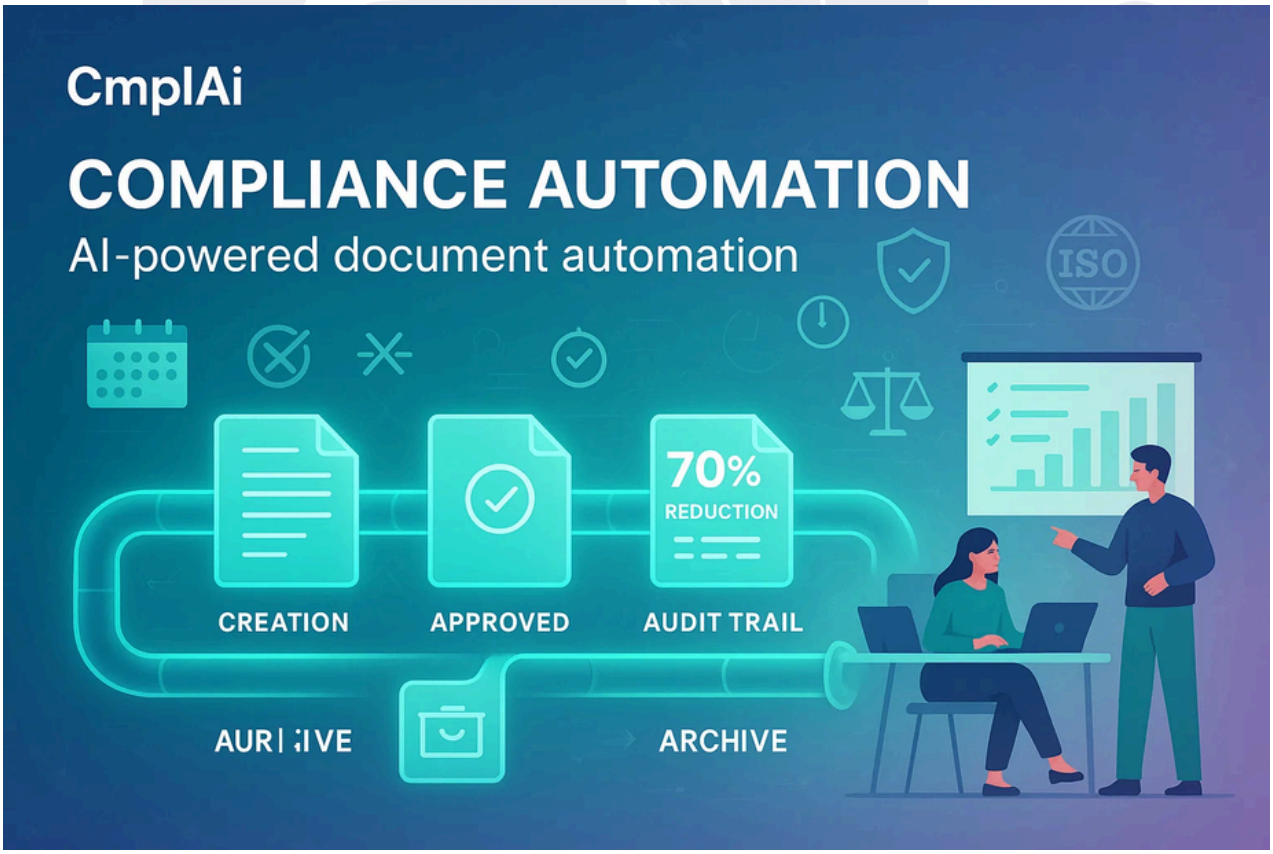
I am an MTech student from the Department of Entrepreneurship and Management at IIT Hyderabad. I have developed Cmplai, a GenAI-powered documentation platform set to transform regulatory compliance in industries such as pharmaceuticals, FMCG, life sciences, and speciality chemicals. Guided by Dr Lohithaksha Maniraj Maiyar and Dr Maunendra Desarkar, I have built the platform as part of MTech thesis, which earned the prestigious V.S. Prasad Best Thesis Award in Techno-Entrepreneurship.

Cmplai leverages a fine-tuned proprietary Large Language Model (LLM) trained on regulatory frameworks like GMP, QMS, ALCOA+, and 21 CFR Part 11. It enables automated generation of critical documents—BMRs, validation protocols, deviation reports—through text-based prompts, drastically reducing manual errors and accelerating compliance workflows. The platform ensures 21 CFR-compliant audit trails, version control, AI-powered risk alerts, and structured templates aligned with global regulatory bodies such as USFDA, TGA, EMA, and CDSCO.

With increasing regulatory stringency and complexity, AI-based documentation tools have become essential across regulated sectors. These systems help reduce manual effort, eliminate errors, and ensure real-time compliance with evolving global standards. Especially in the pharmaceutical industry, where precision and traceability are critical, such platforms play a pivotal role in meeting regulatory expectations efficiently.

McKinsey & Company "Generative AI in the pharmaceutical industry: Moving from hype to reality" https://www.mckinsey.com/industries/life-sciences/our-insights/generative-ai-in-the-pharmaceutical-industry-moving-from-hype-to-reality

Supported by the MeitY and iTIC Incubator @IITH, Cmplai is now moving from proof-of-concept to market deployment, promising up to 95% reduction in documentation errors and substantial cost savings for regulatory-heavy sectors.



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