

ELECTRONIC BATCH PROCESS RECORDING SYSTEM

Process Overview

For pharmaceutical companies, accountability is an important component of quality management and regulatory compliance. Batch records, required under the FDA's Current Good Manufacturing Practice (cGMP) regulations, demonstrate accountability by providing proof of proper handling of every significant step in the production of each batch of a drug product. In addition, manufacturers those execute and document batch records electronically must comply with 21 CFR part 11 requirements. As computerized systems have become so prevalent, FDA has worked closely with industry to prepare guidelines and regulations governing electronic records and signatures.

Need For Automation

Electronic Batch Record (EBR) is designed for comprehensive data collection, operator work instruction execution, and electronic batch record reporting. Batch record data are integral to tracking and maintaining the quality, safety and efficacy of the product(s). EBR displays batch records and manufacturing work instructions online, providing the advantage of paperless data recording. Benefits expected from eBPR system are

- ❑ Online documentation of process steps
- ❑ Reduction of administrative work for maintaining manufacturing documents
- ❑ Recognition of deviations at an early stage
- ❑ Reactor dedicated annunciations (Visual)
- ❑ Reducing the number of lost batches

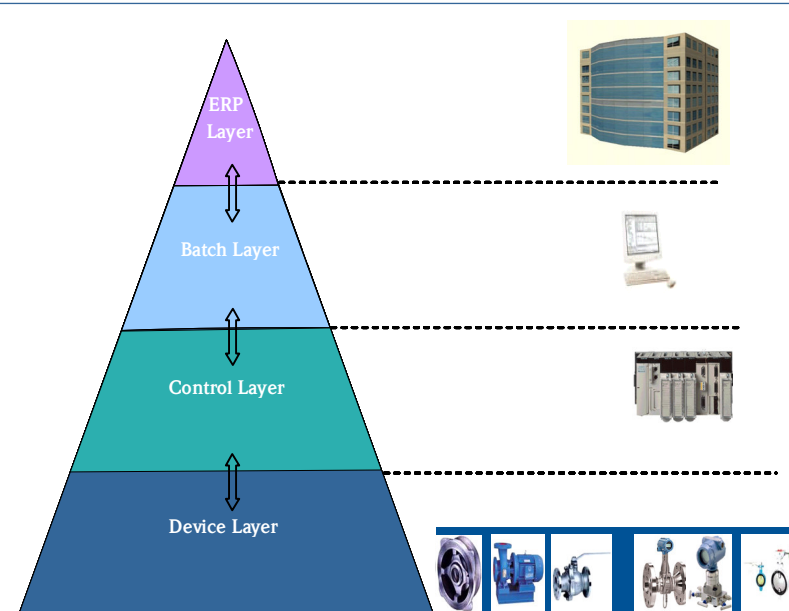
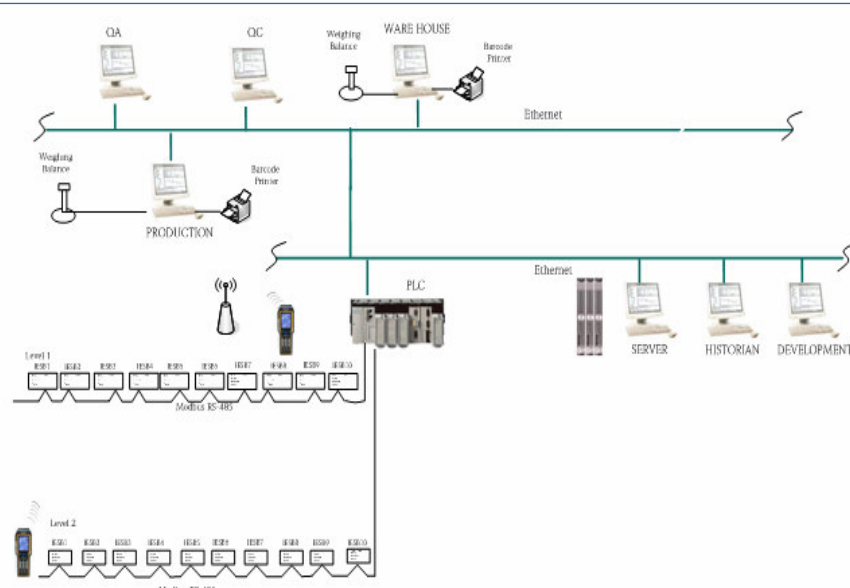
System Components Control System (Software- Hardware) HMI, SCADA

A **control system** with Open architecture design provides complete flexibility, high performance & ease of operation to the end user. The high-performance processor is considered which is capable of multi-tasking, best memory management & high reliable. **Remote I/O modules** for far spread blocks, **HMI's** at various production blocks for ease of operation. Remote process monitoring is performed by **SCADA** and various management information reports.

The system uses advanced software tools and components to build the necessary logic for better process controlling and process. The software includes features like Graphics, Trending, History and reports on customized formats.

An **internal FAT** will be conducted on the Panel Engineered & simulation test will be conducted at our in-house to analysis right logic & controlling developed in the system to ensure stringent control.

System Architecture



System Components Field Instruments (Sensors, Transmitters, Control Elements)

The better controlling needs effective sensors to read the process, transmitters to send the read parameters to control system, better logic to address and best control element to execute. The hooters & annunciators, alarms on process deviation. The precise controlling enhances the accuracy of the system. The performance of the system is dependant on the Instruments.

The field instruments used in the projects is from **POLMON manufactured** instruments or **from the reputed manufactures**. The instruments used are **tested at our in-house** and sent to end-user after checking to ensure product quality.

System Benefits

- ❑ Improve Productivity
- ❑ Process Parameter control as per Recipe.
- ❑ Wrong Material, Expiry Material identification
- ❑ Online documentation of process steps.
- ❑ Meeting compliance requirement
- ❑ Reduction in administration work
- ❑ 21 CFR Part 11 Compliance

More Information

For more information on Pharma IT Solutions, contact your POLMON account manager

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