Welcome
Serialization and Track & Trace Project Management Do's and Don'ts

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ISPE.

Who are we?

Providing Total Operational Solutions for Industry

- An independent Systems Integrator serving Life Sciences, Consumer Products, and other industrial sectors since 1986.
- Backed by a $1 billion automation company.
- Over 650 skilled professionals in 20 locations throughout the United States and Puerto Rico offering scalability of resources and diverse skills.
- Professionals specifically trained to support the Life Sciences.
- Range of services include Packaging Integration, Process Automation, Facilities & Infrastructure, Manufacturing Intelligence, Industrial Controls.
- Ability to offer off-site system integration, pre-certification & qualification, and complete construction responsibility for our systems.

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Why are we talking to you on Serialization?

- Design Group has consulted with 14 of the top 20 pharmaceutical companies.*
- Leading provider of packaging automation solutions.
- Extensive experience with leading Serialization solution providers and Packaging OEMs.

*Contract Pharma July 2010

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Serialization/Track & Trace Do's and Don'ts

Achieve Organizational Alignment
- IT
- Engineering
- Supply Chain
- Operations
- Quality

Underestimate Scope of Project
- Not confined to single line, site, etc.
- Far reaching coordination
- Far reaching changes
- No harmonized global requirements

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Serialization/Track & Trace Do's and Don'ts

Takeaway – Make sure you have the right players involved. Serialization is an enterprise wide project.

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Serialization/Track & Trace Do's and Don'ts

✓ **Execute a Single Project Scope**
- Not a series of independent projects
- Assess entire network
- Comprehend all areas of change
- Develop re-usable elements
- Prove solution for all formats

✗ **Multiple Non-Integrated Projects**
- Non similar software/hardware
- Long term support challenges
- New regulation upgrade challenges
- Loss of procurement advantage

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Takeaway – Single, corporate driven strategy works best.

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Serialization/Track & Trace Do's and Don'ts

✓ Plan/Communicate Resource Needs
- Corporate Personnel (100%)
- Site Personnel (25% - 75%)
- Installation, start-up, qualification
- Ongoing support/maintenance
- Added activities in production

✗ Assume Site Availability
- As-built conditions
- Site visits, reviews, hosting visitors
- Competing site improvement projects
- Procedures, training, standards, etc.

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Takeaway – This is a big effort that will require a lot of resources. To be successful you can't just wave a hand at it...

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Serialization/Track & Trace Do's and Don'ts

Practice Thoughtful Standardization
- Top 3 printing systems – unit level
- Top 3 inspection systems – unit level
- Single system for aggregation
- Regional single system S95 levels 2 & 3
- Single system S95 level 4

Assume Universal Compatibility
- Drivers, interfaces, protocols
- Upgrades, new revisions, etc.
- Serial #1
- Paying for industry

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Takeaway – You need to maintain some standardization and consistency or you are not building on your previous learnings, i.e. a bunch of separate projects.

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Serialization/Track & Trace Do's and Don'ts

Start Now
- How many lines to serialize
- Which regulation dictates deadline
- Design and be ready
- Implement as regulations solidify
- Multi-site, lines, time zones

Wait
- Strained industry resources
- Extended equipment lead times
- Production requirements
- Implementation times

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Serialization/Track & Trace Do's and Don'ts

Takeaway – Serialization is a big, time consuming project and everyone is waiting until the last minute and the industry can't support this model. The time to act is now.

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Questions and Other Topics?

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