CASE STUDY

EMSIGNER · HEALTHCARE & LIFE SCIENCES · INDIA

A Leading Pharmaceutical and Life Sciences Company in India Automates 20,000+ Medico-Legal Documents Monthly with eMudhra emSigner

SECTOR	REGION	SOLUTION
Healthcare & life sciences	India	emSigner

CLIENT OVERVIEW

The organisation is one of India's largest and most respected pharmaceutical and life sciences enterprises, with a presence spanning research, manufacturing, and distribution across multiple countries. Operating a workforce distributed across numerous business units — including Quality Control, Quality Assurance, Legal, HR, Finance, and Procurement — the organisation manages a complex, high-volume document ecosystem that is subject to stringent domestic and international regulatory requirements. Its digital transformation ambition centred on building a resilient, agile, and fully paperless signing infrastructure.

THE CHALLENGE

With more than 20,000 documents generated regularly from multiple sources and for multiple purposes, the organisation faced mounting pressure to make its operations smooth, cost-effective, automated, and globally competitive. The shift to remote working during the pandemic exposed the fragility of paper-based signing workflows, making it impossible to ensure that documents were being signed on time and by the right authority.

The organisation needed a Zero Trust model for its large-scale distributed environment to maintain authenticity and non-repudiation of documents. It required verifiable and actionable compliance with FDA 21 CFR regulations, covering regulatory admissions, investigational filings, patent submissions, internal compliance, trademark registrations, and a range of operational document types including sales contracts, order processing, and field service reports. The lack of a scalable digital workflow platform meant the organisation could not effectively reduce its time-to-market or support the cultural transition to digital operations across all business units.

> *"In a situation where the majority of the workforce was working from home, a major challenge was to ensure that documents were being signed on time and by the right authority."*
>
> **Chief Information Security Officer and Data Protection Officer**

THE SOLUTION

eMudhra integrated emSigner with the organisation's on-premise infrastructure through open APIs in a controlled, on-premise deployment setup. This approach allowed a greater degree of customisation and internal data governance, ensuring the confidentiality required to mitigate the risk of data breach across the enterprise. Identity Validated Signature Certificates were issued to all authorised signatories, enabling them to digitally sign both individual documents and multiple documents simultaneously for regulatory submissions, lab notes, and contracts.

emSigner automated the entire document signing and processing workflow and was seamlessly integrated with the existing IT infrastructure. The eMudhra Authentication Server (emAS) was deployed to authenticate and verify digital signature certificates in real time. The solution also encompassed configuration modules for signature and encryption, electronic signature components for conducting e-KYC, and end-to-end workflow templates across all relevant business units.

On a macro level, automation enabled the organisation to comply with GxP — the collection of quality guidelines and regulations ensuring that pharmaceutical products are safe, meet their intended use, and adhere to quality processes during manufacturing, control, storage, and distribution. The solution also enabled bridging the gap between business, technology, and perceived digital risks, while delivering excellent Return on Security Investment (ROSI) and Total Cost of Ownership (TCO) improvement.

The on-premise deployment model provided built-in contingency, ensuring that operations could continue seamlessly even in the event that the primary platform became temporarily unavailable. The solution was designed with one-click scalability, enabling the organisation to standardise its processes globally as operations expanded.

RESULTS

emSigner transformed the organisation's document-intensive operations, enabling it to maintain business continuity through the pandemic and beyond, while delivering measurable improvements in efficiency, compliance, and security.

METRIC	BEFORE	AFTER
Monthly document volume processed digitally	0 — all paper-based	20,000+ documents per month
Compliance with FDA 21 CFR	Manual, inconsistent	Fully verifiable and actionable
Signing turnaround for remote workforce	Days — dependent on physical presence	Minutes — digital workflow from anywhere
Audit trail completeness	Fragmented, paper-based records	100% tamper-proof digital audit trail
Business continuity during disruption	Severely impacted	Zero downtime — built-in contingency
Manual effort in document processing	High — printing, coordination, physical storage	Reduced by up to 80%

About eMudhra. eMudhra is a globally trusted provider of digital trust services, offering eSignatures, PKI, Certificate Lifecycle Management, Multi-Factor Authentication and Identity & Access Management solutions. Licensed by the Controller of Certifying Authorities (CCA), India, eMudhra serves 1,000+ enterprises across 40+ countries, helping organisations build secure, compliant and paperless digital ecosystems.

Customer name withheld for confidentiality.