Effective Management of Electronic Batch Records
Many manufactured products can have a 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.

Examples of these industries include Pharmaceuticals, Medical Devices, Diagnostics, Food & Beverage (Nutritionals / Animal Nutrition), Cosmetics / Personal Care products, and others.
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 mandatory 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, records were—wholly or in part—collected, managed, and represented manually.
As with most manual operations there were concerns with accuracy, consistency, and repeatability.

The arrival of 21 CFR Part 11 and PAT brought 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

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 effectively, economically, and non-disruptively address these issues.
It is crucial 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.
An Electronic Records based solution with connection to the process via MOM software can completely change the complexity of the factory, not only from a compliance viewpoint, but also from a Continuous Improvement and real-time analysis viewpoint.
Utilizing Electronic Records

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 Sources

The electronic record requires the inclusion of the designated information that must be recorded for each batch. Consistent, accurate, and secure data is a fundamental requirement 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.

Real-time Notifications

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.
Historian

As both 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 to ensure operations with specification limits (within which each process variable must be controlled).

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.
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 automatically captured by other means. TrakSYS™ even allows for defining the rules governing the recording of user observations (e.g., conditions, permissions, topics, events, areas).
Utilizing Electronic Records

Such meticulous and organized management of the recorded data (including observations/notes) makes it possible to quickly and effectively analyze batch records and decide upon timely and proper response.

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 set points
- 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.

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.
Taken together, utilizing Electronic Records in regulated industries with other tools available in MES software to optimize value streams, can have a dramatic impact that provides substantial rewards to the plant team by reducing risk of violations, improving processes, reducing risk of recalls, improving throughput and customer service levels, and improving the bottom line performance of the business.
About Parsec

Parsec is the developer of TrakSYS™, a proven operations management software application and solution platform designed to significantly improve manufacturing processes. Parsec is committed to providing best-in-class products and solutions to our worldwide community of clients to assist them in optimizing their manufacturing operations. There are thousands of TrakSYS™ licenses in use around the globe in a wide variety of Industries.

TrakSYS™ helps manufacturers to maximize asset utilization and efficiency, increase capacity with no new capital equipment, reduce production costs, decrease lead time, and improve profitability. For more information about Parsec and TrakSYS™ please visit the corporate website at www.parsec-corp.com.