



CUSTOM APPLICATION DEVELOPMENT FOR EQUIPMENT AND PROCESS QUALIFICATIONS/VALIDATION

The custom application allows for the planning and tracking of equipment, as well as manufacturing process qualification and validation activities

IN BRIEF

CHALLENGES

- ❖ Elimination of Excels® files
- ❖ regulatory compliance

BENEFITS

- ❖ Complete traceability
- ❖ Improved adherence to deadlines
- ❖ Gain de temps
- ❖ Overall process optimization through data analysis

CHALLENGE

Our client is part of an international group that manufactures medical devices. He has used Excel files to manage their qualification and validation activities. Our client wanted to invest in a compliant tool that would allow traceability of each action, simplified management, and immediate data analysis.

SOLUTION

A dynamic client/consultant relationship, coupled with no-code/low-code configuration technology, enabled the fast development of the application in just 12 days: requirement analysis, configuration, training, implementation support, and performance qualification (PQ).

Solution Features :

- ❖ Inventory of buildings, equipment, and processes
- ❖ Qualification management
- ❖ GxP-compliant validation management
- ❖ Automatic publication of the Master Validation Plan and qualification reports
- ❖ Traceability/audit trail: All actions are traced in audit trails and tracked through electronic signatures, ensuring data integrity.

BENEFITS

- ❖ Complete traceability and compliance
- ❖ Overall process optimization through data analysis: Measuring the time spent between document drafting, verification, and approval allows our client to identify where protocol implementation takes the longest time and initiate improvement actions
- ❖ Better organization through action planning
- ❖ Improved adherence to deadlines
- ❖ Time savings, primarily through automatic publication of the Master Validation Plan



CUSTOM APPLICATION

The No Code Low Code approach enables the rapid creation of applications without spending months on requirements gathering. Project management using agile sprint methodology fosters close collaboration between the consultant and the client.

ADVANTAGES

- ❖ Reduced development timelines
- ❖ Cost savings
- ❖ High flexibility



Contact us !

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