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.
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

- 48.3% Data exchange
- 20.7% Line solution / manufacturing technology
- 20.7% Testing and validation
- 10.3% Labeling and artwork
- 47.3% Lack of line vendor’s ability to deliver a solution on time and within scope
- 26.3% Lack of Level 3 functionality and flexibility to fulfill business requirements in the solution
- 21.1% Lack of Level 4 corporate repository to manage serial numbers and exchange data
- 5.3% Lack of Level 5 communication with regulators, wholesalers, and pharmacies

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

- Less than 20%: 15.3%
- 20%-50%: 7.7%
- 50%-75%: 23.1%
- Greater than 75%: 53.9%
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 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.”

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

CDMOs should:

- **89.1%** Integrate serialization into current packaging lines, with data management
- **6.2%** Treat serialization as a separate operation, with dedicated serialization lines; plus data management
- **3.1%** Offer packaging services but no L4 data management
- **1.6%** Do not offer service – let customers sort out their own serialization solutions

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:

<table>
<thead>
<tr>
<th>Country</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turkey</td>
<td>50.0%</td>
</tr>
<tr>
<td>U.S. DSCSA</td>
<td>28.6%</td>
</tr>
<tr>
<td>Saudi Arabia</td>
<td>14.3%</td>
</tr>
<tr>
<td>EU FMD</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

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

- Turkey: 50.0%
- U.S. DSCSA: 28.6%
- Saudi Arabia: 14.3%
- EU FMD: 7.1%
- Argentina: 17.8%
- Greece: 2.2%
- Italy: 6.7%
- China: 4.4%
- South Korea: 40.0%
- Saudi Arabia: 0.0%
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.

| Planning to aggregate | 61.6% |
| Will not aggregate | 21.5% |
| Considering aggregation | 9.2% |
| Unsure | 7.7% |

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

<table>
<thead>
<tr>
<th>Benefit with the greatest value beyond compliance</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply chain visibility</td>
<td>58.0%</td>
</tr>
<tr>
<td>Customer interaction</td>
<td>23.2%</td>
</tr>
<tr>
<td>Brand protection</td>
<td>8.7%</td>
</tr>
<tr>
<td>Quality improvements, like process harmonization</td>
<td>7.2%</td>
</tr>
<tr>
<td>Other</td>
<td>2.9%</td>
</tr>
</tbody>
</table>

**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**

- Information security / data privacy concerns: 45.3%
- Added complexity of associating the drug with the device: 23.4%
- Total cost of ownership: 18.8%
- Complex business / monetization model: 9.4%
- Liability concerns: Potential increase in field and patient complaints: 3.1%
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**

- Information-sharing to achieve value beyond compliance: 65.1%
- Cost-effective and expedited integration with partners: 27.0%
- Serialized data exchange for compliance: 7.9%

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.