USE CASE
PHARMA

GxpManager
application builder

QUALITY MANAGEMENT SYSTEM FOR A PHARMACEUTICAL LOGISTICS COMPANY

The application enables simplified management of quality processes and regulatory compliance with 21 CFR part 11

IN BRIEF

CHALLENGES

- Implementation of a comprehensive quality management system
- Regulatory compliance

BENEFITS

- Reduced workload
- 21 CFR part 11 compliance and traceability of every action
- Facilitated audits

GxpQMS APPLICATION

Our GxpQMS application allows the implementation of a compliant and auditable quality system in a few days. The No Code Low Code approach enables the rapid creation of applications without spending months on requirements gathering.

ADVANTAGES of No Code Low Code:

- Reduced development timelines
- Cost savings
- High flexibility

CHALLENGE

- Regulatory compliance with 21 CFR part 11
- Simplify user processes
- The solution should incorporate employee training tracking.
- The QMS will be used by a minimum of 20 people.

SOLUTION

Implementation of the GxpQMS application solution will enable:

- Management of non-conformities and complaints via CAPAs
- Change control via out-of-production and in-production action plans
- Training tracking
- Management of quality documentation (with tracking of employee readings)
- Traceability of all actions thanks to audit trail and electronic signatures

BENEFITS

- Full compliance with 21 CFR Part 11
- Reduction of the quality team's workload
- Faster access to information
- Easier information transfer
- Better overall view of the QMS
- Facilitated audits
- Simplified training tracking
- An agile solution that can be deployed on a newly acquired site by the company.

Contact us !
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