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TRACK AND TRACE

A Step-by-Step Guide to Implementing An Effective Program

ALTHOUGH A UNIVERSAL STANDARD for pharmaceutical track-and-trace solutions has yet to emerge, the California Board of Pharmacy's ePedigree requirements are currently driving action in efforts toward implementing serialization to provide supply-chain integrity to the public. While several states are actively pursuing similar legislation, California's pending requirements are the most demanding in that they track product to the smallest saleable unit level.

Enforcement of California's ePedigree legislation has been delayed several times; however, the current initial enforcement date of January 1, 2015, is expected to stand, and similar efforts on the federal level may not be far behind. This, combined with the accelerated pace of regulatory involvement worldwide in serialization and track and trace, means that it is now vital that the industry accelerate its efforts to put compliance measures in place.

At Aphena Pharma Solutions, we have developed a step-by-step process that has helped us establish a very effective track-and-trace program, and we are sharing the steps we followed in hopes that they might be beneficial to others in the industry seeking to implement compliant track-and-trace systems. ›››

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The use of best practices in today's world for well-tested and documented business-critical systems is a safe assumption.

COMPLIANCE MATTERS

ANY AND ALL SYSTEMS added or maintained to resolve the ePedigree initiative must be compliant with the regulations. Although the need to attack the problem of counterfeit medicines in the supply chain is obvious, many of the system-design considerations may be derived from an analysis of the regulations the system(s) will address. The following are regulations to keep in mind to help guide your process:

1. **ISO REQUIREMENTS:** Depending on the extent to which a company implements serialization for a packaging operation, there will be significant regulatory impact to a serialization project. At a minimum, there are ISO requirements for a formalized computer-system life-cycle management process. In any case, the use of best practices in today's world for well-tested and documented business-critical systems is a safe assumption.

2. **CFR PART 11:** Other regulations may also be impactful. In the case of pharmaceuticals, 21 CFR Part 11, Electronic Records; Electronic Signatures, there are many requirements that must be met. These include specific actions to ensure authenticity, integrity, and confidentiality of e-records where appropriate.

3. **GAMP 5:** The pharmaceutical industry adheres to industry standards that can be found in a document published by the International Society of Pharmaceutical Engineers (ISPE) in its most recent guide, *GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems.* Immediately upon the formalization of a systematic serialization approach within an organization, the resulting project then becomes subject to standard Good Manufacturing Practices (GMP) Quality Management System requirements. GAMP 5 will drive the project planning and implementation of a structured track-and-trace program in the typical pharmaceutical company.

Within GAMP 5, topics include how:

- the system will be *designed, built,* and *tested*
- the system will be *documented*
- the system will be *handed over to the users*
- incidents will be *documented,* and corrective and preventive measures will be *captured* and *coordinated*
- system changes will be *managed*
- system audits will be *conducted*
- electronic records will be *maintained, retrieved,* and *archived*
- ... and *more.* ›››

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ASK THE RIGHT QUESTIONS TO FORM YOUR STRATEGY

APPLY A STRUCTURED ANALYSIS of the integrated automation system to assure adequate understanding of the processes and scope of the effort (i.e., determine what business processes, system interfaces, and human control activities need to be assessed) prior to formal project Scope Statement.

Questions to be addressed for this phase should include the following:

- Is this a global project? If so, what communication and collaboration tools will be used to support the project?
- What is planned for a proof-of-concept?
- Which lines will be upgraded?
- Are multiple facilities involved?
- Is there a serialization system already in place? If so, has a gap analysis been performed to identify the differences between the "as-is" and the "to-be" processes?
- Have all important stakeholders been included?
- How will we be able to insure a good level of communication with stakeholders?
- Is there an opportunity to leverage standardization in order to reduce or eliminate the need for redundancy and duplication?
- Is there potential for leveraging corporate standards or guidelines and supplier standardization?

The project plan should consider task ownership so that there are clear expectations of who will deliver what and when. Although this consideration is universally applicable to all elements of the project, the bottom line is that the delivery of the system, including all software, hardware, documentation, and ongoing support and maintenance, must be well understood and agreed upon in writing.

TEST, AND TEST AGAIN

AS WITH ANY COMPLEX PROJECT, there will be a lot of trial and error, potentially resulting in rejects and rework. This is primarily because now we are aggregating serial numbers into containers holding smaller serialized units. When the serial-number "chain" is disrupted for whatever reason, the human business processes' and automated systems' capabilities to cope with the management of such an issue are key. ›››

See **Pharmaceutical Online The Magazine's** article titled *"Serialization Item List and Time Line"* for an implementation guide flow chart.

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››› Although there are a number of potential scenarios that will inevitably occur, the following is an example based on a standard high-speed packaging operation of between 100 to 200 bottles per minute:

Assumptions:

- All labeling within the batch must be uniquely serialized, verified, authenticated, and aggregated during the packaging operation.
- At a minimum, the following automated systems, including mechanized ejection capability, are parts of the packaging train: (1) controlled creation and issuance of a pool of uniquely serialized values for the specific packaging operation; (2) confirmation and verification following application that the bar code is machine readable and is an issued value from the approved pool; (3) aggregation of the serialized product during the final boxout into shipping containers to create the parent–child relationship between the uniquely serialized bar code applied to the shipper case and each uniquely serialized container within the shipper; (4) reconciliation of used, destroyed, and remaining values against the issuance for the original pool.

1. **PRODUCT, LABELING, AND PACKAGING MATERIALS** (e.g. container, closures, corrugated shippers) are issued to a packaging suite.

2. **INEVITABLY, EQUIPMENT FAILS,** whether using inkjet, laser, thermal transfer, or some other labeling technology.

3. **UPON FAILURE, DEFECTIVE UNITS RESULT,** causing rejects that are automatically detected and separated from the rest of the batch.

4. **DEPENDING ON PRODUCT VALUE,** rejects are placed in a secured location and destroyed at the conclusion of the batch, or rejects are fully reworked using an approved rework process that specifically addresses the final disposition of the serialized, labeled, primary container.

5. **AS THE REJECTS CONTAIN CONTROLLED SERIALIZED VALUES** created for the specific batching operation, these units must be closely controlled and reconciled during the batch-approval process. Discrepancies will result in delayed batch release, potential quarantines, and investigations.

It is evident that any fault in the data linkage will result in significant lost production time. Moreover, considering throughput on today's high-speed packaging lines, a failure scenario such as the one described above could have significant cost and/or compliance impact. ›››

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Failure to establish a plan certainly guarantees the inability to effectively comply.

INTERNAL CORPORATE REQUIREMENTS

OF COURSE, NOT ALL OF THE SYSTEM REQUIREMENTS will be gleaned from a review of the regulations. So, in addition to the user requirements focused specifically on meeting the regulations, additional requirements will need to be gathered and documented clearly describing internal users' expectations for the delivered system. Examples of requirements for this group may read similarly to these:

- "The system shall be able to monitor availability of serial numbers and notify an operator when a 'low level' limit is reached."
- "The system must be able to 'read' all serial numbers applied by scanning with appropriate equipment and immediately reject defective units and notify operator(s) when illegible serial number(s) is/are encountered."

Although the expectations from legislators, regulators, and standards regarding track and trace of pharmaceutical product are being communicated to the industry, it is quickly becoming evident that there are resource limitations throughout the industry in addressing these new expectations. Attention must now be focused on the extended project piloting and implementation time requirements to get these systems up and running in an accelerated fashion.

At this point, you must implement an aggressive timeline to meet the minimum compliance requirements of the California ePedigree Law. We have included here one project plan approach that is focused on fulfilling the basic requirements. Adherence to this plan does not guarantee a successful implementation, as there are myriad variables; however, failure to establish a plan at this late stage certainly guarantees the inability to effectively comply. •••