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# 2016 Global Drug Supply, Safety and Traceability Report™

Using 2015 Lot-Level Learnings to Understand Future Serialization Challenges



# Introduction

**In the world of pharmaceuticals, there is a common belief that prescription medicine follows a simple, straightforward path: pharma companies sell most of their drug products to one of the “Big Three” wholesale distributors – AmerisourceBergen, Cardinal Health, or McKesson – and those major wholesalers supply these medicines to hospitals and pharmacies. From there, the hospitals and pharmacies dispense the medication directly to patients. This simple flow is often referred to as a “normal chain.”**

When DSCSA was signed into law by President Obama in November 2013, much of the industry developed core assumptions about the impact of compliance, predicated largely on this idea of a normal chain. Those in the pharmaceutical industry believed that:

- Meeting lot-level compliance – or exchanging just one file between two parties for every shipment – would be easy;
- Regulatory requirements wouldn’t take much time to address;
- The industry would be ready for the move to a fully electronic world.



Heading into 2015 - the first year of DSCSA requirements - these beliefs were put to the test. The reality was that lot-level regulations, which required data – transaction history, transaction information, and transaction statements, or T3 – to accompany all products as they moved from one party to another throughout the supply chain, necessitated a level of connectivity between customers and suppliers that never existed before. That connectivity and the lack of defined data standards called for deep IT resources with sophisticated skills.

With more than 240,000 companies on the TraceLink Life Sciences Cloud network, we see every day how complex the pharmaceutical supply chain really is. After the first year of lot-level compliance, we set out to test the myth of a “normal chain” with two primary goals: understand how well companies managed lot-level requirements and where specific challenges lie; and – more importantly – gauge how the industry is tracking towards the first DSCSA serialization deadline.





We partnered with Actionable Research on an industry survey, and we also drew upon data from the TraceLink Life Sciences Cloud, the world's largest track and trace network for connecting the life sciences supply chain.

The results shared in this report demonstrate that the journey to lot-level compliance was far more difficult than the industry anticipated. The data raises compelling challenges about what the industry must do in order to successfully move to a serialized and electronic world, and about the ability for medicines to continue to flow safely through the supply chain without interruption to patients who need them.





# Methodology and Demographics

## ABOUT ACTIONABLE RESEARCH

Actionable Research is a marketing research consultancy that delivers both qualitative and quantitative primary research solutions on a global scale. Actionable Research is focused on the healthcare and technology vertical markets, and is specialized in project-based solutions which forecast future demand for new products, quantify brand value and listen to the voice of the customer for some of the world's largest companies.

# Methodology

## Survey and Sample Development



- Created collaboratively between TraceLink and Actionable Research
- Survey addressed multiple life sciences supply chain business metrics including:
  - Volumes and linkages
  - Tools and expertise to manage supply chains
  - Use of paper records
  - Experience with lot-level compliance
  - Expectations for serialization
- Actionable Research programmed the survey and fielded online questions to supply chain professionals whose companies had a DSCSA requirement

## Data Collection and Screening Criteria



- Data collection was accomplished using a combination of TraceLink internal marketing lists and an open survey to industry professionals
- Respondents were screened into the following segments:
  - Pharmaceutical companies
  - Wholesale distributors
  - Hospital pharmacies
  - Retail pharmacies
- Purchase decision makers and users were the primary targets

## Final Sample

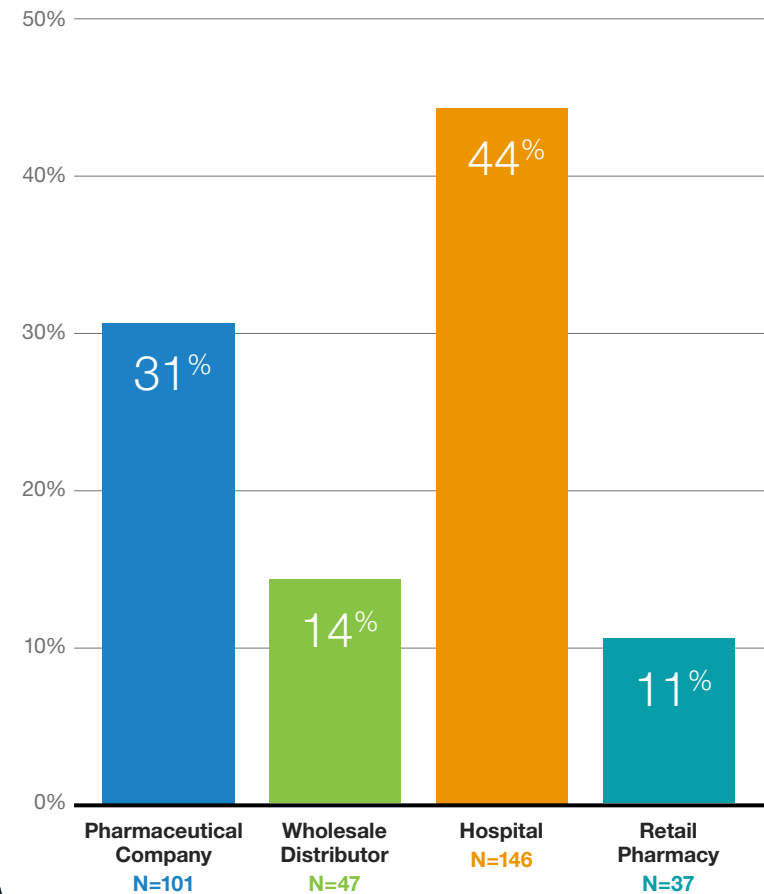


- Total Number (N) of Respondents=331
- Pharmaceutical companies: N=101
- Wholesale companies: N=47
- Hospital pharmacies: N=146
- Retail pharmacies: N=37
- Overall the sample had a sampling error of +/- 5% at 90% confidence

# Final Sample

Other studies have looked at serialization readiness, or queried portions of the industry, but the 2016 Global Drug Supply, Safety and Traceability Report is the only body of research that looks at lot-level experiences in this depth, with this large of a sample from pharmaceutical companies, wholesale distributors, hospitals, and retail pharmacies.

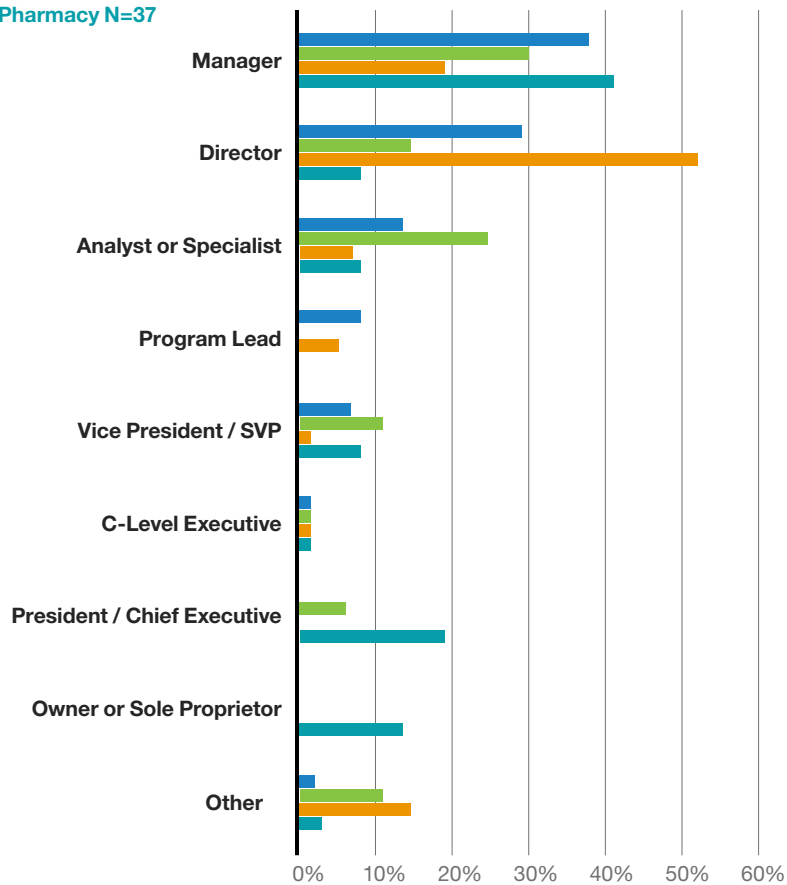
Company's Primary Role



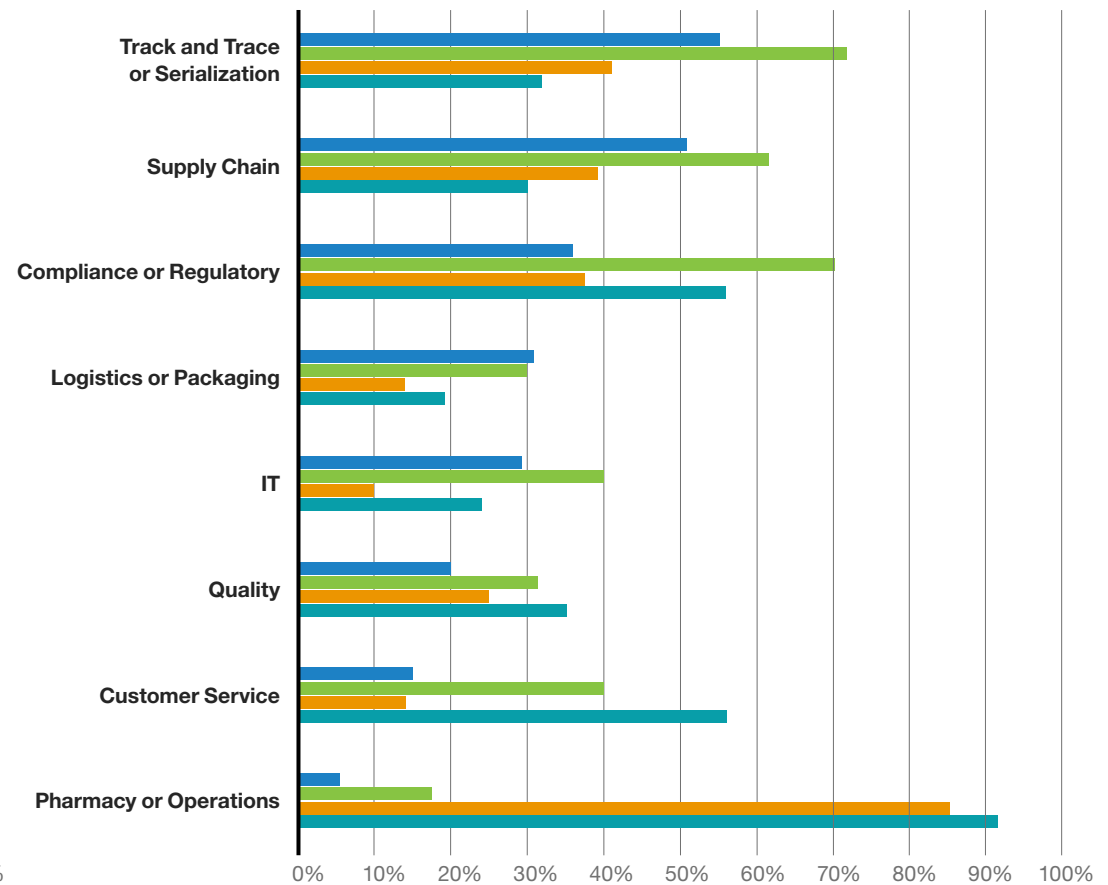
# Respondents

Pharma N=101  
 Wholesalers N=47  
 Hospital N=146  
 Retail Pharmacy N=37

## Role at Company



## Primary Area of Focus





# Understanding the Real “Normal”

In the industry’s vision of a normal chain, pharmaceutical companies sell the vast majority of their product to AmerisourceBergen, Cardinal, and McKesson - collectively known as the Big Three - and hospitals and pharmacies do most of their purchasing from this same trio. The belief is that while pharma companies and dispensers may work with a limited number of additional distributors, primary relationships are with the Big Three, and product moves in a very linear fashion from pharma to wholesaler to dispenser, with rare deviation.



Survey respondents painted a very different picture of their trading networks, where customers and suppliers number in the dozens to thousands, and product movement is much more complex.

**Pharmaceutical companies sell to a large number of customers.** 26% of pharma respondents had more than 10,000 customers, and another 31% had between 500 and 10,000.

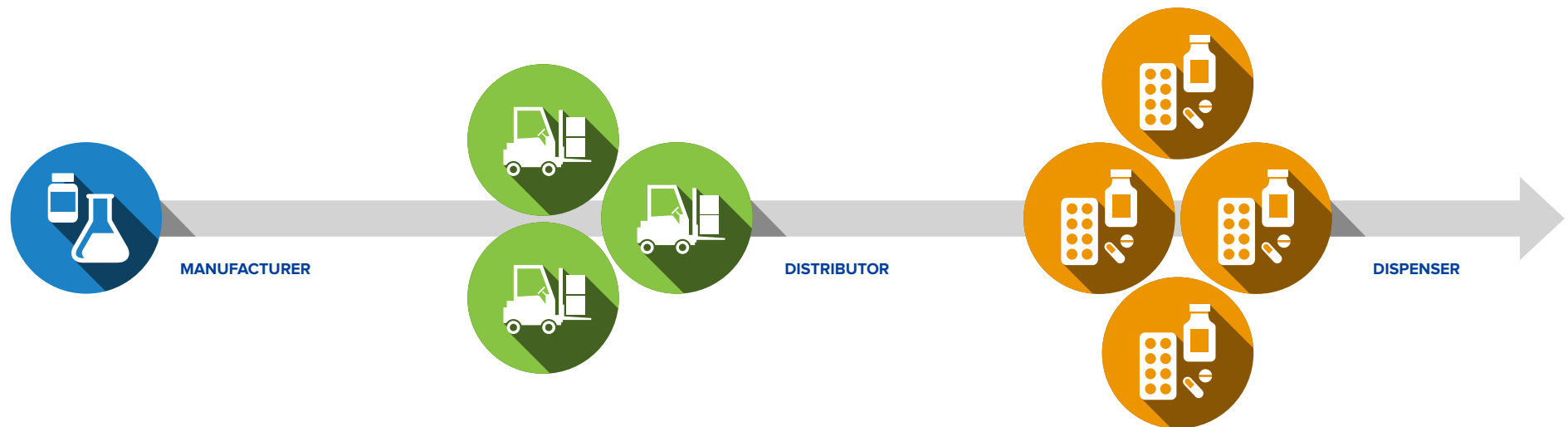
**The Big Three are three of many.** All in all, 43% of pharma companies' product was sold to parties other than the Big Three.

**Nearly a third of product moved from Point A to Point C.** 29% of pharma company sales were made directly to hospitals and pharmacies, with no wholesaler in the middle.

**Wholesalers buy from dozens to hundreds of partners, and often sell to thousands.** 60% have anywhere from 16 to more than 500 suppliers, and 58% sell to between 500 and over 100,000 customers.

**Dispensers rely on many suppliers.** 35% of hospitals purchased product from 16 to 500+ partners, and a quarter of retail pharmacies purchased from distributors other than the Big Three.

**Hospitals and pharmacies frequently play a wholesaler role.** 42% of hospitals and 19% of retail pharmacies resold product to downstream partners.



# Pharma Supply Chain: The “Real” Normal

**26%** of pharma companies had more than 10,000 customers

**31%** had 500 to 10,000 customers



**42%** of hospitals and **19%** of retail pharmacies resold to downstream partners

**35%** of hospitals purchase from 16 to 500+ partners



**43%** of pharma companies' product was sold to partners other than the Big Three

**29%** of pharma company sales were made directly to hospitals and pharmacies

**58%** of wholesalers sell to between 500 and 100,000 customers



Survey respondents also bought and sold a staggering amount of prescription products in 2015. While that's not as surprising, it does add another dimension of complexity to their trading ecosystems.

**Pharmas produced a lot of products, and managed the most eaches.** Nearly 30% produced at least 500 products, and almost half of all pharma respondents manufactured anywhere between 10 million and more than 1 billion eaches.

**Wholesalers and dispensers sold more product types.** 30% of wholesalers and dispensers sold 5,000 or more products.

**Wholesalers and dispensers purchased similar volumes of eaches.** For roughly half of each segment, the number of eaches purchased ranged from 100,000 to over 5 million.

# Pharma Supply Chain: Product Volume



PHARMA



THE BIG THREE

PRIMARY  
WHOLESALE



SECONDARY  
WHOLESALE



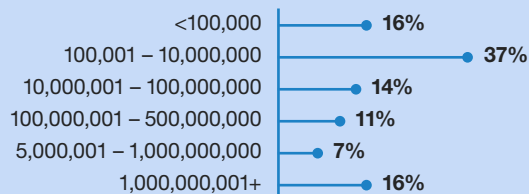
RETAIL  
PHARMACY



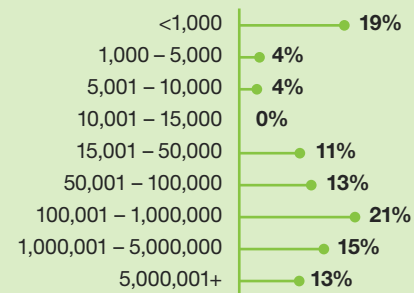
HOSPITAL



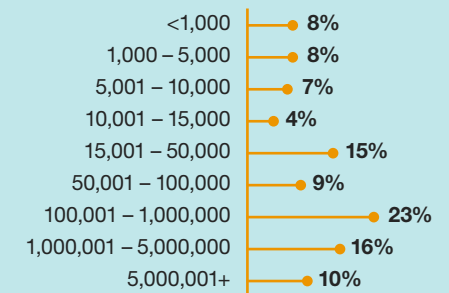
Total Eaches Manufactured



Total Eaches Purchased



Total Eaches Purchased



# The “Real” Normal: What We Learned

Data from the TraceLink Life Sciences Cloud supports this complex rendering of the supply chain. When new customers are onboarded to our network, we create connections between them and the full list of customers and suppliers that they provide to us. During 2015, we established a total of 113,000 connections between our then-200 customers and their trade partners. By the end of the year, those customers had exchanged data with more than 51,000 customers and suppliers, trading an average of 143 files with each for a total of 7.3 million files exchanged. Those files incorporated more than 60 million transaction histories for a total of over 46,000 different NDCs.

While that’s a staggering amount of data, it’s just as important to note that 62,000 – or 55% - of the 113,000 connections we created had not been used by the end of the year. Some of those likely represent connections to partners that our customers only do business with on rare occasions; others probably reflect the challenges of keeping partner master data – and a clean view of your current network – up to date.

Based on both survey and TraceLink data, it’s clear that the industry’s vision of a normal chain is pure myth, with no basis in the reality of today’s supply chain. The real supply chain is anything but straightforward, as huge volumes of product move through hundreds, thousands, or even tens of thousands of partners – and often not in the neat, linear progression of pharma to wholesaler to dispenser.

200  
Customers

143

Average number  
of files traded  
with each

7.3 M

Total files exchanged

113,000

Connections

60+ M

Transaction  
histories

Customer  
and supplier data  
exchanged across

51,000

connections

46,000

Unique NDCs



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# The Impact of Lot-Level Compliance

With large, complex trading networks, exchanging compliance data becomes a much more daunting task, requiring connectivity with dozens to thousands of partners instead of just a few. Sharing compliance documents when product isn't moving in a linear fashion is a challenge, as well. To gauge how well companies managed in the first year of DSCSA requirements, we surveyed them around five key areas.

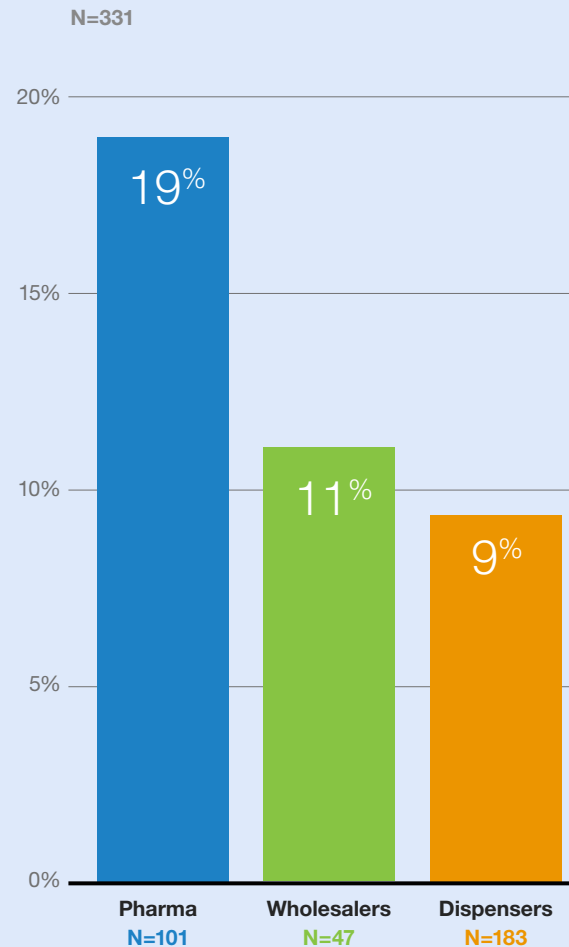
# Compliance Was Difficult for Most

Lot-level mandates took effect on January 1, 2015 for pharma companies and distributors, and on July 1 for dispensers.

Where did respondents stand at the end of the year?

- **The majority of respondents found achieving compliance difficult but achievable.** Across all segments, more than half of the companies were sending documentation to some, but not all, trading partners.
- **Some did not address the requirements at all.** 19% of pharma companies, 11% of wholesalers, and 9% of dispensers did not achieve lot-level compliance.

## Did Not Address Lot-Level Compliance



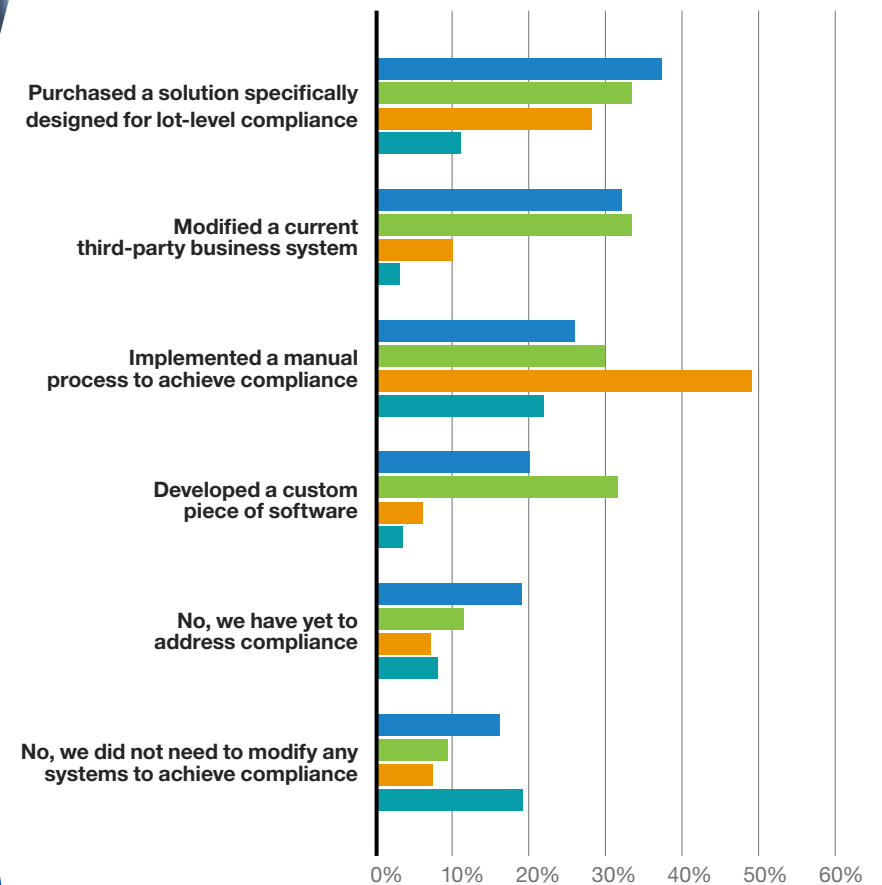


# A Multi-Faceted Approach

- **For pharma companies and wholesalers, solutions specifically designed to address compliance were not the norm.** Only a little over one-third of each segment purchased a solution built for the challenge.
- **Homespun approaches were prevalent.** Modifying existing business systems, developing custom software, and using a manual approach were common for both groups.
- **Almost half of hospitals chose a manual route.** Only 28% purchased a compliance solution.
- **Retail pharmacies relied on manual processes plus wholesaler portals.** Over one-third depended on portals and 22% went with manual.
- **Many took a multi-faceted approach.** Compliance was complicated, with many respondents using a combination of a purchased solution, existing business system, custom software, and a manual approach.

## Systems Used to Address Lot-Level Compliance

Pharma N=101  
Wholesalers N=47  
Hospital N=146  
Retail Pharmacy N=37



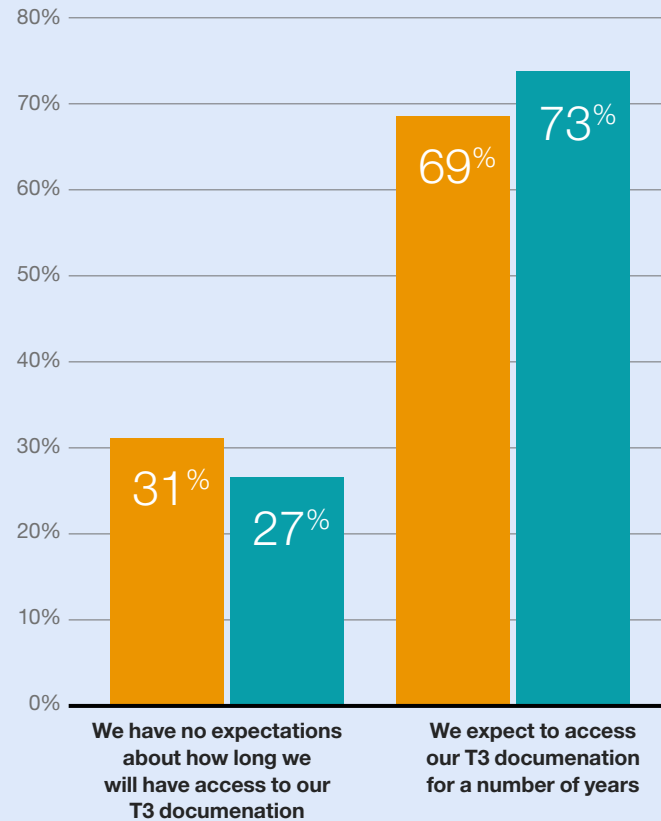
# Data Gaps Were Created

DSCSA calls for T3 to accompany all prescription products through the supply chain, but complex trade partner relationships led to gaps.



## Access to T3 Via Wholesaler Portal (N=76)

Hospital N=60  
Retail Pharmacy N=16



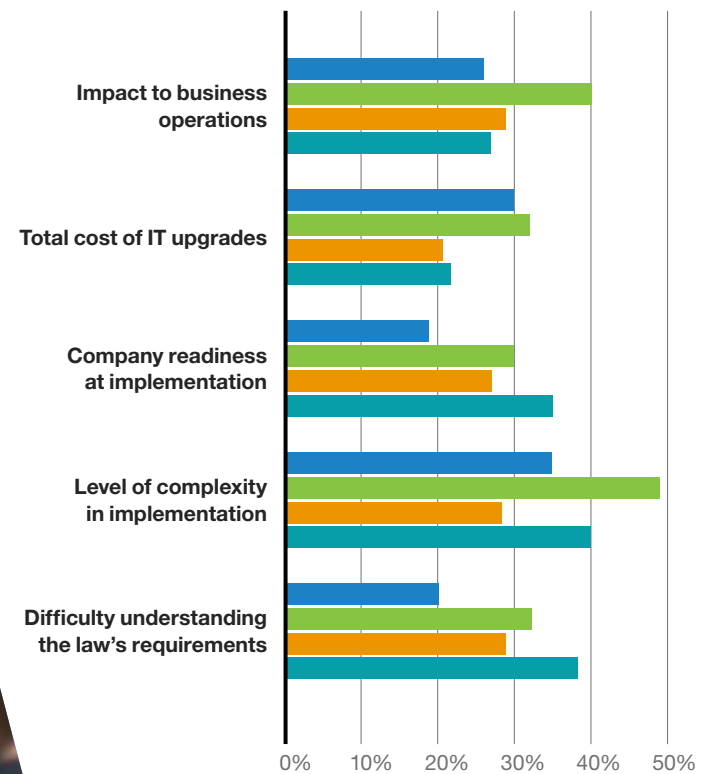
# Expectations Compared to Reality

Those who did achieve compliance reported that it was more difficult than anticipated on multiple fronts.

- **For pharma companies, implementation complexity and cost of IT upgrades were the biggest surprise.** 35% underestimated the former; 30% underestimated the latter.
- **Wholesalers were challenged by implementation complexity and operational impact.** 49% of distributors underestimated implementation, and 40% did not predict the extent of the impact on business operations.

## Where Respondents Underestimated Lot-Level Challenges

Pharma N=101  
Wholesalers N=47  
Hospital N=146  
Retail Pharmacy N=37



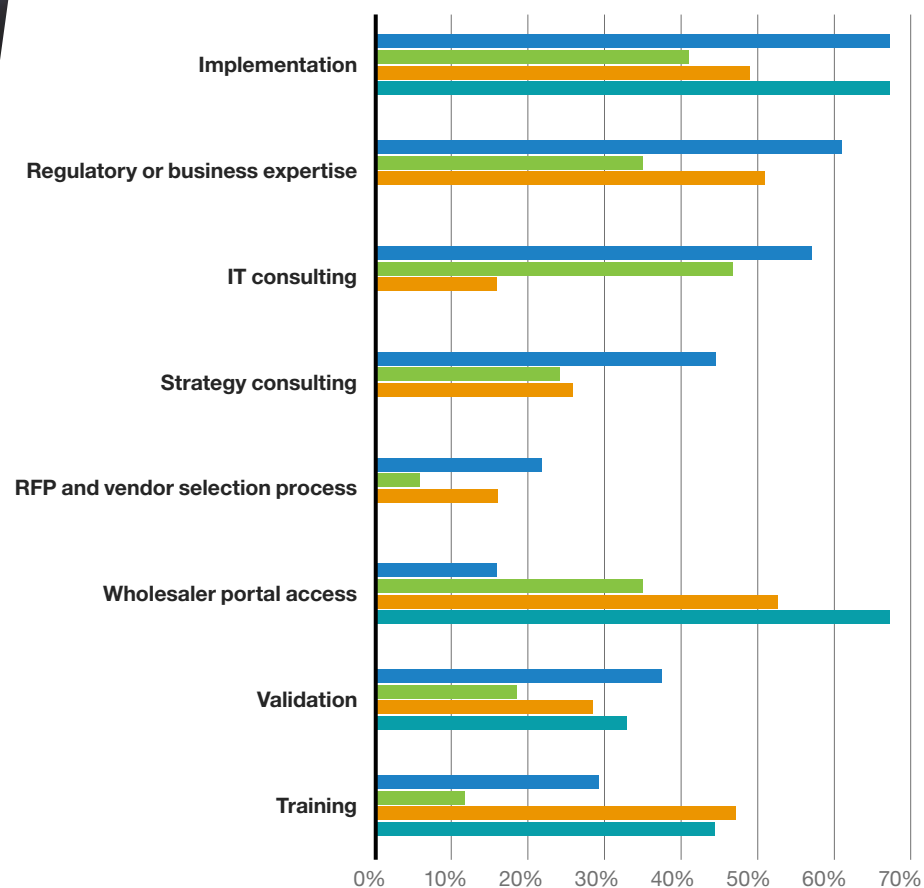
# Staff Requirements

Tackling lot-level required significant managerial, staff, and third-party resources.

- Managers were involved across the board.** Pharma companies involved the most senior staff with an average of 22; hospitals and retail pharmacies were next with 8; and wholesalers pulled in an average of 6.
- Existing staff were trained, and new staff was added.** At pharma companies and wholesale distributors, the biggest staff investments were made in the supply chain, operations, and customer service departments. At hospitals and retail pharmacies, it was pharmacists and technicians.
- Third-party resources were employed.** Pharma companies relied most heavily on third-party help, with nearly 50% reporting they contracted with an outside party, as opposed to nearly a third of wholesalers and a quarter of dispensers. Pharmas and wholesalers were most likely to tap into these consultants for implementation, IT consulting, and regulatory or business expertise, while dispensers relied on them for wholesaler portal access.

## Third-Party Resources Needed to Support DSCSA Lot-Level Compliance

Pharma N=49  
Wholesalers N=17  
Hospital N=43  
Retail Pharmacy N=9



# Exceptions

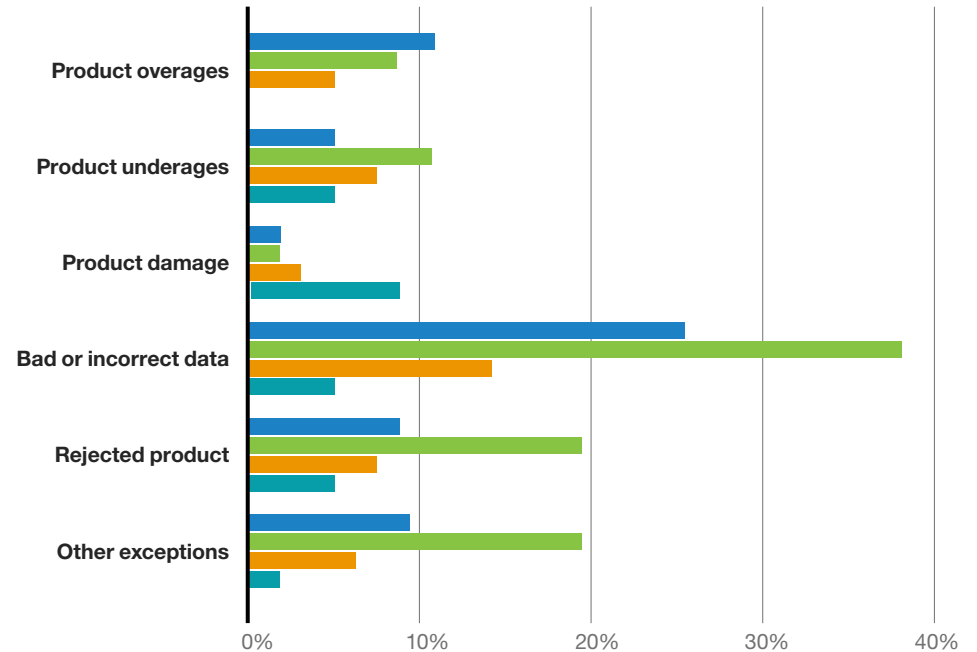
With the correct documentation now required to accompany product throughout the supply chain, all segments reported at least some increase in exceptions and product quarantines.

- **Bad or incorrect data exceptions increased significantly.** 38% of wholesalers and 26% of pharma respondents reported an increase.
- **Dispenser exceptions increased less.** Or did they? While only 14% of hospitals and 5% of retail pharmacies reported an increase in bad or incorrect data exceptions, only 53% of hospitals and 46% of retail pharmacies reported that they confirm the proper compliance documentation during product receipt. While that confirmation is not required for dispensers by law at this point, it means we don't yet have a true gauge for the quality of data being sent to dispensers.
- **Wholesalers saw a rise in rejected product exceptions, also.** 19% of distributors reported an increase.

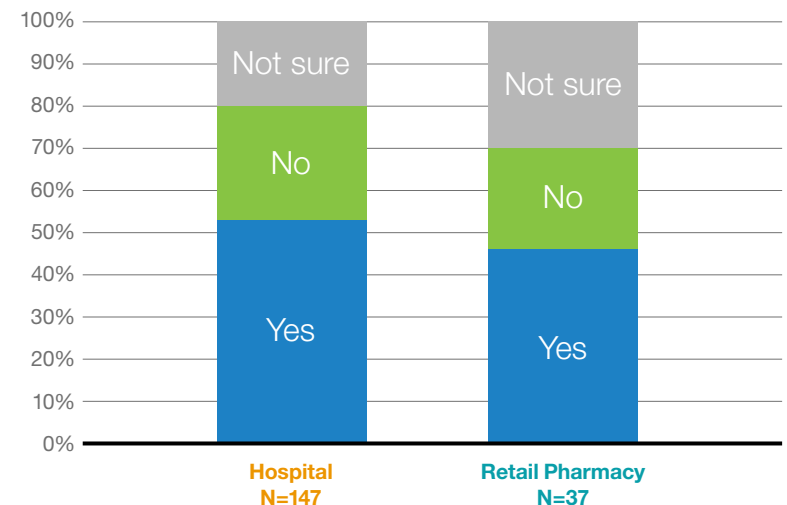


## Exception Increases Due to Compliance

Pharma N=101  
Wholesalers N=47  
Hospital N=146  
Retail Pharmacy N=37



## Confirm DSCSA Compliance Documentation for Prescription Products

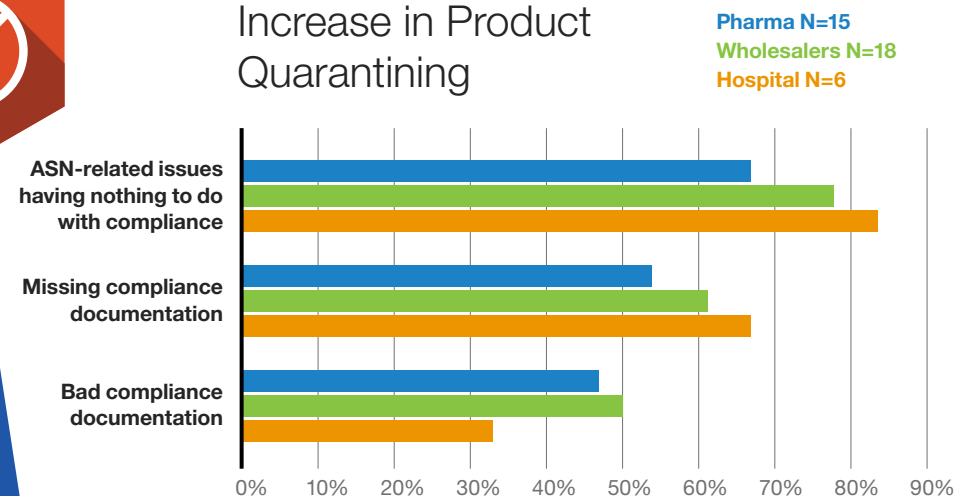


# Quarantines

- Product quarantines increased.** All supply chain segments saw an increase in quarantines. Wholesalers saw the biggest leap, with 38% reporting an increase due to compliance, followed by 15% of pharma companies, 4% of hospitals, and 3% of retail pharmacies. For all segments, the reasons for the increase included missing or bad compliance documentation or ASN-related issues having nothing to do with compliance.
- Not all companies quarantine product.** A startling number of respondents – 19% of retail pharmacies, 10% of hospitals, and 4% of pharma companies and wholesalers – reported that they do not quarantine product under any circumstances.



## Main Reasons for Increase in Product Quarantining



# Lot-Level Compliance: What We Learned

Even with significant staff resources applied, compliance was harder than anticipated. So hard, in fact, that some companies were not able to achieve it at all, and others have a false sense of security: they think of their companies as compliant, but they are not sending or receiving T3 with every partner, and significant data gaps leave them vulnerable in the event of an inquiry or investigation. With so many customers and suppliers to exchange data with in multiple fashions, the level of effort to meet DSCSA lot-level requirements was higher than most expected.

In a regulatory landscape that now requires product to be accompanied by the correct documentation, all of this raises questions on several fronts: how effective will the regulations be if supply chain companies aren't able to ensure that data gets to every customer, all the time; and what systems can be put in place to address the complexities, close the gaps, and make consistent data exchange achievable?

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# Trade Partner Demands

Regulatory requirements weren't the only ones that companies had to deal with in 2015: trade partners set their own unique expectations, adding complexity on top of the law. And there is clear indication that customer demands will continue to play a role in the future.





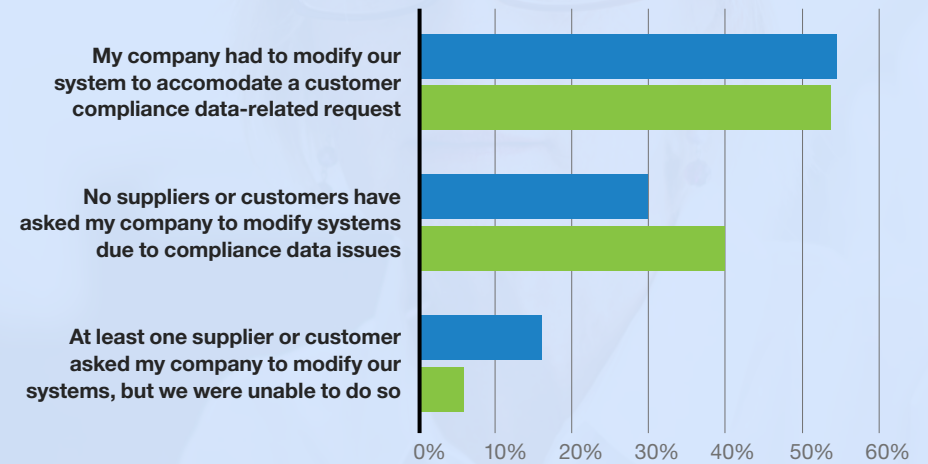
# System Modifications

Companies wanted their suppliers and customers to make changes that suited their company's needs.

- Pharmas and distributors alike complied with customer demands.** 54% of pharmas and 53% of wholesalers modified their systems to meet their customers' data requirements.
- Some couldn't do it.** Another 16% of pharmas and 6% of wholesalers were asked to make modifications but were unable to do so.
- Pharmas and distributors made demands, as well.** 44% of pharma companies and 51% of wholesalers asked at least one customer to modify systems in order to accommodate their compliance-related data requests.

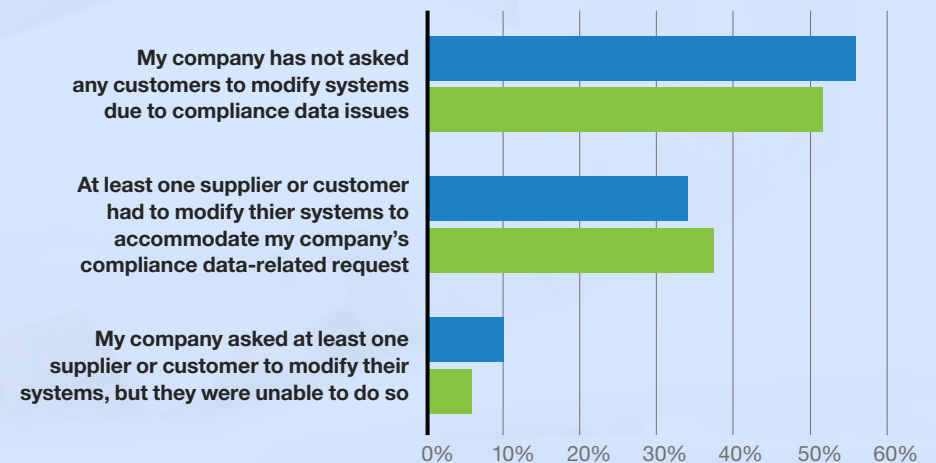
## Changes I was asked to make

Pharma N=101  
Wholesalers N=47



## Changes I asked others to make

Pharma N=101  
Wholesalers N=47



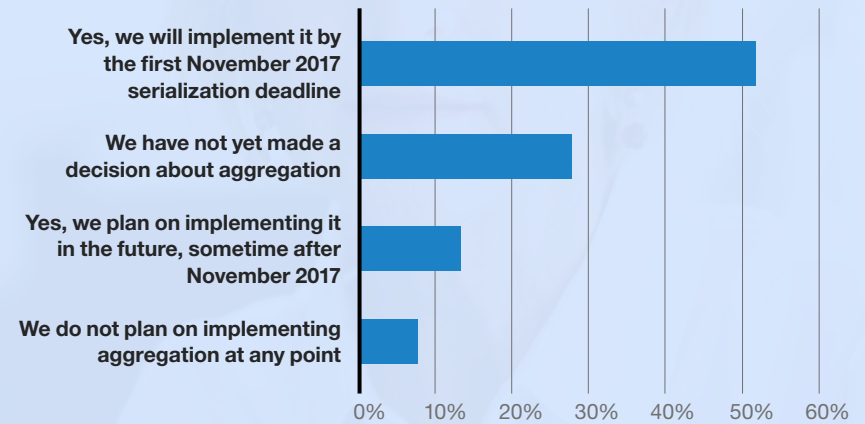
# Aggregation

While aggregation is not required in the U.S. by law, many wholesale distributors have made it clear that they want it. What will the consequences be for trade partner non-compliance?

- **Distributors want aggregation.** 26% of wholesalers plan to tell pharma customers that they require aggregated product, and 23% will express their preference for it.
- **Some pharma companies won't do it, and others are on the fence.** 8% don't plan on ever implementing aggregation and another 13% will do it, but not by November 2017. 28% have yet to make a decision.
- **Wholesalers may make them pay.** 6% of distributors have already decided to change their fee structure for product that isn't aggregated, and 83% are still considering it.

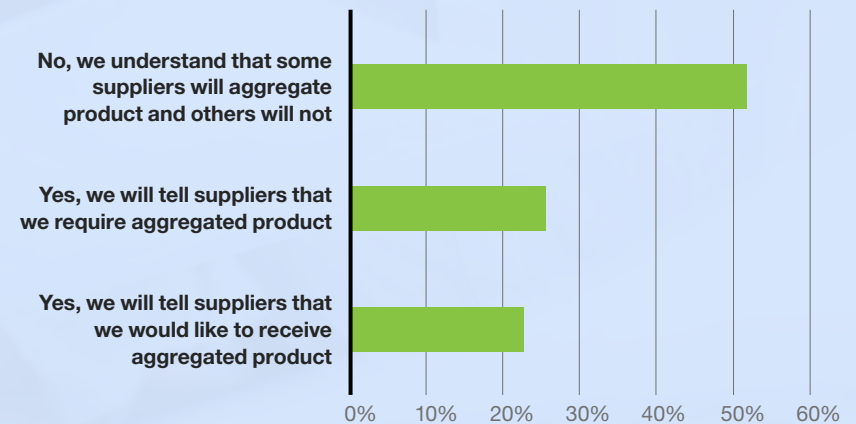
## Pharma Company Plans for Aggregation

Pharma N=101



## Wholesaler Expectations for Aggregation


Wholesalers N=47



# Trade Partner Demands: What We Learned

Meeting DSCSA requirements was just part of the battle: the lack of standards around data formats and exchange opened the door for customers and suppliers to make their own demands. With networks of dozens to hundreds or thousands of partners, accommodating all of these custom requests greatly magnified the burden of compliance, and threatened to disrupt business relationships.





# An Increasingly Electronic World

While providing paper T3 documentation was permissible by law in 2015, it introduced risk for both current-day and future compliance. Managing large quantities of paper presents operational, storage, and – most importantly – retrieval challenges. If an official inquiry or investigation requires that documentation be produced in a tight timeframe of one to two business days, locating the right paper records can be like finding a needle in a haystack. Beyond that, requirements calling for increasingly electronic data exchange phase in beginning in 2017.

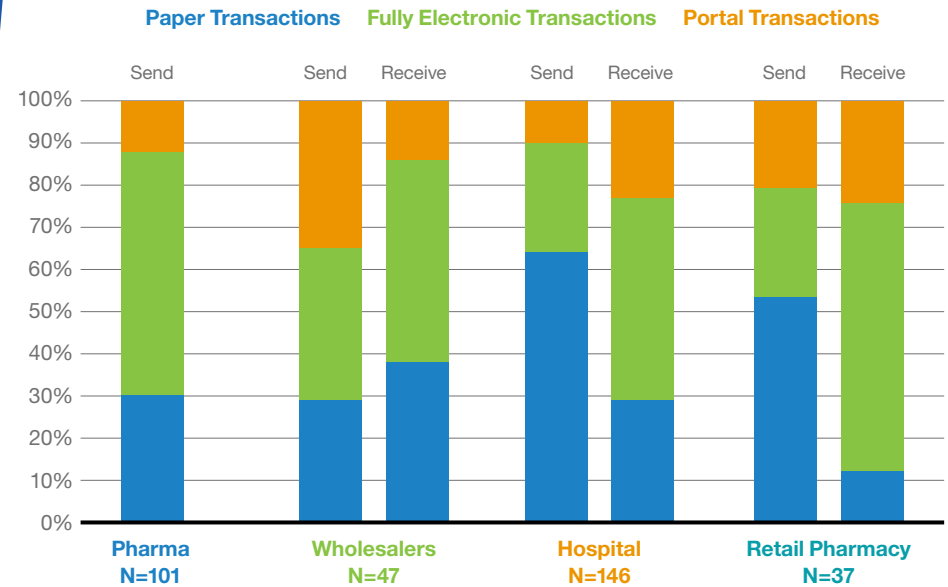
# Paper Dependencies

Every segment sent and received a substantial amount.

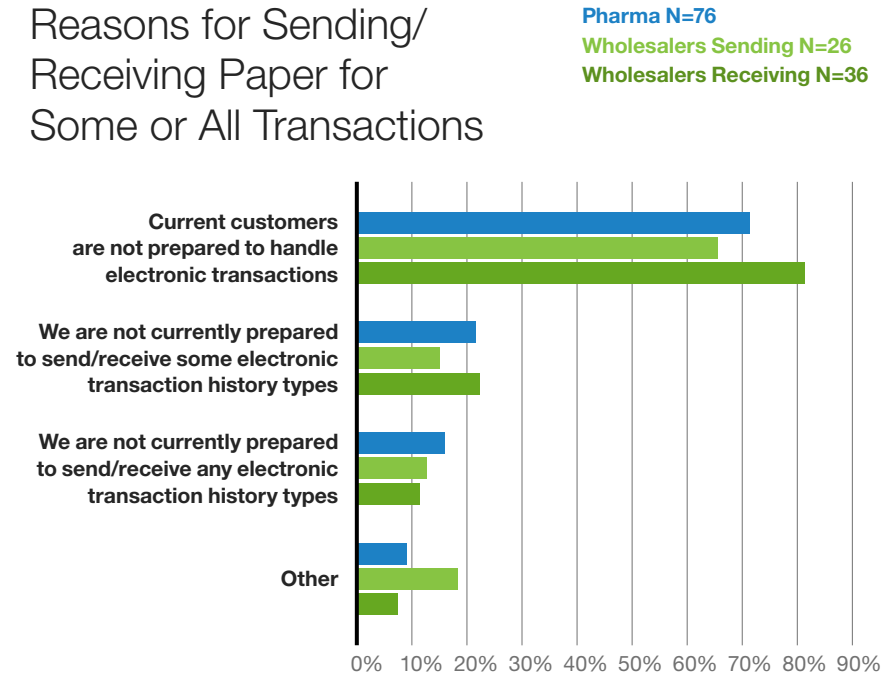
- Customer requirements drove paper sends.** Overall, 30% of pharmas and 29% of distributors' transactions were sent via paper. Pharmaceutical companies, followed by wholesalers and dispensers, were most likely to report that they sent paper because their current customers were not prepared to receive electronic transactions.
- Not all suppliers were electronically able, either.** 38% of wholesalers', 29% of hospitals', and 12% of retail pharmacies' transactions were received using paper, largely because suppliers were not prepared to send electronic types.
- Dispensers who resold product relied heavily on paper.** Hospitals sent 64% of documentation via paper, and retail pharmacies sent 54%.

75%  
 of pharma companies  
 sent at least some T3 via paper.

## Percent of T3s Sent by Transaction Type



## Reasons for Sending/Receiving Paper for Some or All Transactions



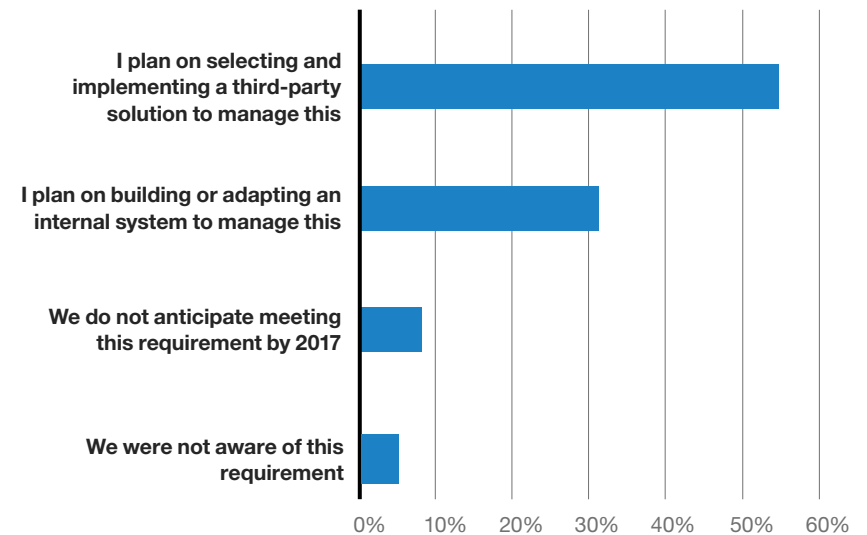
# Meeting November 2017 Expectations

Pharma companies must begin sending all T3 documentation electronically by November 2017, the same time they are required to begin serializing product. How are they planning to approach this requirement?

- **Some didn't even know about it.** 5% were not aware that this electronic T3 requirement existed.
- **Others already know they won't make it, or will cut it very close.** Another 8% of respondents do not anticipate meeting this requirement, and 20% will do so within just a month of the deadline.
- **A quarter of pharma companies haven't thought through the details.** When asked how they will enable and deliver electronic T3, 26% did not know while the others plan to use EPCIS, ASNs, portals, or other means.

## Meeting the 2017 Requirement for Sending Electronic T3

Pharma N=74



# An Increasingly Electronic World: What We Learned

For a law that was designed to help the supply chain electronically track product movement, the industry is off to a remarkably manual start. Paper was prevalent for every segment in 2015, and pharma respondents are not demonstrating a lot of confidence heading into the first electronic hurdle.



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# Gaps for Serialization

While some respondents feel well-prepared for serialization, many others don't, and tough questions on exactly how the serialization challenge will be tackled remain.



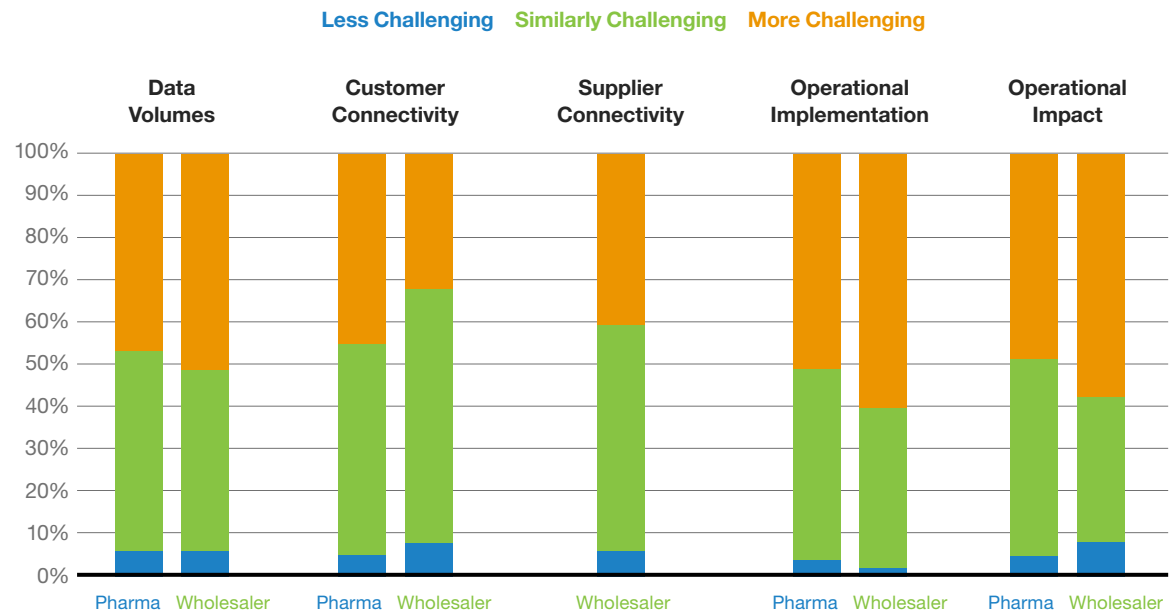
# Expectations for Serialization Challenges

Respondents pinpointed the areas of greatest concern.

- **Pharmas expect increased complexity across the board.** About half of pharma companies feel that serialization will be more challenging in terms of data volumes, customer connectivity, overall implementation, and operational impact.
- **Wholesalers are most concerned with implementation and operational impact.** Those are the two areas pinpointed by the majority of distributors – 60% and 57% respectively – to be most challenging.

## Expectations for DSCSA Serialization On Various Measures

Pharma N=101  
Wholesalers N=47

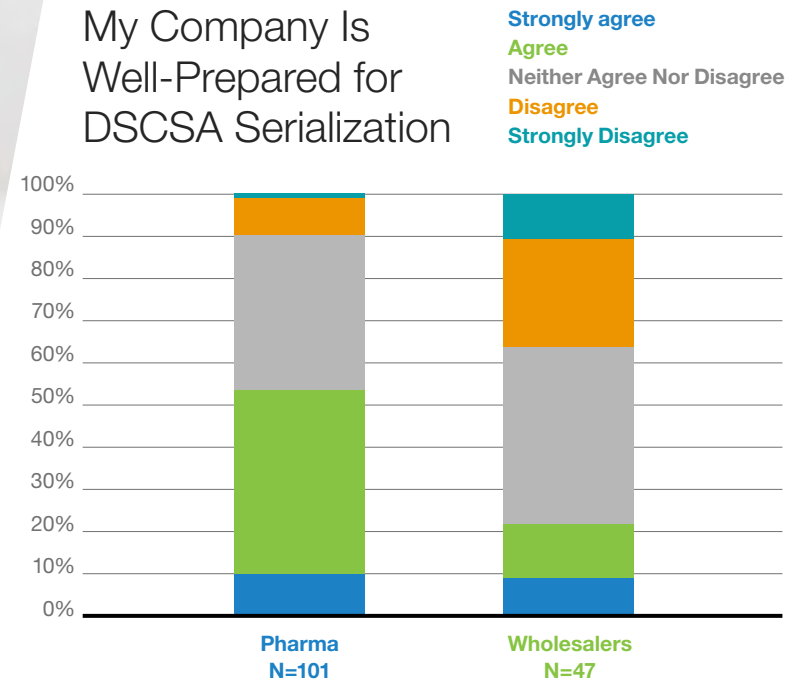


# Serialization Readiness

With the first serialization deadline in November 2017, there is ground to make up.

- **Only 54% of pharmas believe they're ready.** Of those who do feel prepared, nearly a third cited their understanding of all the requirements as the main reason.
- **Far fewer wholesalers feel ready.** Only 22% of distributors feel their company is prepared. Those who don't feel prepared worry about the clarity of implementation requirements, and connectivity to suppliers.
- **Format questions remain.** 35% of pharmas and 62% of wholesalers are unsure of their preferred format for sending serialization data. The pharma companies who know what they want have a clear preference for EPCIS, whereas the undecided wholesalers are split between EPCIS and serialized ASNs.

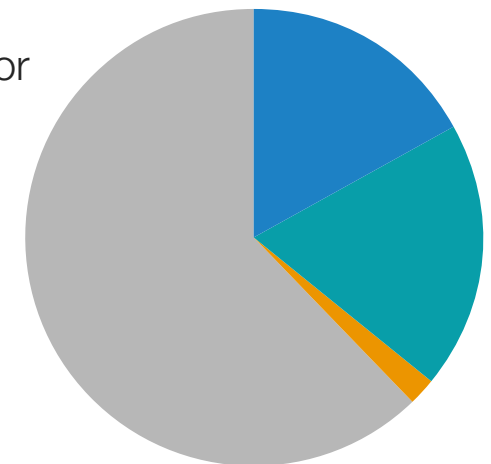
## My Company Is Well-Prepared for DSCSA Serialization



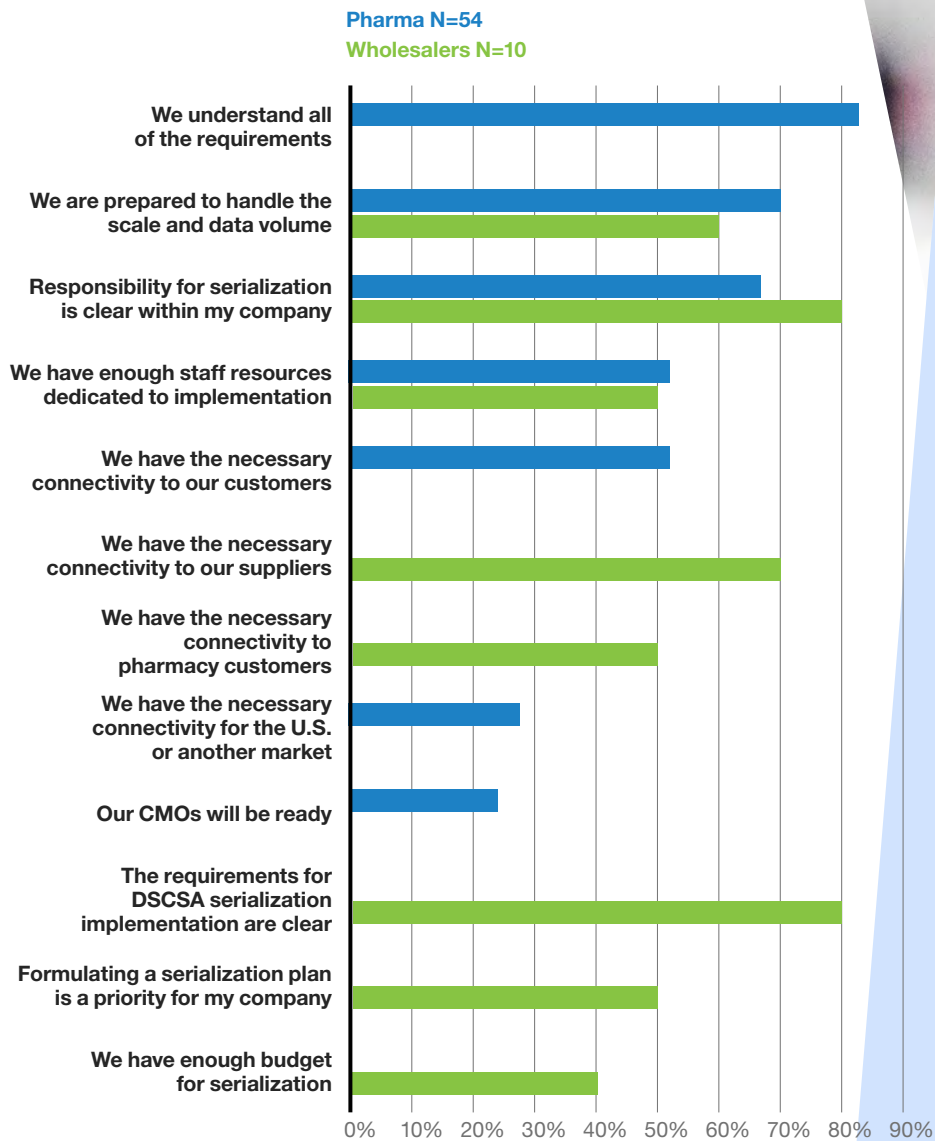
## Preferred Format for Sending Serialized Information

Wholesalers N=47

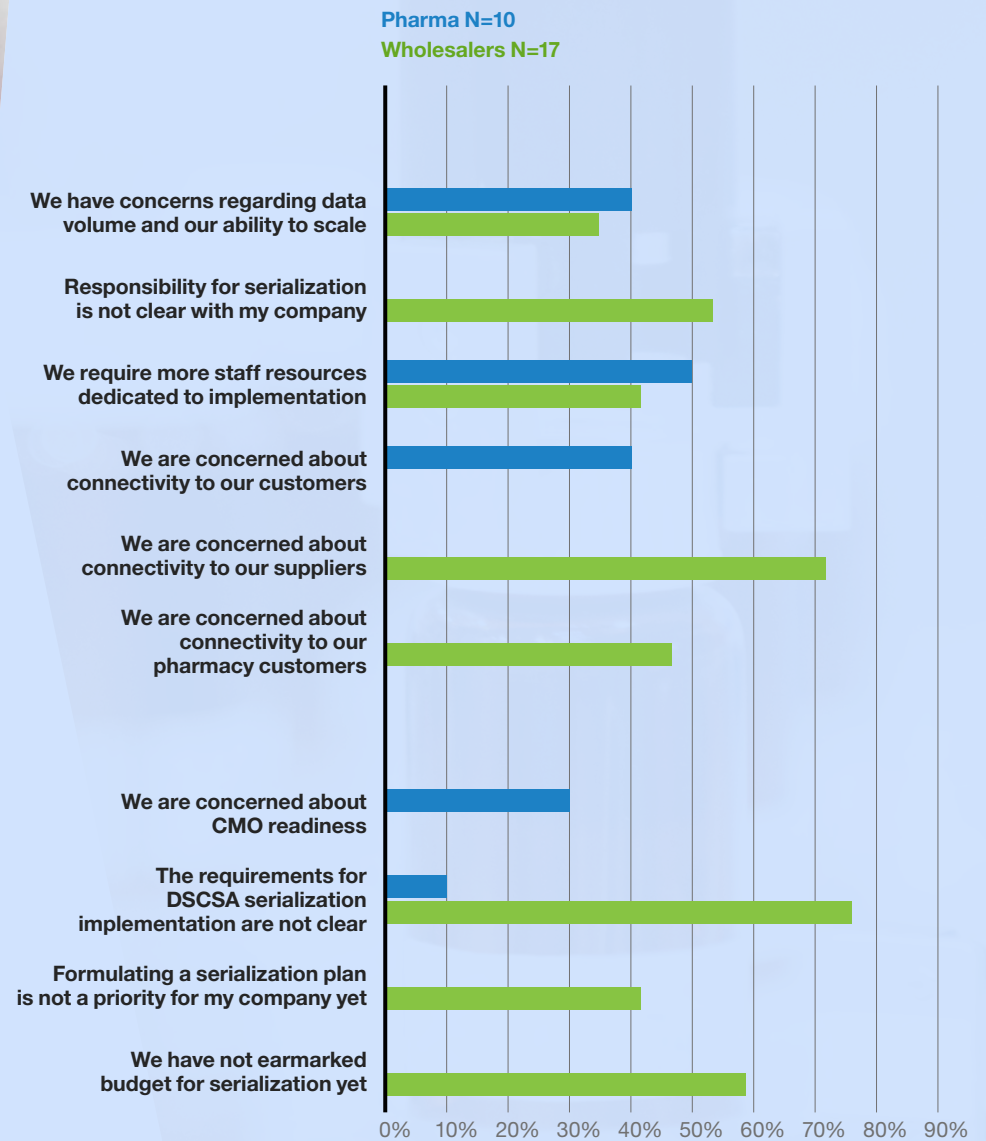
- EPCIS 17%
- Serialized ASNs 19%
- Other 2%
- I don't know 62%



## Pharma Companies and Wholesalers: Why They Feel Prepared for Serialization



## Pharma Companies and Wholesalers: Why They Don't Feel Prepared for Serialization



Note: Question sets for pharma companies and wholesalers varied slightly based on different business needs.

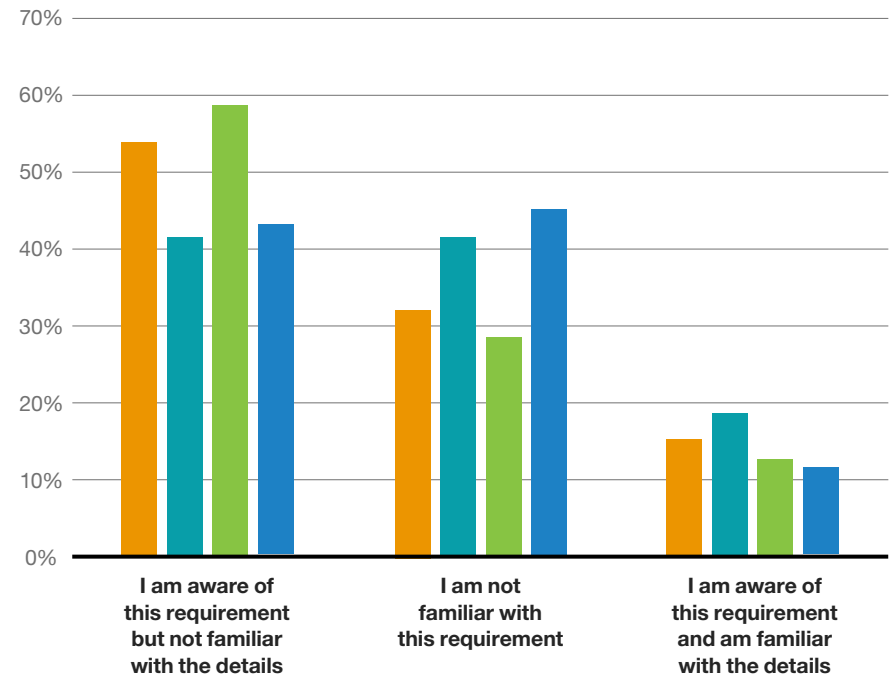
# Hospitals and Pharmacies: Serialization Readiness

## Dispensers are still learning that there is a requirement.

32% of hospitals and 41% of retail pharmacies were not at all familiar with the 2020 requirement that they accept only serialized product. 29% of hospitals and 46% of retail pharmacies were also unaware of the 2023 stipulation that all transaction data be exchanged between them and their suppliers electronically.

## Aware of DSCSA Serialization and Tracing Regulations

Hospital Serialization Regulations N=146  
Retail Pharmacy Serialization Regulations N=37  
Hospital Tracing Regulations N=146  
Retail Pharmacy Tracing Regulations N=37



# Staffing for Serialization

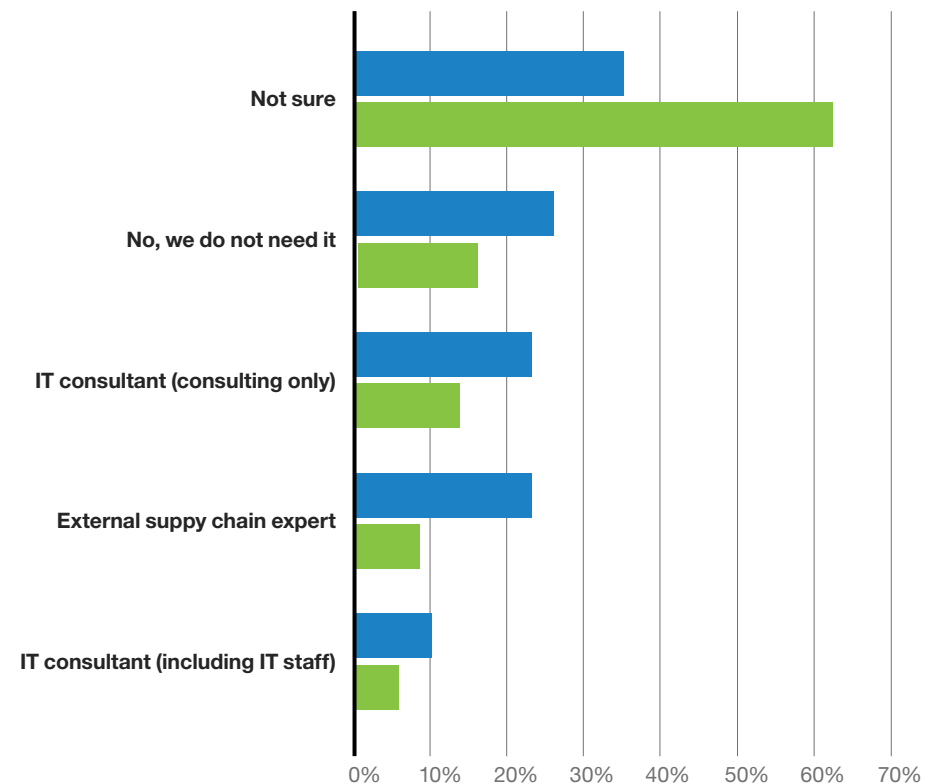
We saw how many human resources were applied to lot-level compliance, and yet companies still struggled. Many respondents are undecided on their plans for serialization support.

- **Pharma companies and wholesalers don't currently have big hiring plans.** The vast majority of both groups say they do not plan to hire more staff, or they are still unsure.
- **Ditto with third-party advisory resources.** 35% of pharma companies and 62% of wholesalers aren't sure if they'll bring in outside help, but some – 26% of pharma, 17% of distributors - have already decided they don't need to.

## Plans for Using Third-Party Advisory Resources for DSCSA Serialization

Pharma N=101

Wholesalers N=47



# System Decisions

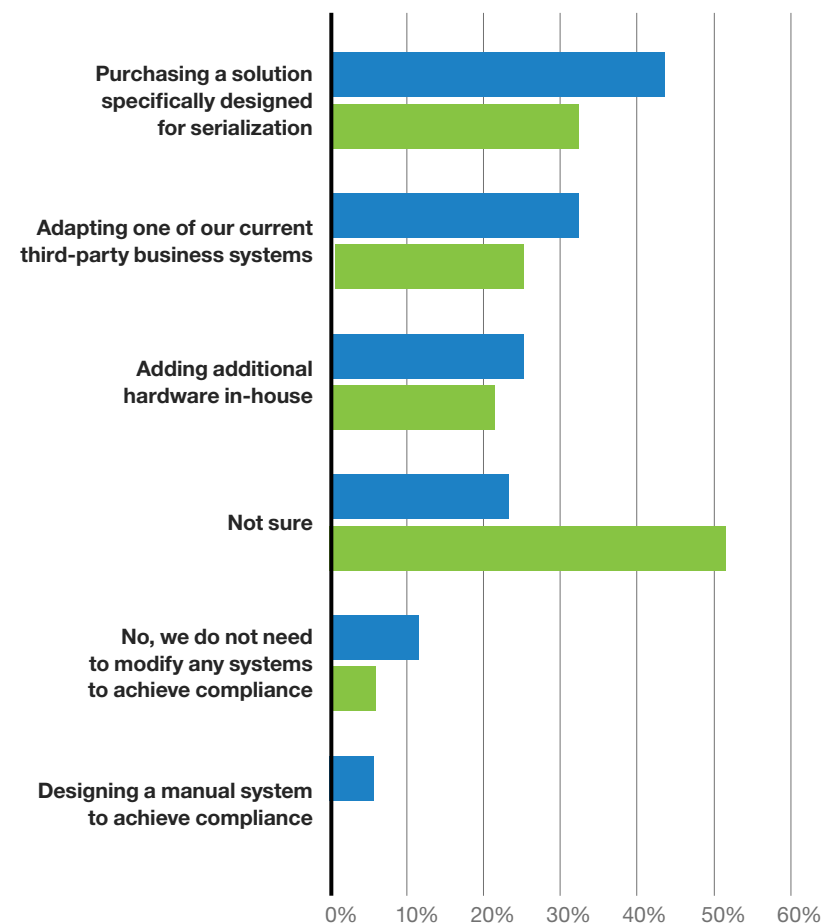
Despite the challenges seen with lot-level, and the widespread acknowledgement that serialization will be even more complex, many companies still plan to risk a jerry-rigged system.

- **Less than half of pharma companies will purchase a system designed for the challenge.** While more plan to pursue this route than did for lot-level – 43% versus 37% – the rest will adapt current third-party business systems, add hardware, or design something manual.
- **More than half of wholesalers are still undecided.** While they have an additional two years before their deadline, most are unclear on their approach.

## Changes to Supply Chain Management Systems for DSCSA Serialization

Pharma N=101

Wholesalers N=47



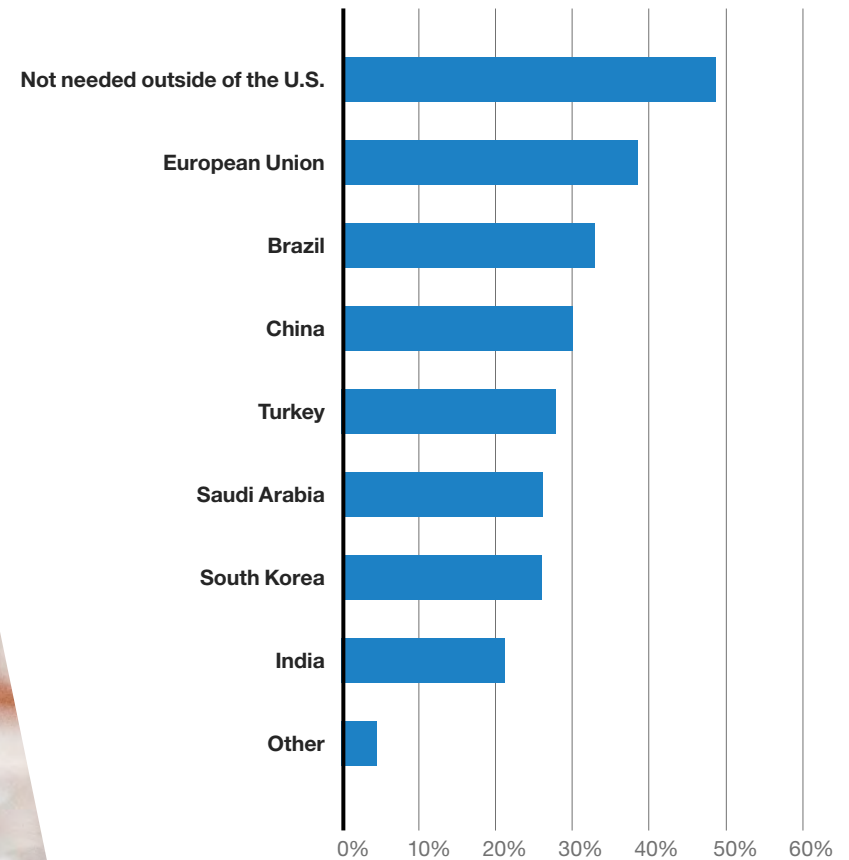
# Serialization: A Global Challenge

Many pharma companies and a handful of wholesalers will need to prepare for other markets as well.

- **The European Union tops the list for pharma companies.**  
Companies focused on the U.S. and the European Union – with its early 2019 deadline – have a lot of work to do in a short time.
- **A small group of wholesalers have a non-U.S. requirement.**  
11% must prepare for another market, primarily the European Union.

## Additional Serialization Market Requirements for Pharma Respondents

Pharma N=101



# Gaps for Serialization: What We Learned

Lot-level compliance was more difficult than anticipated, and many companies did not fully rise to the challenge. Our survey data suggests that the industry is going down a similar, but more concerning path towards serialization: respondents acknowledge it will be harder and generally don't feel prepared, and many key questions remain.







# Conclusion

**The 2016 Global Drug Supply, Safety and Traceability Report is the first and most comprehensive data set to evaluate the impact that new pharmaceutical supply chain regulatory requirements are having on the ability for prescription drugs to reach patients safely and securely. With an equal weighting applied to every manufacturer, distributor and dispenser across the entire pharmaceutical industry, the Report reveals that the real supply chain is much more complex than products flowing through a simple and “normal chain.”**

Without question, DSCSA lot-level compliance in 2015 was significantly harder to implement than expected. Complex ecosystems of hundreds to thousands of partners, many of whom made unforeseen demands for custom accommodations, meant that meeting the requirements was a daunting – and for some, completely unattainable – endeavor. In 2015, the reality was that the regulations did not always protect drugs and patients in the way that DSCSA intended.



As companies prepare for serialization, the industry faces numerous challenges in achieving fully electronic data across complex trade partner ecosystems. Serialization adds even greater complexity as CMOs begin to play a role in compliance, and data volumes increase dramatically. Pharma companies will be coordinating with dozens to hundreds of contract partners, and generating 10,000 to 100,000 or more times the data that they've managed with lot-level requirements. That data must be exchanged with partners, stored for a required period of time, instantly accessible for verification, and managed in such a way that it doesn't impact critical business efficiency.

The 2016 Global Drug Supply, Safety and Traceability Report reveals that the impact of not achieving compliance is real. Products are held up in the shipping process. Some are quarantined – proving that medicines won't reach patients if they are out of compliance. In the name of patient safety, it is imperative for all businesses across the supply chain – regardless of product volume, revenue size or global reach – to continue working together toward an effective and efficient, interoperable model that facilitates end-to-end digital connectivity and information exchange.

**Those who perpetuate the belief of the normal chain – and a simplistic view of interoperability – will undoubtedly fall short of meeting regulatory requirements, delay the flow of critical medicines to key markets, and put patients' lives at unnecessary risk.**

A close-up photograph of a person's hand holding several capsules. The hand is in the foreground, and the background is blurred, showing another person's hand holding a glass. The image is partially overlaid by a blue geometric shape on the right side.

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# 2016 Global Drug Supply, Safety and Traceability Report™

Using 2015 Lot-Level Learnings to Understand Future Serialization Challenges

For more information email [questions@tracelink.com](mailto:questions@tracelink.com).