ARE YOU GAMBLING WITH MEDICAL DEVICE COMPLIANCE?

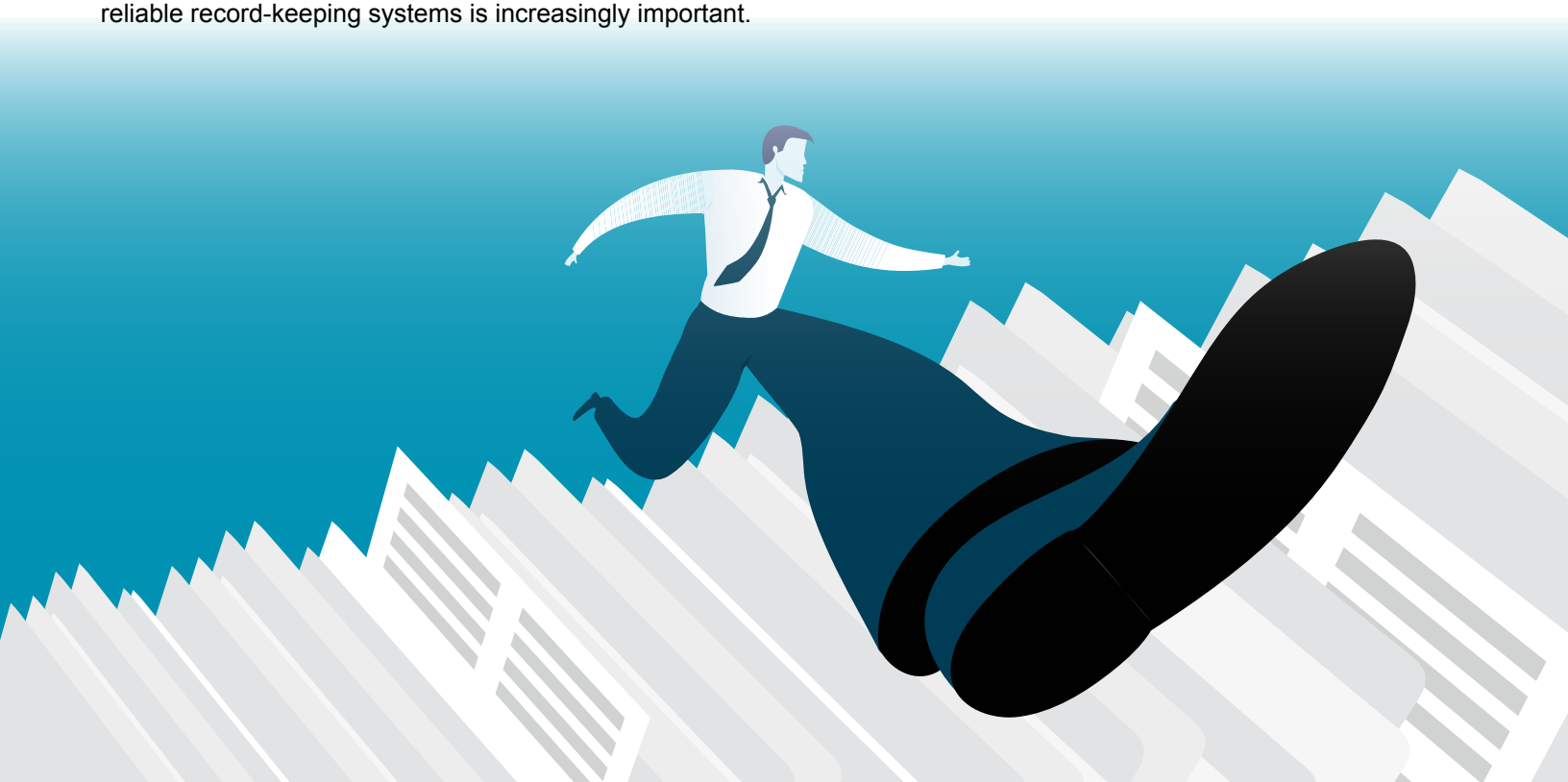
8 REASONS TO DITCH PAPER DEVICE HISTORY RECORDS

By Harold Sant, Vice-President of Operations

What is the probability thousands of handwritten records created by production employees are error free? That's the gamble OEMs make when they accept handwritten device history records (DHRs) from their contract manufacturing organizations (CMOs).

One medical device manufacturer found up to 20% of all in-process DHR packets contained an error[1]. Such errors can lead to consequences such as FDA warning letters or even a shutdown. According to www.malcombatchrecords.com, 84% of warning letters issued by the FDA had observations for inadequate or missing documentation.

With OEMs now responsible for the regulatory compliance of their CMOs, and with outsourcing predicted to grow by 11.5% annually through 2022 according to Grand View Research Medical Device Outsourcing Analysis, the need for CMOs with reliable record-keeping systems is increasingly important.



For compliance purposes, if an event is not recorded in the DHR, then it did not happen and the true product quality can be deemed irrelevant. This concept of quality being irrelevant when compliance is not met can be a key differentiator for CMOs. Most CMOs do all the right things to produce a quality product. However, compliance is where some CMOs fall short while others have a competitive edge. How will you know a reliable DHR system when you see one?

HOW IS A DHR CREATED?

The FDA requires CMOs to maintain a DHR both as proof that each finished device was made according to a validated process and for traceability in the case of a defect. Most CMOs use manual, paper-based processes to document production and store the records. A DHR is required to have all of the historical records pertaining to the production of a batch. The details include:

- lot/batch number
- source information for raw materials or subcomponents used
- a reference to each procedure used
- a reference to each inspection and test procedure used
- identification of machines used for the batch along with a reference to the calibration records for each machine
- the names of individuals performing each process step and the dates the steps were performed
- a reference to the training records of each individual performing process steps
- the quantity manufactured (pass/fail)
- the quantity released to distribution
- the name of the individual responsible for releasing the lot/batch for distribution
- a sample of the product/package labeling used.

In a paper based system, each step in the production process, causes an employee to create paper records. The amount of documentation required for a typical batch can fill a file with 2 to 10 inches of paper[2]. Each step in the process and each point of documentation are prone to error and are thus potential areas of failure in creating the DHR.

PAPER SYSTEM, AUDIT NIGHTMARE

The challenges of a paper system come from relying on employees to document thousands of records by hand. Even in the best case, with the right culture, training, and quality checks, hard copy records can fail in a number of ways:

- Recording errors
- Filing errors
- Omission errors
- Skipped steps
- Poor legibility (unreadable equals noncompliant)
- Data entry errors (if applicable)

If errors are not caught before filing, this becomes a problem in the case of a defect or recall. If the record is wrong, you are not only out of compliance, but you cannot identify and fix the root cause of a problem.

In the case of audits, paper files are notoriously time-consuming to retrieve and have higher rates of non-compliance due to the reasons listed above.

CAN THE DHR SYSTEM BE AUTOMATED?

Documenting device history seems like a process ripe for automation. Yet, most CMOs are deterred from creating a fully automated system because the records needed for the DHR contain fragmented data stored in several disconnected systems. Most manufacturing environments use 5 to 10 different systems (e.g., training, equipment, machine performance, subcomponents, employee performance, ERP). It is not possible to simply create an electronic DHR for each batch by cross-referencing the data without integrating the systems. DHR integration into one record requires compatibility across multiple systems. Connecting these systems is not easy, and requires financial investment and time.

Some partial solutions exist in the industry. For example, handwritten records can be converted to electronic records by data entry. But data entry introduces potential for errors, and does not solve the problem of disconnected systems. Some software applications can create a partially electronic system. But, these software systems cannot integrate with the CMO's existing systems.

8 BENEFITS OF A FULLY INTEGRATED DHR SYSTEM SOLUTION

The power of a fully integrated system comes from connecting the data, in real time, from the manufacturing systems that house data needed for the DHR. Not only does this achieve traditional compliance for the DHR, but it enables the following benefits:

1. Complete DHR is available in one view from one system.
There is no need to cross-reference records from multiple systems.

2. Enforced regulatory compliance.
Unlike the paper system, a fully integrated system ensures manufacturing processes are performed in the required order, steps are not missed, and documentation occurs. The DHR is complete because real-time checkpoints do not allow missed steps or missed records.

3. Elimination of manual processes.
Documentation needed for the DHR is collected passively by the system as the steps of the process occur. Handwritten records and the errors associated with them — inaccuracy, missing data, illegibility, misfiling — are eliminated.

Separately, production time spent documenting is eliminated, improving productivity.

4. Automated error prevention.
The connectivity of systems in real time enables programmable error prevention. For example, the connectivity with the training system only allows employees who meet training requirements to log in to perform a manufacturing step. Likewise, connectivity with the equipment system ensures a machine has been calibrated before a step can be performed. Steps cannot be skipped or partially done and must be performed in sequential order as programmed. Barcoded and electronically scanned parts further reduce errors.

5. Reduced audit time.
A typical audit using paper-based records takes two to three days. Much of this time is spent with two to three employees running to find the right files. Once the files are found, additional data must be cross-referenced from the disconnected systems. With a fully integrated system,

the audit takes about half a day. The time savings benefits OEM auditors, regulatory auditors, and the CMO.

6. Remote audit capability.
Customers have the option to perform a scheduled or surprise audit remotely using a shared screen to review random batches for DHR compliance.

7. Elimination of paper trail, storage, and retrieval costs.
The hassle of a paper system is removed, including filing and retrieval time. Offsite storage is no longer needed. Onsite storage is now available for another use.

8. Real time data availability.
With real time data, information is easily obtained to make informed, timely, and effective decisions.

DETECTING A PARTIAL VERSUS FULLY INTEGRATED SYSTEM

When evaluating CMOs, how can you tell if the system is fully integrated? Ask to see a completed DHR. With a fully integrated system, the supplier can show you a completed DHR from one system, in one look.

Some CMOs have a system where parts of the records are electronic, but their systems are not integrated. This will be evident if multiple systems need to be accessed to show two sets of data. To test this, ask the supplier to show the names of individuals who worked on the batch and also the training records for those employees. A second test would be to ask for a list of machines used for a batch, and also the calibration records. If the supplier has to pull records from a separate system, the systems are not fully integrated.

FULLY INTEGRATED SYSTEMS LEAD TO OEM CONFIDENCE, PATIENT SAFETY AND BEST VALUE

Integration of all the systems is where the power resides to create the DHR in one view, enforce the correct manufacturing process, and build in real-time error prevention. This level of systemic control over quality gives OEM's confidence that: 1) regulatory requirements are being met, 2) manufacturing processes are in control, and 3) ultimately, every medical device sold under its brand name is safe for the patient.

In the bigger picture, integrated systems provide benefits well beyond DHR compliance. A supplier with integrated systems has immediate access to data that opens up a whole new world of insights to help improve operational efficiency, which in addition to patient safety, will result in the best value.

References

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2. Medical Device Manufacturer's Continuous Improvement Approach Reduced Errors In Records. Retrieved from http://www.mddionline.com/article/developing-dynamic-device-history-records.

ABOUT THE AUTHOR

Harold Sant, Vice President of Operations

Harold Sant has served as Flexan LLC VP of Operations since September 2015. Harold leads the company's U.S. operations, overseeing more than 150 employees. He is responsible for the U.S. Flexan and FMI divisions of manufacturing, engineering, and operations. Prior to his current position, Harold held various engineering roles and most recently was the VP Operations of FMI, Inc. He holds a Master's degree in Chemical Engineering from the University of Illinois at Chicago and a Bachelor's degree in Materials Science and Engineering from the University of Washington.

ABOUT FMI

FMI is dedicated to producing medical-grade silicone components for Class II and Class III medical devices. In fact, custom silicone moldings are the only products we manufacture and health care is the only industry we serve. That singular focus allows us to provide the highly customized components that medical device manufacturers depend upon for patient safety, efficacy and reliability.

Since 1989, we have been supplying micro-precision molded components to leading medical device manufacturers and helping them expand their global market reach. We understand the intricacies of FDA requirements and global manufacturing standards and we aim to exceed them with our ultra-clean silicone molding facilities.

Our Chicago area headquarters and offshore manufacturing facility in Suzhou, China are both ISO 13485-certified with Class 5, 6 and 7 clean rooms. We work with our clients to speed products to market through our rapid development program, while maintaining the highest quality and competitive pricing.
FMI Medical is a privately held company, owned by Flexan Corporation, founded in 1946, with more than 500 employees worldwide.