Serialization Snapshot: The Current State of Readiness

Polling Data from NEXUS 17

At NEXUS 17 in Barcelona, more than 200 people from over 120 companies met to discuss how they're preparing for the challenge of serialization, how the process has affected their operation and partnerships, and what potential benefits they've identified beyond achieving compliance with EU FMD, U.S. DSCSA, and other market regulations.

Here's what attendees shared as part of our live polling throughout the 2-day collaborative forum.

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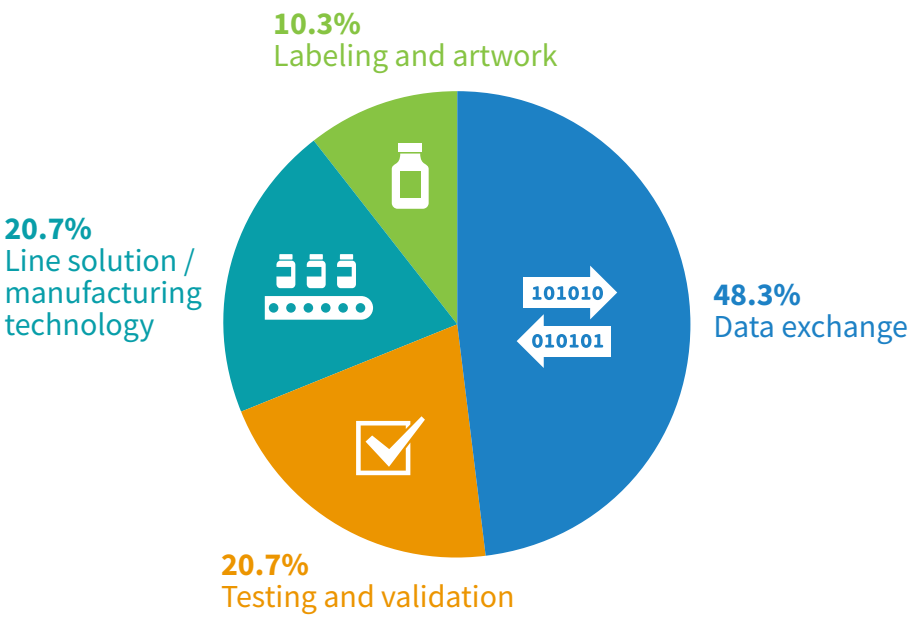
Serialization: Will the Industry Be Ready in Time?

With EU FMD serialization requirements less than 2 years away—and the U.S. serialization deadline for manufacturers in November 2017—concerns about readiness and knowledge persist.

Nearly one-half of participants are **worried about the exchange of information.** Testing and validation of systems is also top-of-mind for many.

Greatest serialization concerns



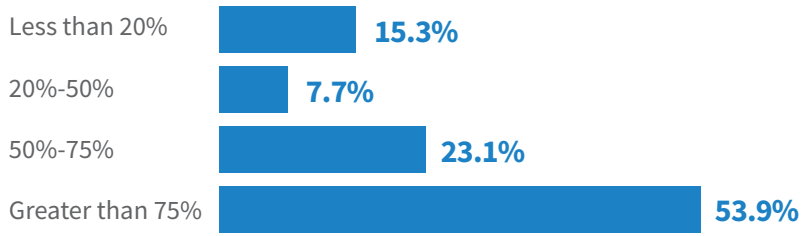
In examining the challenges posed by **the 5 levels of serialization**, information exchange remains a concern – but it's not as troubling as getting product serialized on the line.

Greatest serialization challenge so far

Lack of line vendor's ability to deliver a solution on time and within scope	**47.3%**
Lack of Level 3 functionality and flexibility to fulfill business requirements in the solution	**26.3%**
Lack of Level 4 corporate repository to manage serial numbers and exchange data	**21.1%**
Lack of Level 5 communication with regulators, wholesalers, and pharmacies	**5.3%**

Although companies are showing progress preparing for the U.S. serialization deadline, nearly 1 in 4 **still need to serialize half their inventory** - or more.

Percentage of NDCs already serialized for DSCSA requirements



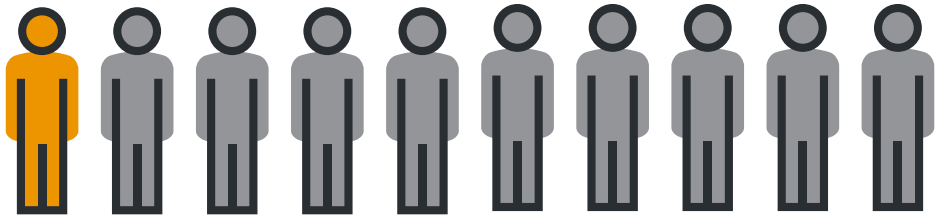
The Pharma Company-CMO Relationship May Present Barriers to Readiness

Successful partnerships between pharmaceutical manufacturers and CMOs are crucial to the industry being ready for serialization in time – and pharma company confidence is lacking.

68%

of respondents feel their CMOs or CPOs are not well prepared to meet serialization requirements.

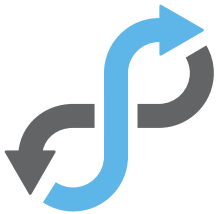
Only 1 in 10 considers their partners to be very well prepared.



General State of CMO Readiness

Only 6% say data exchange with their CMO is in place, tested, and validated.

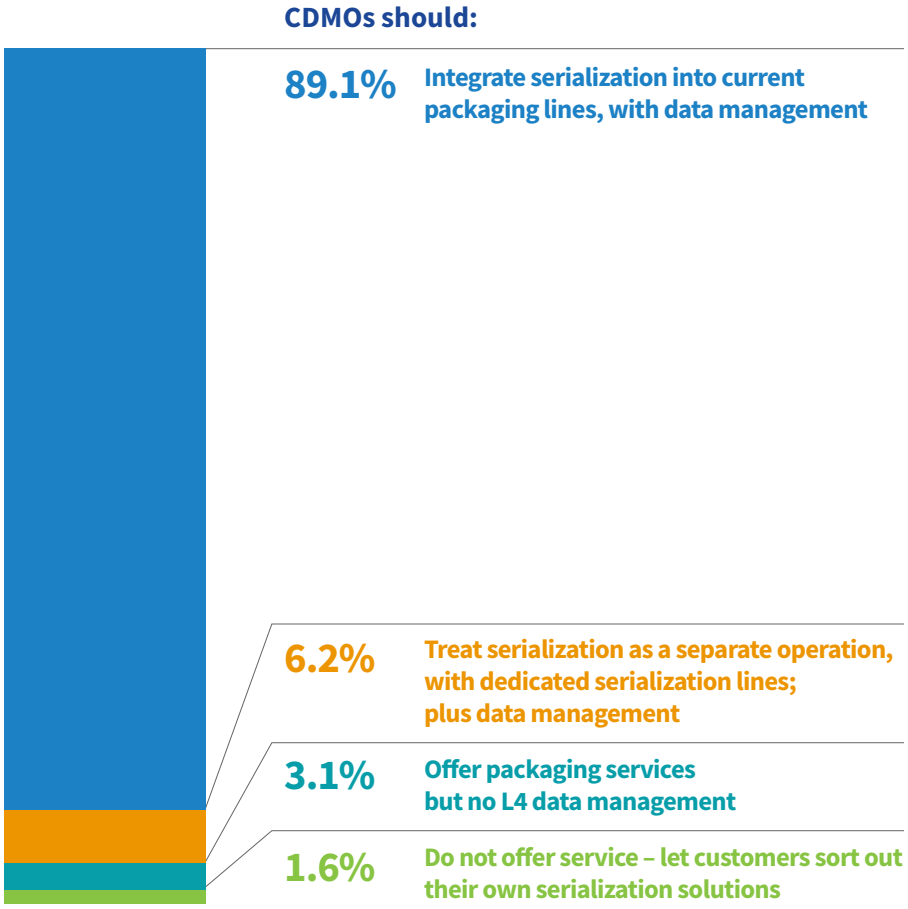
18% don't know their CMO's readiness or haven't started to implement their plans.



The other 76% are somewhere in between, either having exchanged general information or "working on it".

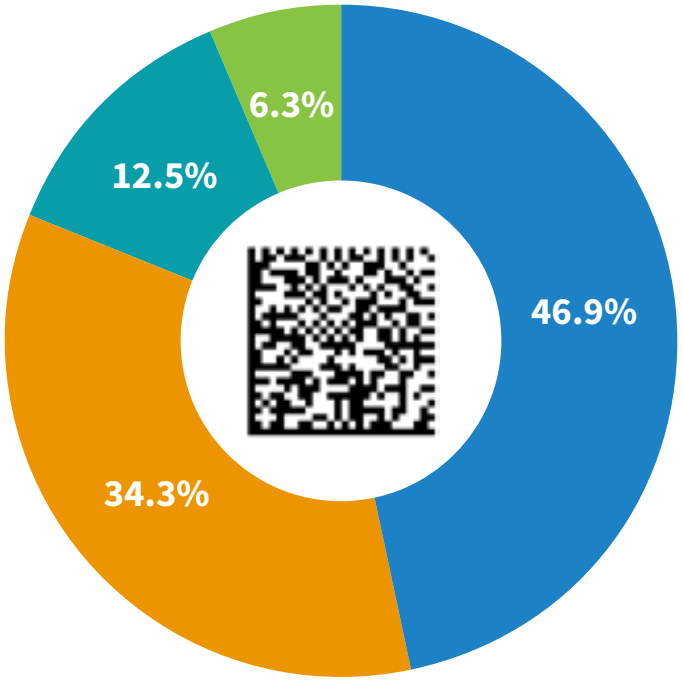
The Pharma Company-CMO Relationship May Present Barriers to Readiness

When asked how CDMOs should address serialization complexity, an overwhelming majority of respondents **recommended that CDMOs integrate for their customers.**



More than half of respondents are **rethinking their current 3rd party manufacturing strategy** because of serialization requirements:

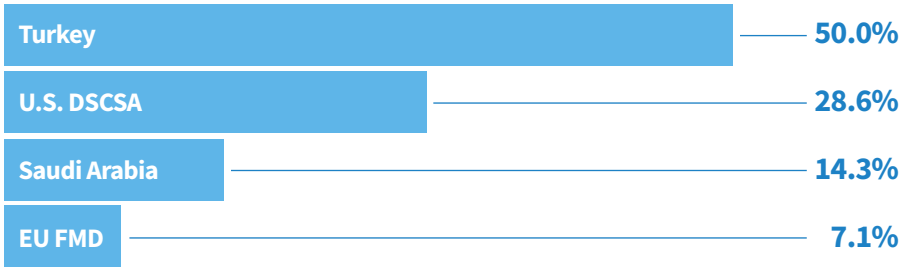
Expect to make changes in the future	46.9%
Current strategy will meet serialization needs	34.3%
Have already started to implement changes	12.5%
Unsure – serialization strategy still being developed	6.3%



Companies Have Varying Opinions—and Knowledge—of Market Regulations

Differing levels of confidence abound, both in the value that legislative requirements can deliver, and the understanding of those requirements.

When asked to name the regional legislation with **the highest levels of brand protection and product security value**, participants chose Turkey by a landslide:



Knowledge gaps exist for companies facing regulation in multiple markets:

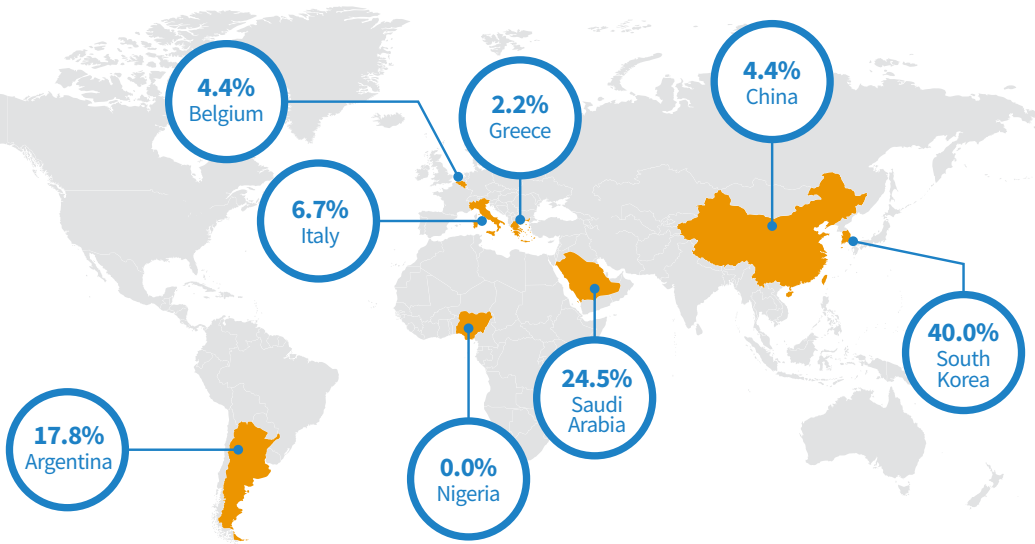
- **29.2% said they were not very confident** in their knowledge of requirements across most of their markets.
- **Only 20.9% said they were very confident** in their knowledge across all of their markets.
- The rest said they were very confident in some markets, uncertain in others.

Attendees were quizzed on their knowledge of global requirements - here are their answers. Do you know which are correct? *(Answer on the last page.)*

Question:

Of these countries, **which has current traceability regulations based on the Global Concept** - employing a global standard rather than a regional one?

Quiz Answers from Respondents



Companies are Eager to Identify Value Beyond Compliance

An overwhelming majority of supply chain companies have started considering the business benefits of track and trace, beyond meeting legal requirements.

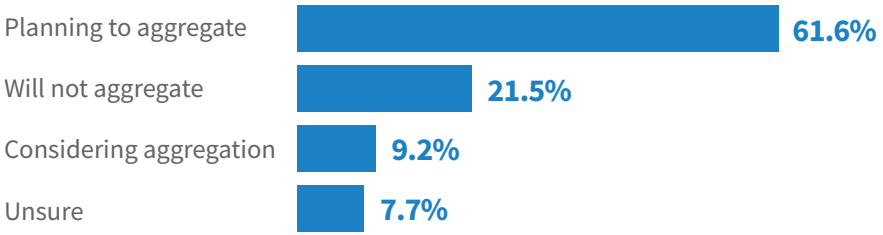
70.2%

of pharma supply chain companies **have identified high-level advantages** to track and trace initiatives.

19.4%

have already performed cost and benefit analyses, with positive outcomes.

Although aggregation is not mandatory for EU FMD compliance, **more than 6 of 10 respondents plan to aggregate** based on the value it might offer.



Among potential benefits, participants consider **a clear view of the supply chain to be the most valuable.**

Benefit with the greatest value beyond compliance

Supply chain visibility	58.0%
Customer interaction	23.2%
Brand protection	8.7%
Quality improvements, like process harmonization	7.2%
Other	2.9%

Capability that would add the most brand protection value

Full track and trace from factory to dispenser	69.6%
Patients' ability to scan and authenticate serial numbers	17.4%
100% data accuracy in the corporate EPCIS repository	13.0%
Serialization of primary pack (vial, blister, bottle)	0.0%

Companies are Eager to Identify Value Beyond Compliance

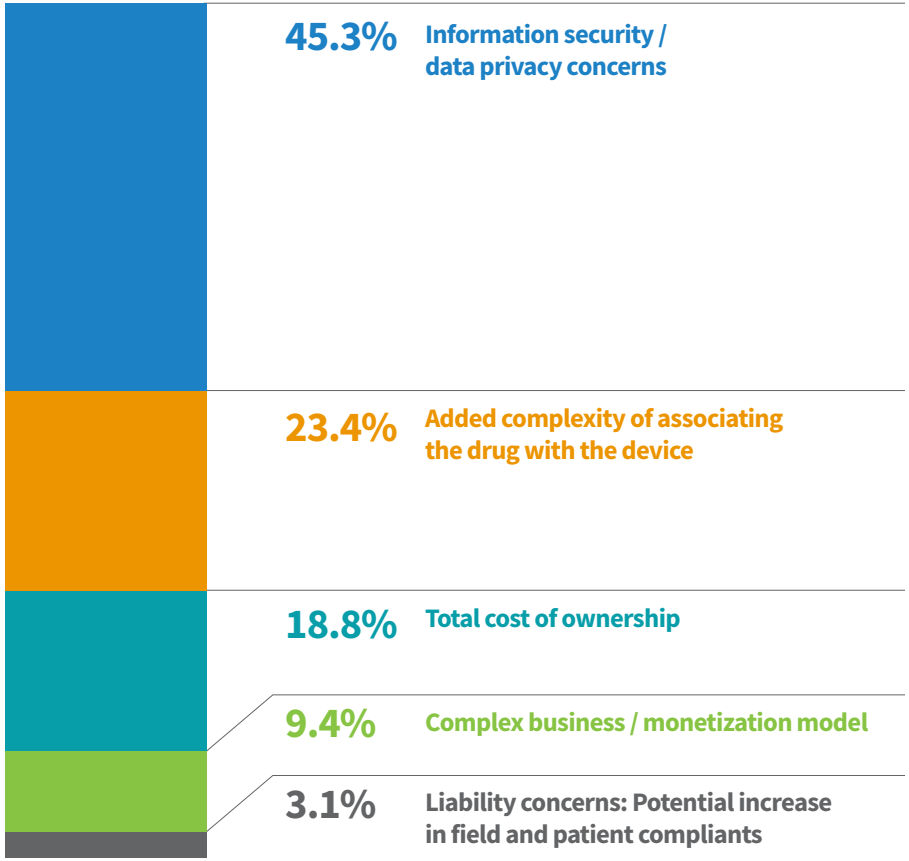
78% of respondents believe **end-to-end supply chain visibility** is achievable within the next 5 years.

69% say the greatest benefit of end-to-end medication management would be **improved patient safety.**

Other benefits include improved patient preference, increased medication adherence, opportunity for post-market surveillance, and strengthened supply chain integrity.

When considering the development of a **drug traceability solution at the device / patient level**, nearly half of respondents see privacy as the greatest concern.

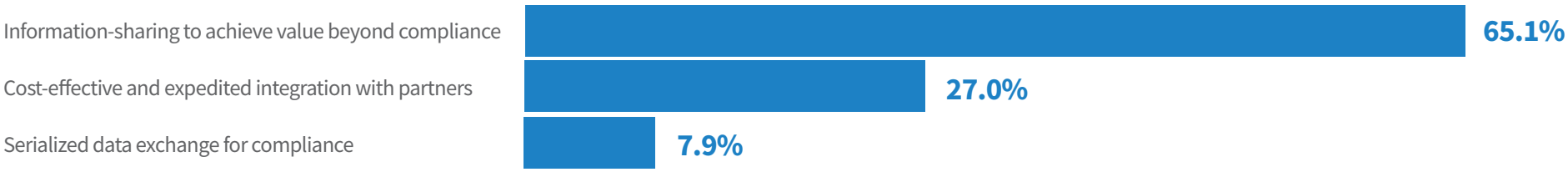
Biggest challenges / risks of a patient-level traceability solution



Companies are Eager to Identify Value Beyond Compliance

In assessing the value of a **network software architecture for their supply chain**, a large majority of respondents see benefits that are not necessarily compliance-related.

Most valuable benefit of a network



63% of respondents who have implemented serialization or track and trace processes say it **has caused them to change their quality practices.**

3 out of 4 say serialization solutions **will lead to business transformation.**

With the largest track and trace network in the life sciences industry, TraceLink can help you meet serialization requirements in any region – and enjoy operational benefits beyond compliance.

Find out more and request a serialization demo today.

Correct answers to the question on page 5: South Korea, Saudi Arabia, Argentina

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