CLARKSTON CONSULTING

Serialization & Traceability

| Project Startup | Proof of Concept (Serialization) | Engineering Trials (Track & Trace) | Validation | Go-Live & Roll-Out Strategy |

With regulatory requirements looming and a growing desire to prevent counterfeiting, tampering, theft, and diversion, companies must begin to look at Serialization and Track & Trace solutions to better control the chain of custody in their supply chain. Solutions such as SAP Auto-Id and Object Event Repository, also known as AIE, provide companies with robust solutions to address these challenges.

Clarkston Approach & Methodology

Clarkston's methodology provides a systematic approach to implementing these solutions:

Proof of Concept

Once traditional project startup tasks have been completed, functional requirements are gathered and approved. During Proof of Concept, these requirements are configured and the systems are installed and connected. Collaborative tasks include:

- Gather requirements
- Develop functional specifications
- Install SAP ERP/ECC and SAP AIE (PI, OER, Aii)
- Connect to MES server and packaging lines
- Install bar-coding scanning system(s)
- Test Serialization processes
- Sign-off Proof of Concept

Engineering Trials

The next phase supplies the Track & Trace functionality. Clarkston installs and tests on both a functional and technical level to ensure business and system functions are in line. Key steps include:

- Configure Track & Trace processes
- Verify processes through bar-code scanning and shipping station
- Establish reporting
- Perform unit and integration tests
- Test Serialization and Traceability processes
- Develop validation master plan
- Sign-off Engineering Trials

Validation

Prior to system start-up, Clarkston ensures that systems are properly validated to assure both appropriate functionality and regulatory compliance.

- Migrate solution to quality testing environment
- Execute validation master plan (Global AIE, MES, and packaging line)
- Fully test AIE systems
- Update impacted SOPs
- Perform knowledge transfer
- Develop cutover plan
- Sign-off Validation

Go-Live and Roll-out Strategy

Once the solutions have been developed, tested, and validated, Clarkston and the client develop a go-live and roll-out strategy. Training, change management, and all documentation, including lessons learned, benefit implementation and future rollouts to manufacturing lines, contract manufacturers, and warehouse facilities.

Serialization Success Story:

A global pharmaceutical company initiated a Serialization and Traceability pilot project in February 2011 to both meet global Serialization and US Track & Trace regulations and combat potential counterfeiting. Clarkston helped this company design, develop, and implement a global SAP AIE Serialization and Track & Trace solution. The AIE solution interfaced with their SAP ERP systems, as well as with the manufacturing facilities' MES and packaging line systems.

The company now has a fully validated global AIE solution, integrated with their ERP, MES, and packaging line systems, and a good understanding of master data harmonization requirements. Valuable lessons from the implementation will be leveraged to plan subsequent roll-outs, including an understanding of organizational change impacts to the Planning, Manufacturing, Warehouse, and IT departments, and a better understanding of managing relationships with trading partners.

Key Lessons

Start Early – Really Early

Start preparing as early as possible once a decision is made to implement Serialization and Traceability. Mechanical packaging line changes have long lead times, and the change will likely impact your infrastructure complexity and space needs. A comprehensive, strategic plan, will ensure success.

Strong Project/Program Management Needed

Several partners and participants will be involved in the process, including the MES vendor, packaging line engineers, AIE and SAP consultants, CMO/CPOs, business resources, and regulatory resources. Use your program management skills:

- Communicate regularly
- Keep to agreed milestones
- Seek and retain strong business program sponsorship

Plan in Advance

Take time to make key decisions early to anticipate issues, get ahead, and stay ahead. Successful planning will allow focus on key milestones, including the necessary investments in AIE infrastructure and EDI.

Data & Standards Create Harmonization Challenges

- Master data standards: GTINs, GLN, Material numbers
- Barcodes and packaging
- Labeling standards
- Multi-site (global) acceptance to standards-based system

Key Takeaways

The technology selected for serialization matters

Because regulations are new and still evolving, the solution and design need to be standards-based, scalable, and allow for future requirements. SAP's AIE is a solid technology, but expect growing pains as regulations and system features evolve.

Approach serialization one piece at a time

By approaching Serialization one piece at a time, lessons learned can be leveraged for planning subsequent phases.

- Serialization pilot demonstrates the organization's preparations and readiness for regulatory compliance.
- Track & Trace engineering trial adds warehouses and 3PLs.
- Scale up to additional facilities.

Serialization is a big commitment and doing it right takes time, investment and hard work

Because of the volume of data being exchanged and the complexity of exception processing, organizations must plan enough time to analyze and adapt their solution to achieve benefits such as brand protection, anti-counterfeiting, and verification/authentication solutions.

Companies have much to gain from getting ahead of legislation

Every business and site is unique, so no perfect "out of the box" solution for Serialization and Track & Trace exists. Develop a Corporate Standard and provide local guidelines. Because countries and regulatory bodies are not heading toward any common requirement, businesses should:

- Design a flexible base to allow for adaptations as legislation evolves.
- Take an incremental approach to implementing Serialization, rather than a risky last-minute big-bang approach.

Don't Count on Common Serialization Requirements

Again, countries have different requirements and are not converging. A flexible base allows for adaptations as legislation evolves by allowing for serial number assignments from different sources.

Master data harmonization is always more complex than anticipated

Much of the work can be done well in advance of the implementation. It is extremely important that individuals involved with data migration understand the business processes that act on that data and the repercussions of potential changes.

Ensure the entire team understands the validation requirements

Validation at the packaging line will be the longest lead time activity and all parties must be aware of dependencies and timing of the validation activities.

There can never be enough time allocated to testing

- With long lead times, schedule testing cycles early with CMOs and distributors.
- Don't assume CMOs and distributors are Serialization and Track & Trace ready. CMOs and 3PLs are at various stages of automation.
- Develop test scripts that ensure business requirements are met.
- Emphasize unit testing, which facilitates smoother integration testing.
- Start testing early – feature by feature, then scenario by scenario.

Cutover planning is a critical activity to successfully cutover to production

Involve the business in cutover planning to eliminate the potential for non-system tasks being missed.

Remember Patient Safety

The real bottom line is patient safety. Reminding yourself that you could be protecting your own family can get you past the issues and onto solutions.

Thinking about Serialization?

Clarkston can help

For more information, visit us at **www.clarkstonconsulting.com** or contact us at info@clarkstonconsulting.com.

About Clarkston Consulting

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a 10-year average client satisfaction rate of 97%.