USE CASE
PHARMA R&D

GxpManager
application builder

INVENTORY MANAGEMENT OF COMPUTERIZED SYSTEMS

Create a regulatory compliant application for the R&D department that facilitates the management of the inventory process

CHALLENGE

The R&D department uses computerized systems and equipment with varying qualification and validation statuses. Need to track changes in information and status, with the system owner to approve them; Provision of activity and analysis reports.

SOLUTION

Implementation of the GxpXL application with the drafting by the customer of a user specification that GxpManager analyzed and accepted.

The Excel files were replaced by a GxpManager application «Inventory».

The application allows the inventory of systems and equipment, the management of suppliers, system owners and all associated Quality actors.

BENEFITS

The application allowed the client to:

- Respect of data integrity
- Tracking of workflows with electronic signatures in compliance with Annex 11of GMP and 21 CFR Part 11
- Increase productivity with controlled validation and signature circuits
- Trace all modifications/deletions/creations of information thanks to the audit trail
- The use of the audit trail for periodic reviews
- The ability to extract data in standardized and controlled formats for an audit or inspection
- To manage mandatory data entry
- Use the data entered in reports in Word or PDF format, depending on rights
- Secure access to the application and its content in a precise manner
- Perform reviews of user access and rights

IN A FEW WORDS

CHALLENGES

- Facilitate the management of the inventory process
- Provision of activity reports and analyses
- Data integrity

BENEFITS

- Tracking changes
- Use of the audit trail
- Classification of the different levels
- Traceability

GXPXL

The GxpXL custom application allows you to protect your data and ensures compliance and agility for your projects by transposing classic files (Excel, Word, Lotus Notes, Visual Basic©…).

COMPLIANCE

- Compliance 21 CFR Part 11
- To international regulations: EMA, FDA, GMP, ISO
- Qualified application

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