

The Challenge

Because the client manufactures a pharmaceutical-quality product, its process must be in compliance with Title 21, Part 11 of the Code of Federal Regulations (21 CFR, Part 11), which requires, among other things, double signatures on recipe changes in order to guarantee the safety and efficacy of the product. The client had interest in a pilot project to select and install software to automate the required signature process.

The Solution

As this site's preferred HMI/SCADA vendor is GE Fanuc, PAC's engineers researched and recommended the use of the GE Fanuc iBatch software enabling the client to electronically implement the double signature requirement of 21 CFR, Part 11. iBatch answers all FDA regulations regarding the maintenance of data. It is also compliant with the international batch processing standard, the Instrumentation Systems and Automation Society's S88 (ISA-S88). In addition to saving signatures electronically, iBatch will ensure a repeatable quality product independent of operators and makes recipe changes quick and easy. It also maintains an audit trail so that all changes are saved and can be easily traced, preventing unauthorized tampering with ingredients.

The Result

The technical solution selected provided this client with the ability to meet their current and future compliance requirements while providing the foundation for low cost expansion of their manufacturing processes.

The Benefits

Benefits to the client include:

- Achieve Regulatory Compliance.
- Increased profits by minimizing product quarantine, reducing inventory costs and shortening product to market time.
- Reduce batch approval time by implementing "Review by Exception" faster material reconciliation.
- Because configurable software components are employed, there is simplification and reusability of technical resources.
- Simplified validation and revalidation of new recipes.
- Reduce document management and control by automatically generating electronic batch record.
- Significant improvement in Right First Time paperwork metrics.
- Cycle time reduction.

Your Goals - Our Experience - Exceptional Results