CQS Innovation. Inc.

The Truth About Electronic Batch Records

Introduction

The FDA's new emphasis on a risk-based approach to 21 CFR Part 11 has enabled the pharmaceutical industry to refocus on the holy grail of manufacturing automation: Electronic Batch Records (EBRs). The determined struggle toward a paperless future state is not new, but may have finally re-emerged in an era of electronic infrastructure and software tools that offer real hope for achieving its lofty goals, which include:

- Improved regulatory compliance,
- Cost savings from reduced paper handling, reviews, and long-term storage,
- Reduced product variability (and product loss),
- Increased production capacity and agility through real-time resource management, and
- Introduction of powerful tools for quality assessment (e.g., incident investigations) and process engineering.

But, as with all noble quests, the path to EBR is fraught with hazards and uncertainties. While this paper cannot offer a comprehensive roadmap for reaching the ultimate EBR infrastructure, it is intended to alert the reader to some widespread misconceptions and important EBR considerations.

A Brief History

The earliest Computer Integrated Manufacturing (CIM) concepts, dating back to the 1950's, included plans for electronic data capture. However, it wasn't until the 1970's that the use of computers for process control and manufacturing data collection became commonplace. Early attempts to exploit the power of plant-floor computers resulted in the now infamous "islands of automation". Associated with these localized automation solutions were limited localized data stores and reporting solutions.

By the late 1980's, the need to link these "islands" and put electronic data into context spawned a number of initiatives, including Manufacturing Execution Systems (MES) and Enterprise Resource Planning (ERP) systems. For the remainder of the millennium, both MES and ERP generally failed to live up to their promises due to a lack of standards for manufacturing and business practices. Eventually ERP gained traction in the transaction-based supply chain, enabled by re-engineering of business practices to match de facto standards imposed by ERP vendors. Standardization of plant floor practices proved much more difficult. Infinite process variations, prohibitive re-engineering costs, and the general inability to bridge the gap between manual and automated processes made MES cost-ineffective.

Just as the MES bubble was deflating, ERP began to take off and 21CFR Part 11 became the law. The resulting diversion of IT and/or automation engineering resources put EBR efforts on the back burner for most pharmaceutical manufacturers. Now, with the regulatory requirements for electronic records "under control" and widespread rollout of ERP accomplished, the quest for EBR is again taking center stage. The MES vendors are back touting monolithic transaction-based solutions, with off-the-shelf "EBR Modules", process historian vendors are bulking up their integration capabilities, and process automation vendors are building more and more capable point solutions. The game is afoot…

EBR = Electronic Batch Ticket?

For the past 100 years, the principal batch record for most manufacturing facilities has been the "batch ticket"; a paper worksheet that provides detailed product-specific operating instructions and "fill-in-the-blank" operator entry fields. These batch tickets have been authored by product manufacturing experts who made sure that work instructions were clear and sufficient and that each entry field was important enough to warrant the time needed to make the entry. Where discrete entries proved insufficient for quality control, trend charts were produced and attached (either literally or figuratively) to the batch ticket. Also attached (either literally or figuratively) were offline records such as laboratory results and equipment logs.

In considering EBR, the batch ticket paradigm is both a help and a hindrance. Historical batch tickets clearly articulate important information, especially the sequence of manufacturing and the critical control parameters. Unfortunately, they also imply a level of control and quality assurance that is sometimes misleading, for instance:

- If a specific instruction and/or data item is present in the batch ticket, it is essential to product quality assurance,
- The operator faithfully follows each operating instructions in the prescribed sequence and accurately and completely documents her/his actions and observations, and
- If it isn't recorded in the batch ticket, it didn't happen.

Critical investigation of actual operating practices in batch ticket manufacturing can quickly uncover the fallacy of these assumptions. In fact:

- Most batch ticket entries are related to processing, not product quality. Processing entries (e.g., tare and gross weights, start and end times, and setup verifications) may be used in later manual calculations or may simply help document that the operator is using the equipment correctly. In either case, processing entries may become irrelevant as the use of automation in the process cell is expanded.
- Operators rarely focus on one manufacturing step at a time. As slack time is encountered (e.g., while a timed step is in progress), the best operators look ahead in the batch ticket and get a head start on upcoming activities. So, while steps may be completed in prescribed sequence, the actual processing activity is often very different from that implied in the batch record.

- Unlike computers, operators routinely use discretion and judgment in interpreting instructions. The use of manufacturing shortcuts and "tricks" is commonplace and often essential to good product manufacturing. Also, manually recorded instrument readings rarely tell the whole story (e.g., the fact that a control parameter was in-range when the operator recorded it doesn't mean it was in-range throughout the batch).

MES-based EBR implementations often start with a "paper-on-glass" replacement of the batch ticket, with well-intentioned plans to expand automatic data collection later. The truth is that this approach effectively locks the manufacturing area into outdated, and often inaccurate, manufacturing paradigms. By focusing on batch ticket replacement, the real potential of using computers on the plant floor is dramatically diminished. For example, the following table illustrates the progression of automating manufacturing environmental controls:

EBR Generation	Environment Control Description	Batch Record
Batch Ticket (Historical)	Prior to production, operator is asked to record room temperature and relative humidity. Operator adds a handwritten signature to attest that readings are accurate and in-range.	1 temperature reading 1 relative humidity reading 1 handwritten signature
Paper-on-Glass	Prior to production, operator is asked to record room temperature and relative humidity. Operator electronically signs to attest that readings are accurate and in-range.	1 temperature reading 1 relative humidity reading 1 electronic signature
Automated Paper-on-Glass	Prior to production, the system automatically captures room temperature and relative humidity readings and verifies that they are in-range. Operator electronically signs to attest that the manufacturing step is complete.	1 temperature reading 1 relative humidity reading 1 electronic signature
Desired State	Process automation continuously monitors environment conditions, alerts the operator if conditions are out-of-spec for the current operation, and automatically makes appropriate equipment and/or procedural adjustments.	Complete record of environment control excursions and impact during batch manufacturing

From this example, it is clear that direct replacement of the batch ticket, with Paper-on-Glass and/or Automated Paper-on-Glass, automates history instead of advancing the state of manufacturing. Considering the investment required, a more strategic approach is called for.

EBR = Advanced Historian?

A common approach to collecting electronic data from the plant floor involves uploading process control data to a supervisory process historian such as OSIsoft's Pi™ System. Process historians have been widely used for over 25 years, primarily for the collection and analysis of engineering data. They have been viewed as inappropriate for collection of EBR data due to shortcomings including:

- Inadequate reliability and security (in fairness, mostly related to network issues in primitive LANs),
- Absence of data context/structure (especially relating individual process readings to specific batch activities) and identification of data significance, and

- Lack of integration features (e.g., external system interfaces, support for signed manual entries and record annotation, and robust batch reporting tools).

Over the past decade, many historian vendors have come to grips with the inadequacies of their legacy products and have made great strides to address them. Ubiquitous "store and forward" data buffering techniques combined with secure, high-reliability networks and servers, now provide solid data integrity assurance. Metadata support and flexible storage modalities (e.g., XML schema and relational database structures) add data context without sacrificing open data access. Universal communication standards (e.g., TCP/IP, OPC, and ODBC) and formatting standards (e.g., XML) promote wide-ranging interoperability between systems.

Despite the enhanced and growing capabilities of advanced historians, the truth is that historians alone do not come close to fulfilling EBR requirements. While a historian may be able to record the context of collected data, it cannot effectively create it. Absent are the manufacturing instructions, resource coordination control, links to the master recipe procedure and formulation data, and good batch reporting tools. In short, advanced historians may be marvelous data repositories, but they must be supported by capable front-end manufacturing systems and back-end reporting systems to provide an effective EBR infrastructure.

EBR = Batch Management System?

The 1980's and 1990's saw several attempts to develop standards for batch manufacturing analogous to the business practice standards imposed by ERP. One of the most successful of these was launched by the Instrument Society of America (ISA) and resulted in a published standard for batch manufacturing: ISA/ANSI S88. This standard spawned a number of software products intended to supervise and document batch activities driven by electronic recipes. These products, commonly referred to as batch management systems or S88 batch systems, are now available as add-ons to most process control and/or Supervisory Control and Data Acquisition (SCADA) platforms.

Early versions of batch management systems were designed for use in fully automated batch manufacturing facilities. Functional limitations arising from this unrealistic design assumption dramatically slowed adoption of batch management systems in labor-intensive manufacturing areas. Recent vendor efforts to retrofit electronic work instruction (EWI) capabilities into these products have helped to rekindle industry interest.

Batch management systems provide exceptional "structured flexibility" for batch manufacturing. The object-oriented basis of S88 allows for robust equipment-independent recipe-driven control of almost any process with limited risk of obsolescence due to automation changes. In contrast to typical MES solutions, batch management systems offer the ability drive manufacturing activities; focusing operator attention on pending tasks throughout the manufacturing facility while simultaneously coordinating and managing batch process automation. Electronic batch data captured by a batch management system is extensive, well organized, and includes sufficient metadata to place each data element in precise context.

Despite its advantages, the truth is that batch management systems don't provide the scope of control needed for a complete EBR solution. Resource and materials management capabilities of standard product offerings are typically sparse and inadequate. Integration to data sources and repositories outside the bounds of the plant floor (e.g., ERP, laboratory systems, and asset management systems) typically demands add-on or custom point solutions. Robust integration of manual and semi-

automated (e.g., ingredient pre-weigh) capabilities is not yet readily available. Finally, batch reporting functionality is typically weak (or non-existent) in batch management systems.

EBR = Report Generator?

The earliest batch records from manufacturing automation systems were alarm and event logs, typically produced on or near the plant floor using dot matrix printers. As automation systems have become more complex, two (2) distinct flavors of electronic reporting packages have evolved to replace the printer and the reams of semi-intelligible fanfold paper:

1. Data collection and formatting tools (e.g., Sytech Report Manager), and
2. Database reporting tools (e.g., Crystal Reports®).

Data collection and formatting tools monitor real-time data during production and, either contemporaneously or post-batch, insert the data into a pre-formatted electronic document. This type of solution has a myriad of issues in a regulated environment, including a general lack of electronic records protection and absence of electronic signature support. Database reporting tools extract runtime data, from secure data repositories, into printable documents based on report templates. These report templates become electronic records themselves since they influence the review of batch data.

Both types of report generators require the addition of customized data interpretation functionality and can only reliably report data context specifically included in the batch data and/or metadata. While reporting is an essential function for any EBR system, it is by no means the only function. Since report generators do not provide manufacturing recipes, resource or material management, or even secure data collection functions, they certainly don't represent a stand-alone EBR solution.

EBR = What?

If EBR doesn't come from MES-style paper-on-glass and it doesn't come from advanced historians and it doesn't come from batch management systems and it doesn't come from report generators, how ***can*** EBR be implemented today? The truth is that EBR is a concept that has not (yet?) been successfully "productized". MES packages, batch management systems, advanced historians, and report generators each offer an essential piece of the puzzle, but no currently available product or product suite offers "soup-to-nuts" EBR. To make matters worse, the available "partial solution" products are rarely designed to interface cleanly with other products and systems.

The key to implementing EBR today is to understand the current state and future trends of the "EBR tools" marketplace and develop an integrated system that:

- Intelligently leverages "best-of-class" capabilities from existing product lines,
- Uses custom integration only to achieve high-impact EBR features, avoiding the high cost of seamless perfection (i.e., focuses on "low hanging fruit"), and
- Emphasizes the use of modular functionality, industry standards compliance, and "exportable" data storage methods to reduce the impact of future system re-engineering.

The best EBR infrastructure depends on the type of facility, the level of current and planned process automation, the required interfaces to legacy systems, and at least a dozen other factors. Unlike

applying ERP to business practices, trying to force fit a “one-size-fits-all” EBR architecture to an entire enterprise is, at least for now, inappropriate. A more reasonable approach is to standardize on an EBR “toolkit” that includes solid system components with both complementary and overlapping scope of control. This way individual manufacturing automation projects can select the appropriate technology balance needed to maximize return on investment.

Summary

The competitive advantages offered by the use of Electronic Batch Records in modern manufacturing are too compelling to ignore. After decades of concerted effort, the tools needed to implement EBR are available and mature. However, for every tool there is at least one major functional gap that prevents its use as a stand-alone EBR solution. Forging a composite solution is the only valid choice, and it demands rock-solid systems integration.

Successful EBR implementation begins with a realistic needs assessment and upfront consulting with an experienced independent solutions provider. CQS Innovation is such a provider, with over 25 years of experience providing turnkey process automation solutions to both regulated and non-regulated industries. Give us a call today, and tomorrow we’ll put world-class EBR in the palm of your hand.