

Cygnature's case study published in NASSCOM report 2021

Computer Systems Validation with Electronic Signatures for Pharma Giant

CYGNATURE

by Cygnet Infotech

Computer Systems Validation with Electronic Signatures

Year of implementation:

Oct 2020-July 2021 Phase 2 planned for global launch

Project Maturity

Full scale implementation

Customer Organisation:

Leading Global Pharma company in India

Vertical:

Pharmaceuticals

Customer Location:

India

Use case:

Legal Contracts & 21 CFR Compliance



OBJECTIVE

- Enable employees to sign contracts & internal approvals as a part of their digital transformation initiative
- Ensure CSV (Computer System Validation) guidelines are followed for ensuring compliance with regulations

PROBLEM STATEMENTS

- Eliminate physical signing for legal contracts, quality control & GMP documents
- Digitalize the process and improve compliance Ensuring compliance with 21 CFR Part 11
- guidelines



CLOUD SOLUTION & APPROACH

During the pandemic in 2020, the company took a decision to eliminate physical signing of documents - e.g., legal contracts with customers, vendors agreements, & internal project approvals. The company wanted to initiate digital transformation & use electronic signatures to sign documents. A solution was needed that would help employees to sign documents remotely & be able to track the signing workflow. Compliance with the rigorous 21 CFR Part 11 requirements was also required for the critical GMP (Good Manufacturing Practice) documentation.

Cygnature offered the perfect solution for the company. It was available on the cloud, could be accessed from anywhere via a browser, allowed employees to upload documents & securely send them for signing. It also kept an audit trail of the signatures - from which device they were done, at what time and from which location. Currently the solution is being used by over 130+ employees at the company in India & there are plans to expand the usage to other countries globally.

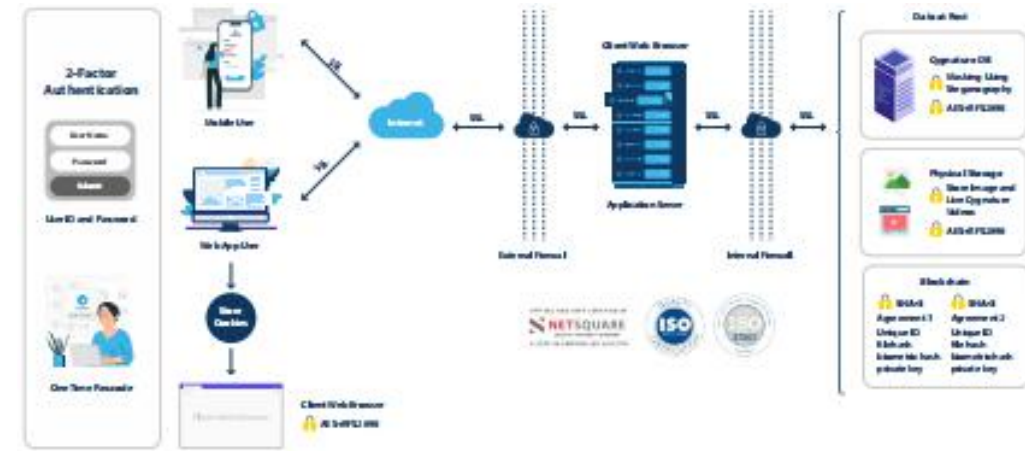
Challenges

Being a pharma company, the security of the data was of primary concern. For users in the European Union, GDPR compliance was a must. Cygnature, being built with ISO27001 guidelines & GDPR guidelines & with VAPT & SOC2 certifications, proved that the data stored & the data in transit is completely secure.

Innovation

One of the INNOVATIVE features of this solution is the use of Blockchain to maintain the audit trail of the signing transactions. It is the first of its kind for a 21 CFR compliance solution to record the process on a Blockchain to ensure complete authenticity of the data.

Cygnature: Computer Systems Validation with Electronic Signatures for Pharma Giant



BENEFITS FOR CUSTOMER:

Quantitative aspects :

- **50%** cost saving
- **80%** increase in operational efficiencies
- Earlier it took over 5 hours to get a document signed physically. With Cygnature, documents are getting signed now in under 2 hours

CUSTOMER TESTIMONIAL:

Cygnature solution for Cygnet Infotech. is a very economical and reliable e-Signature solution with multiple type of Signature, easy to use and secure with MFA and 21 CFR Part 11 compliant and many other features which makes this product worth to use. Support by Cygnature team has been excellent! We use this product for our legal contracts, GMP compliance documents signing and many more things. I would recommend this to everyone who wants to go paperless!!
- IT Head of the Pharma Company