Automating Electronic Device History Records (eDHR)
To Meet Overall Business Objectives and Save Costs...

It’s Not Only About Compliance

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Overview of Compliance Requirements and Business Objectives

Companies that are in the business of manufacturing, deploying and maintaining medical devices face significant challenges when it comes to complying with device history record (DHR) requirements as specified in FDA Title 21 Code of Federal Regulations.

The FDA mandates that companies have the ability to log and track all changes and processing steps in a controlled and compliant environment; but the responsibility falls on each company to assure that their specific methods and software systems comprehensively capture and manage the right information and retain it in auditable formats to assure full compliance.

Even more importantly, companies need to leverage their software investments not just for compliance, but also to meet their overall business objectives. This is especially true for many emerging and mid-size companies that cannot readily invest huge budgets and dedicated staffing commitments to focus exclusively on compliance activities.

Life sciences companies in the $100 million to $1 billion revenue range can achieve significant business benefits from moving their entire device records management systems from paper-based methods to paperless electronic device history record (eDHR) systems.

The fact is that, regardless of the company’s size, paper-based systems cost money; they don’t save it.

Of course, eDHR software investments must be carefully considered, with thorough up-front planning and designed to integrate within overall ERP systems. The commitment is not small but the payoff can be huge in terms of higher efficiency, lower manufacturing costs, better product quality and improved customer service.

By viewing eDHR requirements as an important and integral part of their comprehensive business management processes, rather than just an add-on mandate from the FDA, life science companies can actually turn compliance requirements into a cost savings instead of an expense.

*The bottom line result is both enhanced compliance and improved profitability.*
A Disciplined Approach to “The Big Picture” and “The Little Details”

Successful integration of compliance requirements within an overall business system involves a structured process that clearly defines objectives ahead of time and lays out the specific parameters for the project implementation.

Every company is unique and has specific issues that must be taken into account. Sometimes the sheer scope of undertaking an integrated eDHR implementation can seem overwhelming for in-house staffs that also face a myriad of other responsibilities.

Experience over many such implementations has shown that any successful eDHR project requires a disciplined approach with careful attention to each of the following areas.

- **Up-Front Planning:**
  - Conduct a comprehensive up-front inventory and definition of all data elements and data capture points required to meet DHR compliance requirements
  - Determine the various ways that the same data can be integrated and used for real-time business process decisions
  - Define project implementation responsibilities, milestones, trials and go-live schedule

- **Top-down Design:**
  - Design the data formats, collection points, aggregation and communication methods to provide timely data for business decisions and auditable archives for compliance
  - Consider contingency-action requirements, such as potential recalls or litigation, when defining data collection models (e.g. tracking by lot, batch, serial number, date, etc.)

- **Front-line Automated Data Collection:**
  - Eliminate paper-based device records with their inherent high risk of errors
  - Minimize dependence on active operator-based data entry methods
  - Maximize the use of “passive data capture” methods such as barcode scanning or RFID
  - Make transparent data capture a seamless element within each operational step

- **Comprehensive Systems Integration**
  - Define common data formats, reports, screens and dashboard elements
  - Integrate compliance data retention and analysis processes within overall ERP systems
  - Establish automatic alert parameters, timing and communication sequences
  - Clearly designate responsibilities for taking corrective actions and responding to alerts
  - Define continuous improvement process for on-going review and system enhancement
Up-Front Planning & Design

The first step in getting the most out of your eDHR system investment requires putting the pieces together for a clear and comprehensive understanding of exactly what you need to collect and how you are going to use it.

For many mid-size life science companies (less than $1 billion revenues) this also represents the first major challenge because they often don’t have dedicated in-house organizations with knowledge of the latest FDA requirements or best-practices skills for designing appropriate eDHR software solutions.

Successful design and implementation of eDHR involves an intensely focused effort and special skill set on the front-end in order to create a system that can pay efficiency and compliance dividends over the long term. Therefore most life science companies are now turning to experienced subject-matter experts for help, such as US Data Management for needs assessment and compliance requirements, along with skilled implementation partners, such as Idhasoft Inc. for detailed software design and implementation.

By leveraging outside resources that are well versed in life science business processes, international regulatory compliance, ERP technology and regulatory best practices, such as GAMP, ASTM 2500 ICH Q9 and ISO quality standards, companies gain a broader perspective to ensure that the project is focused on doing the right things from the outset. In addition, by using software partners with focused experience in tailoring comprehensive ERP systems for efficiently integrating eDHR data capture, processing and records management, companies can get the most out of their ERP software investments with faster go-live results and lower overall costs.

For example, the SAP business process software offers an excellent comprehensive ERP infrastructure that is used by many life science companies for enterprise-wide management. However, it takes special Part 11 compliance knowledge and SAP-specific eDHR implementation skills to ensure the best results.
Transparent Front-line Automated Data Capture

By leveraging Idhasoft’s pre-designed SAP extensions, created specifically for eDHR data capture, the SAP system can be adapted to efficiently and completely eliminate the need for manual data entry.

In conformance with Part 11 requirements, Idhasoft-enhanced SAP system modules provide complete functionality for efficiently logging changes to all product-specific business objects and dependent objects, such as special configuration data.

The basic information-set that is routinely captured by the system includes:

- Old value of an attribute of the changed business object
- New value of this attribute
- Person who changed the value (operator identification data)
- Date and time of change (Coordinated Universal Time [UTC] and application server time)
- Action (create, modify, delete)

Immediately upon data capture, each eDHR transaction record automatically becomes a permanent part of the SAP database, subject to all specified security controls and periodic back-up parameters/policies in order to assure a comprehensive and compliant eDHR audit trail.
During data capture, the eDHR system is designed to automatically verify the operator’s user ID, check their authorization status and permissions for performing the action and then to associate the specific operator’s electronic signature with the eDHR data record that is securely retained in the SAP database.

A fundamental objective of the system design is to make data capture as transparent and automatic as possible. Such a “passive capture” approach is intended to eliminate the requirement for operators to take specific action steps to create eDHR events. Instead the system automatically creates each eDHR document as a routine part of the process at hand.

For most operations, integrating barcode scanning or RFID data capture is the most efficient method for transparently acquiring all of the required information. Operators typically will be required to log-in or scan-in their user ID information at the beginning of a shift and then operations that are subsequently scanned, logged and processed during the shift are automatically associated with that operator. Special exceptions or authorizations that require supervisor intervention or approval can also capture the approving authority’s user ID credentials and permissions via scanning or log-in, thereby automatically making any exception approvals a permanent part of the eDHR documentation.
Comprehensive Systems Integration

Implementing transparent data capture and eDHR creation within front-end operations enables Part 11 requirements to be comprehensively integrated as part of the overall ERP infrastructure. The electronic records feed into automatic back-end aggregation and analysis processes, which help turn compliance from an expensive add-on hassle into a valuable strategic advantage for enterprise wide improvements.

Eliminating paper-based systems and automating the capture of eDHR data records not only saves time and cost while simultaneously improving data accuracy. It also turns the eDHR process into a real-time informational asset that can be leveraged to enhance overall enterprise business processes.

Unlike paper records that typically get just filed away and hopefully can be retrieved when needed, online eDHRs created at the point of capture can feed directly into process monitoring, quality control and yield-management systems. By setting custom-tailored alert parameters within the eDHR data capture process, early warnings can be automatically triggered to spot process drift or quality issues, thereby preventing manufacturing problems and downstream waste or rework costs.

Automatic front-end eDHR data capture also gives companies enhanced insight across the entire manufacturing process, providing valuable real-time data for monitoring and improving operator performance, incoming and in-process materials quality, machine set-up parameters, testing criteria, conformance to schedules, etc.
When deeper analysis and/or corrective actions are required, the aggregated eDHR information can also be used to rapidly identify, quantify and analyze problem areas by a variety of criterion, including by batch, serial number, date codes, configurations, etc. Instead of having to sift through stacks of paper DHRs and risk delays or omissions that can result in sanctions and/or loss of reputation, companies that have implemented enterprise-wide eDHR systems can quickly map out mitigation plans to efficiently address and resolve the specific problem areas.

Leveraging the System for Optimal Compliance and Business Results

The key to achieving the best results from an eDHR system is to work with knowledgeable partners for both the up-front definition of What to do as well as the detailed implementation of How to do it.

USDM and Idhasoft bring together the big-picture perspective and specific systems design experience to provide a comprehensive approach that is tailored to specific business objectives while achieving FDA compliance requirements and building a solid foundation to meet evolving future needs as well.

Based on many successful eDHR projects, USDM’s life science process experts understand what it really takes to move from paper-based batch and device history records to an automated eDHR system. By mapping all of the business processes and ERP capabilities to match up with applicable regulations and predicate rules requirements, USDM’s system-wide approach optimizes the integration of front-line operational data within the overall eDHR framework.
Starting with well-defined process flows based on USDM’s industry wide experience, which are then mapped to specific customer requirements, Idhasoft’s detailed system implementation is able to focus on efficiently capturing the front-line operational information and formatting it to support the specified business goals and compliance requirements.

From the initial Conference Room Pilot (CFR) script, through design, coding, testing, training and Go-Live implementation, the entire project is coordinated between USDM, Idhasoft and in-house customer team members in order to fulfill both the high-level vision and detailed objectives of the project.

One key area of collaboration between USDM and Idhasoft is the mapping of eDHR information into specific query/response formats that are tailored for each company’s specific business and compliance requirements. For example, the ability to query by serial number history, equipment type, batch, date range, or other factors can be of critical importance for different companies, depending on the products, market segments and regulatory requirements.

Working together, USDM and Idhasoft provide a complementary range of skills and experience that assures continuity of focus from the initial project definition through detailed implementation and launch; combined with ongoing training, support and process refinement to assure long-term value.
The Bottom Line:

By using a well planned upfront assessment and design process, coupled with tailored eDHR software capabilities and a comprehensive ERP implementation approach, life science companies can automate all of their front-line eDHR functions, thereby both driving down costs and creating a valuable corporate asset to address both compliance requirements and overall business objectives.

Key benefits include:

- Cost-effective paperless manufacturing operations
- Transparent capture of compliance data and creation of manufacturing audit trails
- Data management that meets both FDA regulatory requirements and business objectives
- Shorter time to new product introductions with higher quality results and less risk of recalls
- Real-time enterprise visibility for enforcing and improving manufacturing controls
- Continuous feedback to enhance manufacturing processes and product designs

*eDHR is not just about compliance…

It’s about improving your overall business processes.*
ABOUT IDHASOFT:
Idhasoft Inc. is a global leader in strategic technical solutions, SAP® gold channel partner and 2010 SAP Business All-in-One Partner of the Year-USA, providing innovative end-to-end business solutions to companies around the world. Idhasoft founding vision is to serve the SMB marketplace with a unique blend of business solutions and services. We help our clients drive efficiency, improve profitability and build a lasting competitive advantage.

Idhasoft capabilities and services include the following:

- 100% commitment to SAP solutions, services and technologies
- SAP Gold All-in-One Solution Provider and Premier Implementation Partner
- Partner Center of Excellence Certified master VAR
- SAP Certified Industry Specific Solutions
- Dedicated SAP Practices- ERP, CRM, SRM, SCM, BI and Net Weaver/Portals
- Senior SAP experienced consulting team with both industry and SAP experience
- Invited expert each year at ASUG, SAPHIRE and other SAP conferences
- State-of-art Solutions Center with SAP Ramp-up Applications
- Idhasoft’s pre-configured Industry and Solutions templates
- Our consultants work closely with SAP COE and SAP Product Development

ABOUT USDM:
USDM is a leading global consulting firm focused on life sciences. We specialize in regulated business processes, with an emphasis on compliance and performance. USDM provides innovative services and solutions that enable life science companies to achieve and maintain compliance across the entire enterprise.

USDM capabilities and services include the following:

- A high performance team of subject matter experts with understanding of your regulatory landscape, compliance challenges and validation strategy
- Hands-on working knowledge and experience with risk based validation (ISO-14971, GAMP 4/5) in the pharmaceutical, biotechnology and medical device environments
- Proven competency model, staffing model and project management methodology to align our organization to best meet your quality, technical and regulatory expectations
- Operations leadership and executive management commitment to utilize all USDM resources to support your success
- Two approaches for engagements to our clients: Projects and Long Term Engagements (LTE)
- A company dedicated to your success with a compelling desire to earn your trust as a long term compliance partner