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A faint, light-colored world map is visible in the background of the slide, centered behind the main text.

Top 3 Challenges for Successful Serialization Implementation across your Supply Chain

Inspiring Collaboration Leading Innovation Making a Difference



Top Challenge	As a distributor, each drug product must be evaluated differently due to contracts, partnerships and alliances. The more products the more complexity.			
Impact	<ul style="list-style-type: none">• Evaluation of Multiple Contract Manufacturers and cost structures increase schedule.• Quality agreements and contracts require updates for serialization which take months.• Every label must be updated, all different logistics.• Establishment and staffing of internal infrastructure to manage oversight of newly created systems.			
Mitigation	<ul style="list-style-type: none">• Used phase approach for implementing serialization.• Use questionnaire to get information from suppliers.• Labeling serialization design guidelines (SOPs)			
Length of time to resolve	0-6 mos.	7-12 mos.	12 – 24 mos.	> 24 mos.



Questionnaire to 3PLs and CMOs:

- Who is your main contact for serialization implementation (*Name, Title, Email, Phone*)?
- Who is your Serialization Provider? If currently not identified, when do you anticipate making a decision?
- What is your plan for onboarding any additional support staff and the designation of the DSCSA contact?
 - When will you be ready?
- When will your Serialization Line be running?



Questionnaire to 3PLs and CMOs:

- Do you have adequate space for printing in the product label? If not, how much space is needed on the label?
 - Would you prefer a linear or 2D barcode?
 - What classification of printing resolution will be available?
 - When do you need the GTINs?
- Can you confirm our products can be aggregates to the pallet level?
- Do our Service Agreements need to be updated?
- Have you provided a quote for serialization? If not, please provide as soon as possible.



Top Challenge	Electronic system implementation – Connectivity implementation across CMOs
Impact	Multiple serialization management systems available with each CMO possibly on different platforms and their implementation timeframes may impact your implementation timing.
Mitigation	<ul style="list-style-type: none">• Communicate early with your CMO and agree on timing and implementation requirements upfront.• Ensure part of the implementation/validation includes early testing connectivity.• Partner with reputable vendor
Length of time to resolve	0–6 mos. 7-12 mos. 12 – 24 mos. > 24 mos.



Top Challenge	Variety and complexity of all the onboarding activities <ul style="list-style-type: none">- Big pharma has specific “wants”- Virtual pharma needs support/education
Impact	Each client requires some level of custom handling to progress integration
Mitigation	<ul style="list-style-type: none">• Tools for ease of master data sharing• Coaching through integration processes• Core team support for multi-site clients• Standardization of artwork changes• Standardization of qualification processes
Length of time to resolve	0–6 mos. 7-12 mos. 12 – 24 mos. > 24 mos.



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Distributor Perspective

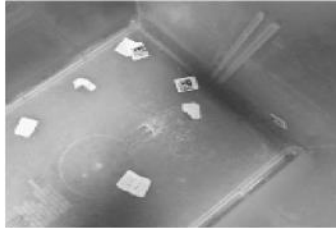


Standards???

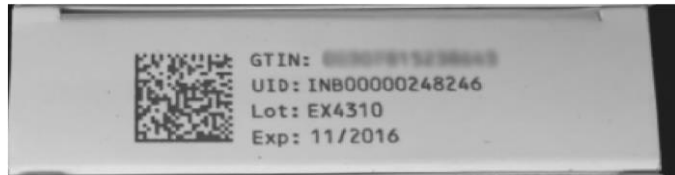


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Distributor Perspective



Incorrectly coded barcodes.
Barcodes falling off (adulterer product).
Missing Human Readable (HRI).



What the heck is a UID?
(yes.. It's the serial number)



Human Readable next to non-serialized
2D Barcodes

Standards???



Top Challenge	Drive adoption of GS1 and industry packaging and labeling standards; use serialization as the driver.
Impact	Inconsistent, or improper, packaging <i>may</i> result in supply chain disruption, drug shortages, and costs to move drugs through the supply chain.
Mitigation	<u>Proactive</u> : Communicate requirements, and provide service to review labeling and packaging. <u>Reactive</u> : Audit current packaging, provide feedback on issues, score card manufacturers, and potentially penalize repeat offenders.
Length of time to resolve	0–6 mos. 7-12 mos. 12 – 24 mos. > 24 mos.



Questions...Ideas



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