



# 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 11 of 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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