Effective Management of Electronic Batch Records (EBRs) with TrakSYS™
INTRODUCTION

Pharmaceutical products have significant impact on the well being of consumers. As such, it stands to reason that stringent requirements and standards be set firmly in place for their manufacture. The US Food and Drug Administration (FDA) has adopted a risk-based approach to establish and enforce regulations for pharmaceutical development, manufacturing, and quality assurance. Mandatory regulations (e.g., current good manufacturing practices or CGMP and 21 CFR Part 11) and voluntary frameworks such as process analytical technology (PAT) are defined to ensure final product quality through proper design, analysis, and control of manufacturing operations. To ensure product integrity and quality, it is essential to have consistent records of:

- Operations and procedures
- Process settings and variables
- Production events and conditions
- Quality and performance attributes of raw and in-process materials

Traditionally, for batch operations these records were – wholly or in part – collected, managed, and represented manually. As with most manual operations, there were concerns with accuracy, consistency, and repeatability. With the arrival of 21 CFR Part 11 and PAT came a clearer regulatory roadmap (and framework) for transitioning to electronic batch records (EBRs). There are many advantages to electronic record keeping:

- Improved regulatory compliance
- Improved accuracy, consistency and repeatability
- Improved information accessibility and real-time analysis
- Improved incident and root cause evaluation
- Improved capacity utilization and yield
- Improved process capability and reliability
- Improved product quality

The challenge now lies in negotiating the various issues related to infrastructure, existing systems, workflow, regulations, training, and the availability of a flexible solution to address these issues effectively, economically, and non-disruptively.

ELECTRONIC BATCH RECORDS (EBRs)

It is extremely important to understand what constitutes a compliant electronic batch record system. Also, it raises considerable questions: What level of electronic data capture is required? How is this data captured? How is it retrieved, analyzed, and reported? How is the integrity of data ensured? While these questions sound simple, their not-so-trivial answers are critical to having the right solution in place.
TrakSYS™ real-time decision support for manufacturing execution is designed to help manage operational complexities and improve quality and productivity. In regulated industries such as pharmaceutical and food, electronic batch records represent a significant opportunity for improvement. TrakSYS effectively paves the road for delivering compliant, paperless EBRs.

**PROCEDURES**

Based on a validated product manufacturing protocol, there are standard operating procedures or instructions in place that must be carefully followed. All exceptions/alterations must be clearly noted and approved by authorized personnel. For example, the instructions may require a detailed and step-by-step cleaning process that precedes the start of any batch operation. TrakSYS provides the option to define the instruction steps (or to retrieve them from other sources) and then record the proper completion of each instruction step.

**TYPES OF DATA AND SOURCES**

The electronic record requires the inclusion of the designated information for each batch. Consistent, accurate, and secure data is a fundamental characteristic of the batch record. Such data must include but is not limited to:

- Work order information
- Product information
- Production targets
- Operator information
- Environmental conditions
- Details of batch steps, stages, and phases
- Batch process variables
- Operator observations and comments

TrakSYS provides a comprehensive modeling and configuration engine that allows the user to define data sources, types, business rules, conditions, and workflow. The flexible configuration management and dynamic change control (keeping track of all modifications to configuration, recorded data, notes, and electronic signatures) make it possible to meet the exact data management and reporting requirements of even the most complex and demanding batch applications.

![FIGURE 1 – Sample Batch Summary](image)
**HISTORIAN**
As both the environmental conditions and batch-specific process variables can affect the quality and compliance of the product, it is required to have a complete record of their values throughout the process. TrakSYS satisfies this through its performance historian functionality that will capture the value of the required process variables, at specification-defined intervals, and provide a complete historical record – including the specification limits within which each process variable must be controlled.

![Temperature vs. Limits](image)

**FIGURE 2 – Sample Process Variable Historical Record**

The TrakSYS historian functionality also makes it possible to study the best settings for the most consistent performance and yield. The historical process variable trends may be studied versus other process-relevant parameters and settings to gain valuable insight for documented process and quality improvement.

**REAL-TIME NOTIFICATION**
As great as it is to have a comprehensive historical record of the environmental and batch process-specific variables, it is as important to have to-the-point, real-time notification of process anomalies and deviations from defined protocols.

TrakSYS makes it possible to alert the responsible personnel (as opposed to indiscriminate broadcasting of process alarms) – through their choice of delivery mechanism (e.g., email, page, SMS) – with specific messaging to expedite proper decision-making and corrective action in real time. This has a profound impact on improved quality and productivity.

![Real-time Notification](image)

**FIGURE 3 – Real-time Notification**
NOTES AND OBSERVATION
In order to provide in-depth context and contrast, specifically for traceability and corrective actions, clear and concise notes must be available. Such notes and observation may play a critical role in root cause analysis and tracing of production anomalies. TrakSYS offers comprehensive and multi-tiered operator/user involvement tools to capture the pertinent process-related observations that may not otherwise be captured automatically by other means. TrakSYS even allows for defining the rules governing the recording of user observations (e.g., conditions, permissions, topics, events, areas).

Such meticulous and organized management of the recoded data (including observations/notes) makes it possible to quickly and effectively analyze batch records and respond in kind.

ELECTRONIC SIGNATURES AND DATA MANAGEMENT
Within regulated industries (and for businesses interested in the methodical management of their manufacturing operations), it is critical to establish a clear means of monitoring and controlling changes to:

- System configuration, settings, and business rules
- Operational setpoints
- Pass/fail criteria
- Collected (actual) data
- Reported data
- Access rights

TrakSYS provides thorough authoring and auditing capabilities – based on the level of required configuration control and appropriate access privileges – for all modification (i.e., changes, deletions, additions) in various areas of operation. Using the TrakSYS knowledge management portal, the modifications can be sorted and reported by type, personnel, date, asset, and other user-definable filters.

FIGURE 4 – Managing the Audit Settings
REPORTING
Collecting the necessary batch process data is an important part of developing effective electronic batch records. Applying the correct analytics and business rules to turn raw data into actionable intelligence is equally important. The actionable intelligence is typically manifested in the form of reports. The electronic reports can offer significant benefits if they are:

- Timely
- Accurate
- User configurable (personalization)
- Flexible
- Accessible
- Secure

TrakSYS offers all these attributes to effectively deliver the needed information to satisfy both regulatory and operational requirements. With the delivery of accurate, timely, and secure information, TrakSYS empowers users – across a wide spectrum of disciplines (e.g., production, maintenance, quality, planning, IT, and regulatory) – to work together to efficiently meet operational excellence and quality-by-design goals.

SUMMARY
TrakSYS, Parsec’s real-time decision support software for manufacturing execution, is designed to help manage operational complexities and improve quality and productivity. Where EBR is concerned, TrakSYS effectively improves compliance, security, record-keeping, accuracy, corrective actions, workflow, quality, yield, and cost management. Since it is a vendor-independent platform, it is deployed rapidly and economically without disrupting operations. TrakSYS extends the functionality of the existing infrastructure and fills in where needed functionality is missing.

FIGURE 5 – Knowledge Management
ABOUT PARSEC

Parsec Automation Corp. (Parsec) is the developer of TrakSYS™, the leading real-time operations & performance management software. Manufacturing companies worldwide rely on Parsec for flexible and configurable tools to quickly track, record, analyze, and report the events critical to productivity enhancement. Without production disruption TrakSYS™ helps manufacturers to significantly improve asset utilization and efficiency, increase capacity with no new capital equipment, reduce production costs, and improve profitability. With measureable ROI TrakSYS™ fuels Lean, Six Sigma, TPM, and Operational Excellence efforts. For more information about Parsec please visit the corporate web site at www.parsec-corp.com.
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