

CASE STUDY

ELECTRONIC BATCH RECORDS

Good Manufacturing Practices (GMP) specifies that the manufacturing process should be thoroughly documented. As manufactured processes have pre-defined specifications, each batch must provide evidence that proper protocols have been followed. This aids in the production of quality, uniform goods.

Software applications store and manage data electronically for each batch produced including the entire manufacturing process on a step-by-step basis. EBR software systematically generates a formal master batch record or EBR. This master record stores all the materials, processes and activities which were required to produce a given product. Electronic batch records provide the structure and means for automatically compiling batch production data into a formatted electronic document, reducing paper and manual records for more accurate record keeping. Data is recorded and stored in encrypted form, guaranteeing data privacy and security. This should lead to quicker release of the product to the marketplace.

Project:

Electronic Batch Reporting with DeltaV® and InfoBatch®, (USA)

HCG led two simultaneous electronic batch reporting and process data management projects at two different regional sites for a top biopharmaceutical company. The first project required reproduction and optimization of existing legacy reporting technology to compliment a major process control system migration from Provox® to DeltaV® using the InfoBatch® reporting solution. Prior to the InfoBatch® software implicitly supporting class-based library implementations, a project library of standards, procedures, and code methods were developed to produce modular and self-documenting reports that reduced time and required technical expertise for development, changes, and maintenance. In the second project, an existing reporting and control logic base was augmented to create modular and easily- modified reporting data capture to minimize disturbances to running process and empower controls engineers to produce reports for new process areas without expertise in the InfoBatch® platform.

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**HCG RESOURCES
ARE NOW LEADING
A COMPLEX
ELECTRONIC BATCH
RECORD REPORTING
DEPLOYMENT EFFORT
FOR ANOTHER MAJOR
BIOPHARMACEUTICAL
MANUFACTURER.”**

Project:

**Electronic Batch Reporting with DeltaV®, Syncade®,
and InfoBatch®, (USA)**

HCG resources are now leading a complex Electronic Batch Record Reporting deployment effort for another major biopharmaceutical manufacturer. In this project, the objective is to produce InfoBatch® reports, perform manufacturing review of Syncade® MES Process Orders, and to aggregate information from underlying DeltaV® Process Control System data and Syncade® Order Management, Workflow, and Resource Text Data sources.



Best
Practices



Central
Repository



Paperless



Encrypted



Insured
Compliance

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