Pharmaceutical Serialisation & Traceability 2016

INDUSTRY REPORT

Report Partners

Cognizant

ADENTS

Pharma iQ
a division of IQPC

FOREWORD

Cognizant

The war against counterfeit pharmaceuticals in the supply chain is well underway, with more than 40 markets – those of which including the EU, US, South Korea, Brazil and China, deploying pharmaceutical track and trace laws. According to industry specialist Tracelink, by the end of 2018 more than 75% of the globe's prescription medications are expected to be protected by legislation.

Our research last year showed that even through pharmaceutical firms seemed to be experiencing growing pains as they evolved to new requirements, the tall task of serialisation is one that appears to be within reach for most via apt planning and testing.

However, minor industry confusion remained in certain corners of the market, aggravated by the lack of cohesion between countries' varying legislative approaches. One survey member highlighted the frustration caused by 'moving targets' and similarly a level of research participants predicted that the publishing of the EU Delegated Acts would be delayed once again. Experts predicted that once the acts (Acts) were published, they would help 'tighten up loop-holes' and be instrumental in the market's maturation towards global harmonization.

2016 witnessed the publishing of EU Falsified Medicines Directive (FMD). The FMD regulations declare that the following specifications must be on every medicines pack: a unique identifier in the form of a two dimensional data barcode and the verification of safety features which include the integrity of the anti tampering device. A lead time of just over two years has been set, leaving some questioning whether this will be enough time for the entire market to evolve to the requirements. Industry players are experiencing another time pressure on protecting their current market access as the next level of the US DSCSA is due to go live next year.

This year's research report maps out and measures the changes in consensus as the industry advances closer to an entirely track and traced pharmaceutical environment.

Hope you enjoy

Chanice Henry
Pharma IQ Editor.

ABOUT THIS RESEARCH

Cognizant

Over the past three years, Pharma IQ has conducted a Serialisation Industry Report as to capture and pinpoint the trends within the global pharmaceutical market's supply chain track and trace progress. Using the rapidly depleting lead time until regulations are enforced around the globe as a backdrop, this research report uncovers the methods and strategies being deployed, allocated budgets and resources, pain points and mistakes made in implementation as well as the opportunities for innovation.

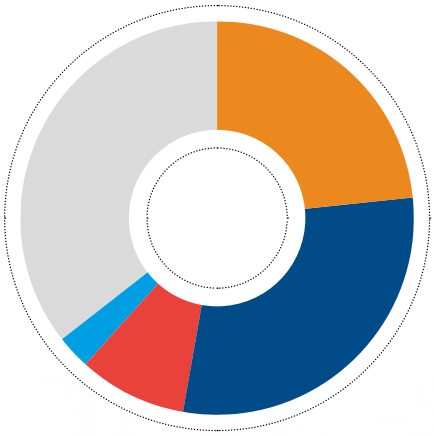
The data presented in this year's report was collected from April to June of 2016 targeted at Pharma IQ's pharma and biotech professionals.

Quite a large segment of the survey base is represented by **SME (small to medium) pharma / biotech manufacturers.** These players are understood to be at the early stages of implementation. Whereas, **large bio and pharma manufacturers,** which make up 23.5% of our respondents, are known to be optimising their projects and tackling the challenges of running a successful strategy that can achieve returns. Other entities represented in the research base include, pharma distributors, logistic service providers, technology providers, training institutes and hospitals.

Functions that individual participants represent are mostly within supply chain and packaging followed by IT. Other verticals featuring include quality assurance, intellectual property and market access.

Where possible this year's survey has been benchmarked against Pharma IQ's legacy reports and expert analysis provided on the results

What profile company are you from?

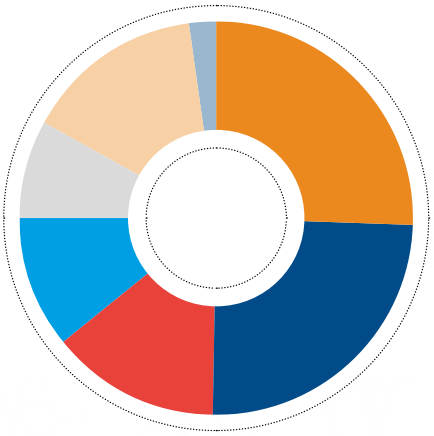


- Large pharma/bio manufacturer **23.5%**
- Small-to-mid-sized pharma/ bio manufacturer **29.6%**
- Medical device manufacturer **8.6%**
- Government **2.5%**
- Other* (please specify) **35.8%**

*Other

Consultant | Security Consulting Documents and brands | Logistics Service provider | training institute | Hologram Manufacturer | we detect counterfeit drugs | Service Company (IT and business) | DQSA Enterprise Solution Provider | C&Q Services | Medium Sized Pharma Distributor | Serialisation and Traceability Technology Provider | IPR. | Premdia Packaging | Mid size virtual pharmaceutical company | Hospital

Which function do you sit in?



- Supply Chain **26.2%**
- Packaging **24.6%**
- Manufacturing **13.8%**
- Quality Compliance **10.8%**
- Regulatory Affairs **7.7%**
- IT **15.4%**
- Procurement **1.5%**

*Other

Project Manager | Business Development | Consulting trainer | Marketing | Quality Assurance | Market access | Manager Track and Trace | SaaS solution provider | Engineering | PMO - Organizational Change Management | Work on counterfeits. IPR | QMS and Regulatory | Compliance with standards | Validation | Serialisation Solution project delivery

PLANNING

Cognizant

Different levels of approach

In regards to the varying approaches to reaching complete serialisation, in a recent article Agnes Shanley of PharmTech (1) outlined 4 distinct strategies:

1. Proactive, aggressive rollout of global track and trace programs.

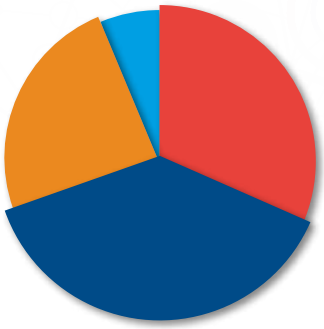
Firms which are following this method are building an agile infrastructure which accommodates worldwide regulatory requirements and aims to futureproof its system so as to flex to compliance updates and new expectations. Cost, risk and time efficiency is of prime importance to preserve their current market access of their products and potentially increase their market share via competitive advantage. Other game-plans could include ensuring optimal team composition and engagement to both comply with and profit from serialisation, through added supply chain visibility and integrating production lines and data usage in real time.

Item 1 shows that 69% of our participants are opting for a global approach to implementing serialisation. A similar trend was seen in 2015, as indicted by item 2. However last year more people expressed strong confidence that their firm was taking a global approach to serialisation.

2014 experienced the most strongly disagreed responses to this question with 12% of the research base opting for this. The 30% of the 2016 base which said their firm does not have a clear roadmap for global serialisation track and trace are likely to have opted for one of the other routes mentioned below.

Item 1

My organisation has a clear and robust roadmap for serialisation / track and trace globally?



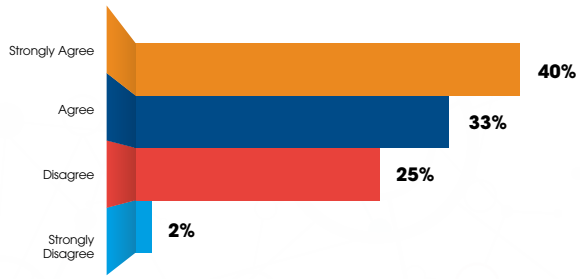
Strongly Agree	31.6%
Agree	38.0%
Disagree	24.1%
Strongly Disagree	6.3%

PREVIOUS RESEARCH RESULTS

Item 2

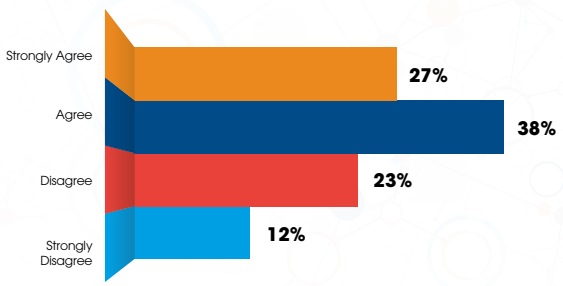
2015

My organisation has a clear and robust roadmap for serialisation / track and trace globally?



2014

My organisation has a clear and robust roadmap for serialisation / track and trace globally?



Cognizant

Jim Cummings, Vice President of Adents (Americas):

It's a fact. Every organization within the pharmaceutical supply chain, will see some sort of impact within the organization as a result of global compliance. How you plan and strategize a comprehensive approach is unique to your organization and trading partners.

So many factors play into planning and strategy for such an effort. First, global compliance is fluid. Countries are continuously changing laws while trading partners also change their strategies.

The numbers on this report regarding planning represent the aggregate. However, the individual organization has unique needs. For example, if your organization is only producing product for China, then you have a pretty fixed target. Even with the recent shake up of Alibaba, China, for now, remains to be adamant that their SFDA Track and Trace serialisation mandates will not change in any significant way.

On the other hand, if you are trying to be compliant with the EU FMD or South Korea, things are still fluid and the target is somewhat of a moving one.

Bottom line is that whether you should take a passive or an active approach to global compliance depends on your organization's unique needs. When choosing a vendor or multi-vendors to help guide you through global compliance. Ensure that the vendor(s) can address your needs satisfactorily.

Finally, another factor to consider are your trading partners. Big guys, like McKesson, must also meet global compliance mandates. Over the years, we have seen these trading partners have a great impact on global compliance, in particular, mandated deadlines.

Cognizant

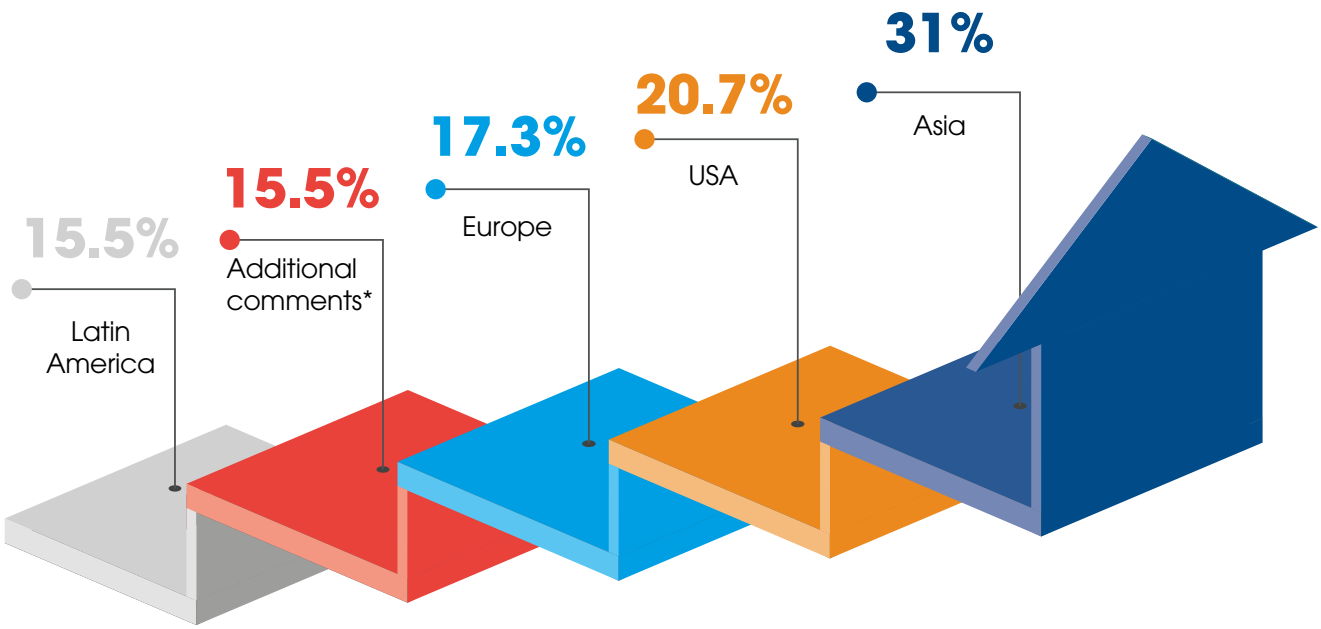
2. Incremental deployment in a "just in time," localized approach

Firms using this route have chosen to compartmentalize the track and trace process by country. This choice can be underpinned by resource limitations or perhaps operating strategies that prefer focused localized decision making.

In regards to which continents are seen as the most challenging in the formulation of a serialisation strategy - Asia was the region which came out on top. One participant noted: **"Europe and the US were the least challenging as these have harmonized approach - Multiple regulations and Track and Trace add significantly to the complexity."** However, even with the harmonized approach and added clarity within the US and EU, the road to full compliance in these regions is highly pressured due to their time constraints.

The next level of the US DSCSA is due to come into force in late 2017 - requesting that all manufacturers serialize product, the following level will come into play by 2023.

What continent is the most challenging when it comes to creating a serialisation strategy?



*Additional comments

No major differences

SFDA, GCC

Europe and US are the least challenging as these have harmonized approach. Multiple regulations and Track and Trace add significantly to the complexity

Cognizant

"AsiaPac and EEME (Eastern Europe Middle East) are shaping up to be highly fragmented regions where there is yet to evolve a cohesive approach similar to the EU or a singular approach as in the US. This fragmented evolution coupled with a lack of visibility – late publications of new regulations often only in local languages with little to no time to react – are the primary drivers for this complexity and risk. The best approach to managing this risk is to leverage local regulatory experts and to tap into local industry forums for knowledge sharing and to actively lobby the relevant National Health Agencies responsible for issuing regulations." - Pari Sanghavi

Cognizant

The EU Falsified Medicines Directive (FMD) was labeled as a slow and arduous process to: 'ratify and may be equally difficult to implement', with some pharma companies being relatively gradual in the renovation of their product lines initially. Industry analysts have identified that the major re-engineering demanded for packaging lines stood as a large, invasive and expensive task - with some questioning as to whether the window given will be achievable especially for smaller firms. The initial lack of speed in implementation was attributed to the need for further clarity of the FMD requirements.

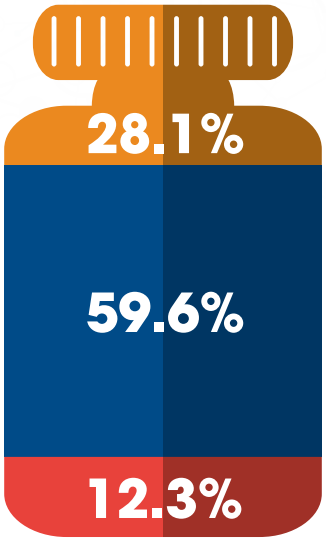
This year has seen a major movement with the Falsified Medicines Directive as the Commission published the delegated regulation in the official journal.

Manufacturers now have until February 9th 2019 to adhere to the requirements, which is when the regulation will come into force.

In response to whether the EU FMD's 2019 deadline is enough for the proper testing of serialisation, 60% of our respondents said yes but only just enough and 12% disagreed that it was enough time. This result highlights the importance of prompt and streamlined implementation.

One participant questioned about the involvement of hospitals within the chain.

Do you think the deadline of Feb 2019 in regards to the EU Falsified Medicines Directive is enough for the proper testing of authentication systems for the unique identifiers?



Yes- The industry will have ample time

Yes- But only just enough.

No

*Additional comments

How are the hospitals are getting involved as part of the chain? The investiments are huge in another pieces in the chain

Cognizant

"Six years (since 2013 and new regulations in 2015) seems time enough for organizations to plan and deploy serialisation processes since a good number of organizations are already implementing something similar across the globe. The industry is clearly showing its commitment to serialisation and driving it on priority. However, the reality underlying this picture is that the pace of adoption is not uniformly advanced. While larger manufacturers are actively mitigating any potential risks associated with meeting the impending deadlines, smaller organizations naively assume that they can effectively delay serialisation related investments until the last possible moment. Due to the limited manufacturing capacity for line level serialisation equipment across the leading equipment manufacturers there is a very high risk of missing key deadlines by taking a 'just in time' approach to serialisation in the EU. Additionally, with the impending Brexit and other EU countries possibly requiring minor local variations to the EU FMD regulations, keeping track of and prioritizing implementations will be a significant challenge if Country specific variation turns out to be significant.." - Pari Sanghavi

3. Just getting started in understanding the regulatory and business requirements, and compliance planning.

This approach is seen within the SME pharma - biotechs and virtual entities. This is a serialisation project within its primary stages where infrastructure required is being outlined, partners and CMOs are being evaluated for these new business expectations. Some firms in this bracket are understood to have planned to outsource serialisation efforts, however this notion has depleted in popularity as more understanding was gained on internal requirements needed for this model and the risks with some forms of complete outsourcing

4. Haven't undertaken a formal internal serialisation compliance program at all.

Here, the entire serialisation compliance and decision making is outsourced. Some in this category maintain that the enforcement of these regulations will be delayed.

Surprisingly, a minority of our participants labeled themselves as not having thought about serialisation yet at all, which will be discussed within the next section

Cognizant

"Compliance is key to meeting serialisation requirements. Processes, systems and training will need to defined, documented, validated, updated, and revalidated. FDA audits, responses to events related to drug and patient safety across the supply chain, suspect product, returns and reintroducing return product into the supply chain will all require an internal compliance program for all entities in the supply chain. Outsourcing the process of building out the compliance program to consulting firms with the requisite expertise such as Cognizant will help to speed up their serialisation programs in an optimal and cost effective fashion. While the FDA will obviously not begin auditing all manufacturers all at once, it is highly recommended that manufacturers and CMOs are complaint with the regulation lest they come up short once the FDA does actually begin to audit such systems, processes, and data. " - Pari Sanghavi

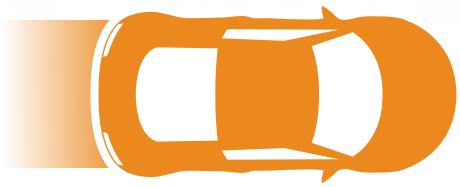
PROJECT PROGRESS

Cognizant

In regards to the status of implementation, in the 2016 research less members stated that they had not started planning than those last year. Some may note the existence of even a small level of people who have not started thinking about serialisation yet is surprising – which is seen in item 3 and 4 .

Item 3

My organisation...



5.4%
Has not started thinking about serialisation yet

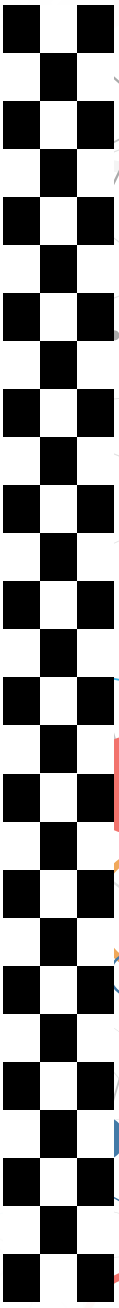
20.3%
Is in early planning phases

21.6%
Is currently looking for solution providers to partner with

13.5%
Has started rollout in one site (pilot)

25.7%
Has started rollout across multiple sites globally

13.5%
Has fully implemented



*Other

We detect counterfeit drugs using NFC technology

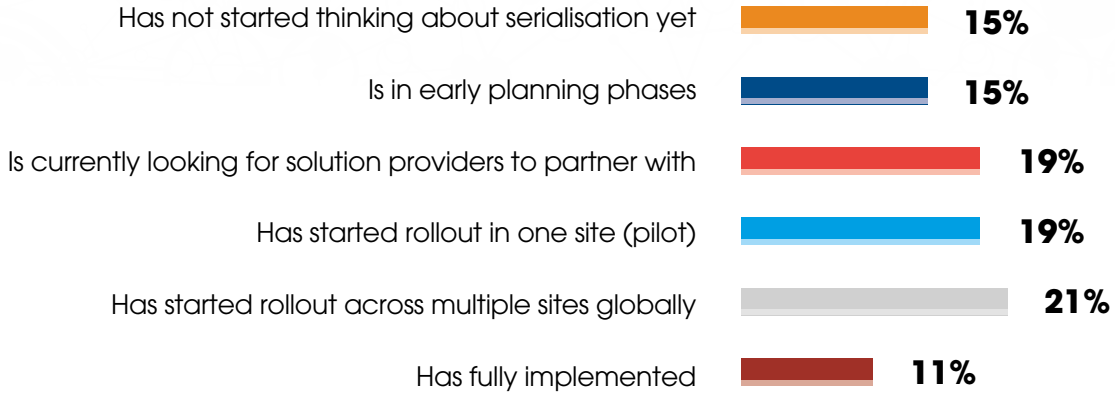
We have customers with worldwide rollout

Cognizant

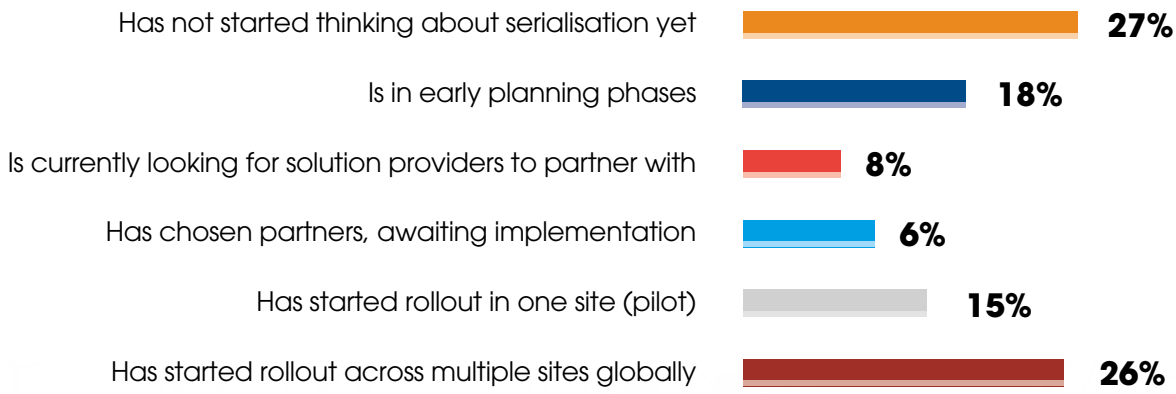
PREVIOUS RESULTS

Item 4

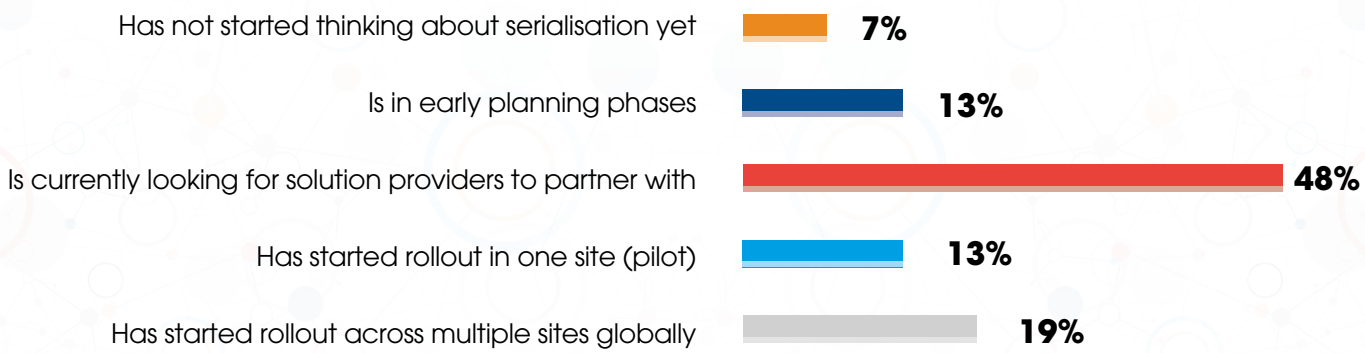
2015 My organisation...



2014 My organisation...



2012 My organisation...



The late adopters who have evaded until now are going to be critically reliant on excellence in project execution to get their programmes in place and delivered on time. Any implementation programme that is being initiated now faces a daunting amount of complex capability that must be delivered in a very short time with little or no opportunity to practice before the deadline hits. This year, more respondents are at roll out stage or fully implemented than in 2015.

Mark Davidson – Bluesphere Health stated: **"Earlier in item 1 around 70% "agree" or "strongly agree" that their organisation has a robust plan, which is encouraging given the lack of time available. Of course, this may be a self-selecting group, who bothered to fill out a survey.**

"But this positive picture of readiness contrasts with item 3:

"A total of 47.3% of respondents have not conducted any pilot projects yet. This means that the established equipment and software vendors will be thinly stretched over the next two years trying to service this demand. For these vendors, the cost per sale will increase because most of the unprepared customers are smaller companies with fewer lines but many of the pre-sale business development costs are the same. This may drive prices up."

This contrast may infer a sense of over-optimism on how the serialisation projects are likely to run. This optimism feeds through to the findings in item 5 with 48% predicting they will need 18 months or less to reach full serialisation.

Jim Cummings, Vice President of Adents (Americas):

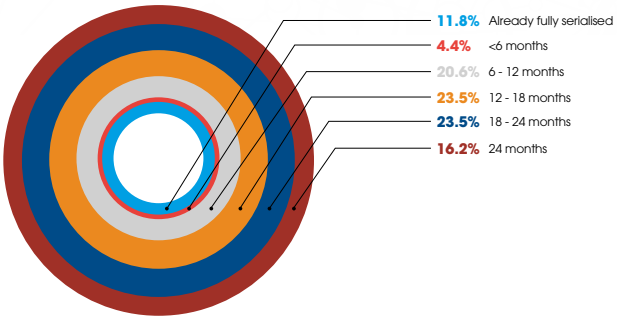
Implementation progress is truly hard to measure as only a handful of markets like, China, are fully implemented. Let's say your organization ships to China, US, and EU. Your China product will be at 100% implementation while the EU and US product may be at 33% or maybe still in the pilot phase.

Organizations are unique. It is very difficult to make blanket statements about the industry's preparedness that are accurate. However, that said, the major trading partners must be as prepared as possible. Trading partners like McKesson, Cardinal, and Baxter. If these guys aren't ready, there will certainly be bottlenecks as each country's deadline approaches.

Could this happen? Yes, as anything is possible. However, there is little danger of this happening. The big trading partners are working very hard to mitigate this scenario. Try as they might, the big trading partners are still at the mercy of individual country's readiness.

Item 5

How long do you anticipate it will be until you are fully serialised?



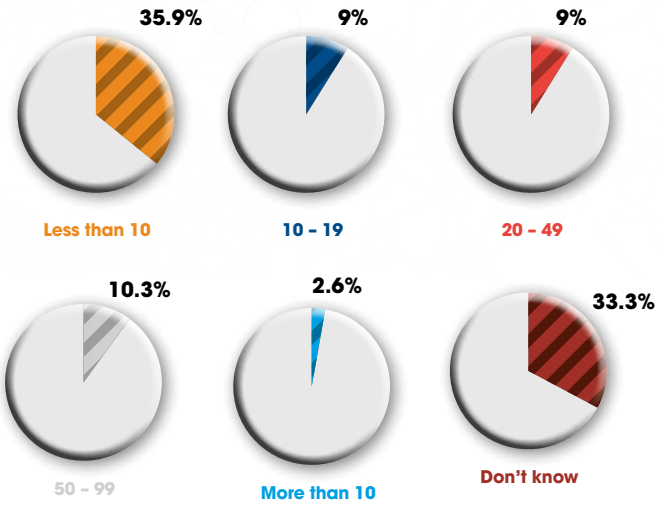
Mark Davidson – Bluesphere Health notes: "Almost everyone thinks they will be fully ready within 24 months, which given the answers to item 3 above seems optimistic bordering on unrealistic. I expect that late-comers and smaller companies will need to use less experienced vendors to get the job done. These might perhaps include new entrants with IT skills and expertise coming from outside pharma."

Also there has been a year on year increase in the amount of respondents stating that only less than 10 packaging lines need to be upgraded in response to serialisation as seen in item 6.

Cognizant

Item 6

If applicable, how many packaging lines will you need to upgrade in response to serialisation?



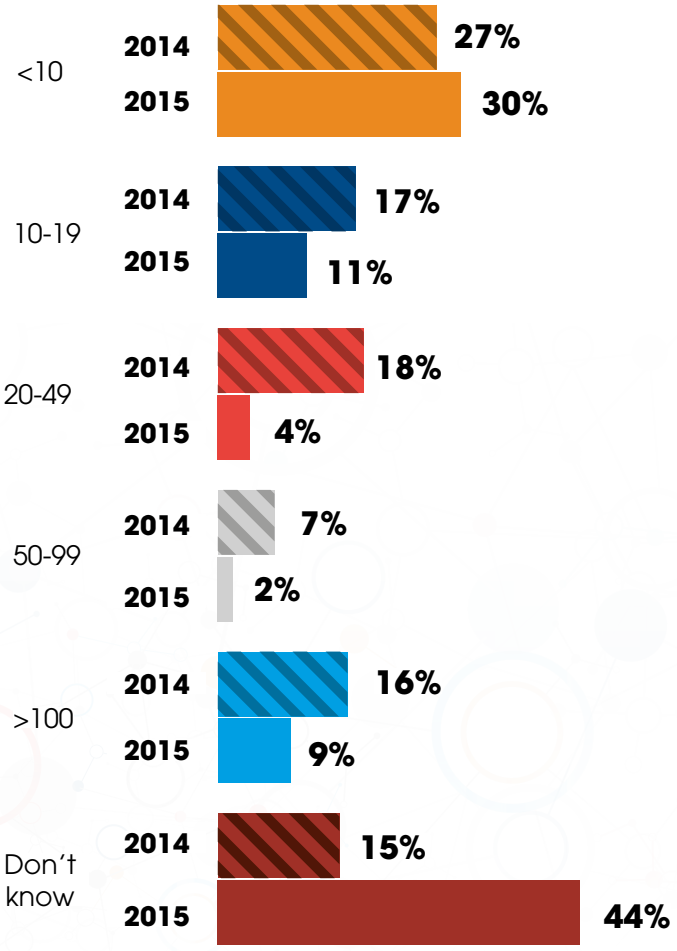
Cognizant

"Big pharma and larger CMOs are adding complete serialisation capabilities to all or most of their lines. They are even consolidating lines with similar requirements so it requires minimum upgrades as new country specific regulations get added on. These companies are considered early adopters as they have designed and implemented their solutions ahead of time in anticipation of the high volume of packaging operations that they may have to serialize once key regulations kick in. Some of the smaller organizations with a lesser number of packaging lines and/or niche products are also following this track. The few such organizations that are early adopters have rightly concluded that there is significant value beyond compliance to be realized and that they will be able to rapidly recoup the upfront/early investments that are already underway.

"However, most mid and small size manufacturers and CMOs seem to significantly trailing behind when compared to the early adopters. Some key reasons are - constantly evolving regulations in some markets, no clear guidance on process like aggregation and grandfathering, industry standards driven by key industry leaders vs the govt., banking on the reasoning that they will have more time despite the deadlines, and resourcing related issues to name a few. Unfortunately, most Global Health Agencies accountable for the enforcement of serialisation regulations will be forced to extend enforcement deadlines at the risk of leaving the pharmaceutical supply chain unsecured for a longer window of time." - Pari Sanghavi

PREVIOUS RESEARCH RESULTS

How many packaging lines will you need to upgrade in response to serialisation?



ADENTS

Cognizant

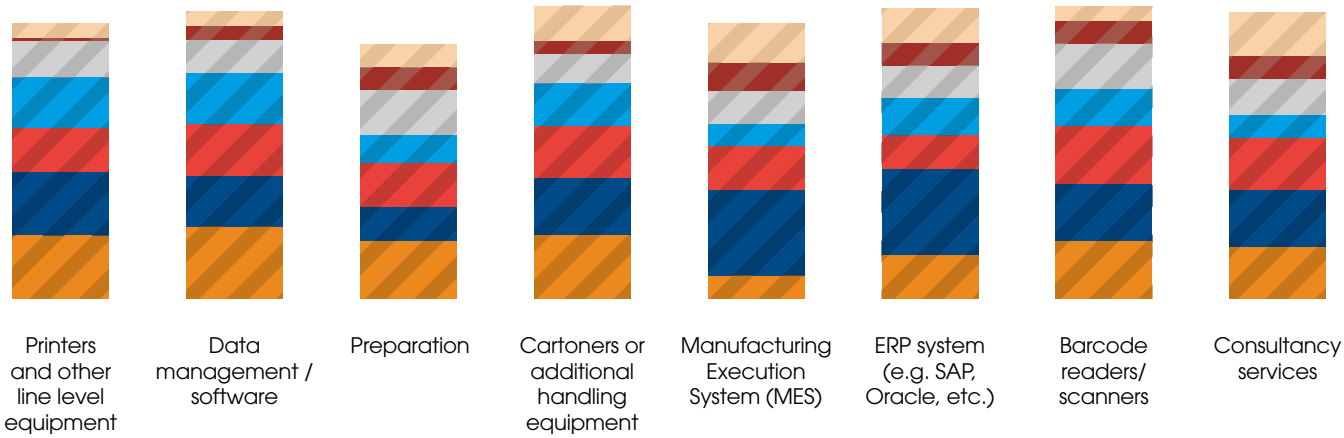
HARDWARE & SOFTWARE

Being further along the implementation process, big pharma is looking at harmonising and centralising systems and integrating software and optimising their strategy.

Item 7 shows consensus is that the majority of verticals have reached vendor selection stage or implementation being underway. One small to medium sized pharma firm noted that they are due to invest over £1,000,000.

Item 7

In preparation for the serialisation deadlines, my company is at the following stage for the below technologies

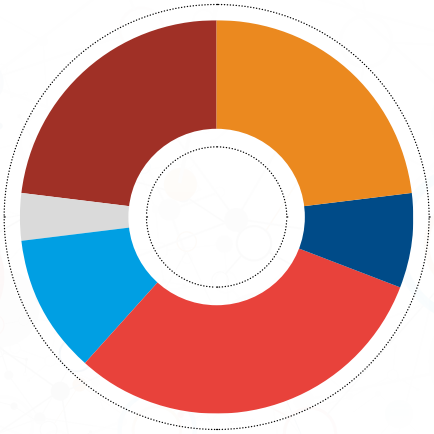


- Implementation complete
- Implementation under way
- Vendor selection complete
- Vendor selection initiated
- Started Initial research
- Not started Initial research
- Don't Know

Different lines are at different stages; some are fully implemented with full track and trace, others not at all

Item 8

Approximately what sort of budget size will need to be invested in the solutions above?



€100,000- €500,000	**23.2%**
€500,000- €1,000,000	**7.7%**
€1,000,000- €10,000,000	**30.8%**
€10,000,000- €100,000,000	**11.5%**
€1,000,000,000+	**3.8%**
Don't know	**23.0%**

*Other
Depends on number of production lines;

HURDLES

Cognizant

The below sections are the main pain areas highlighted by our research base.

Compliance

Unsurprisingly, compliance stands as a considerable concern with the implementation of serialisation participants noting:

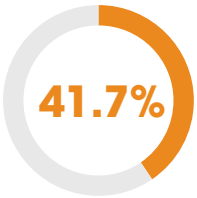
- Moving Targets: continuous modification of target date/expectation level of various countries.
- Compliance with different legislations and integration with third parties including CMOs, 3PLs and CFAs
- Cost increases from multi region compliance, for example with the US barcode standard being different to other regions so imported goods must be relabelled for the rest of the globe.

Integration

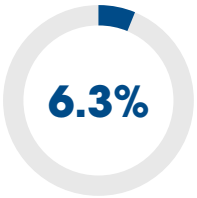
As seen in item 10 optimum utilisation of existing technologies / machineries and integration with enterprise systems were noted as the top operation challenges. Interestingly, both of which ranked as the top pain points by the 2015 research base.

Item 9

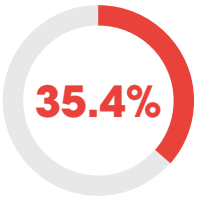
What is the main operation challenge you face/ will face in implementation?



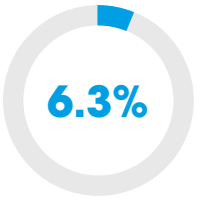
Optimum utilisation of existing technologies / machineries



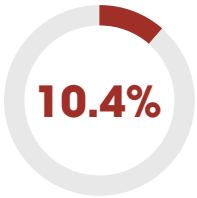
Creation of unique serialisation codes for individual products during the production process



Integration with enterprise systems



Generating high-speed printing and verification of the codes



Cross-site coordination for serial generation for similar product lines

*Other

Interfaces with multiple customers and multiple systems | Least TCO solution deployment | End-to-end chain communication (no standards) | A reliable partner for the introduction of Serialisation | Cross-CMO integration with CMO's working for various brand owners | Sharing of exact info by the manufacturers as to their difficulties | Finding suppliers who can respond quickly

One participant, from a small-medium sized pharma / bio firm noted: **"There are many aspects of serialisation which have significant impacts (on)manufacturers. These include (the) ability to integrate legacy equipment, ability to interface with legacy enterprise systems, interfacing with customer/client systems along with the costs of implementation and ongoing licensing."** Some noted their concerns with supply chain performance in regards to ensuring codes are not repeated.

Cognizant

Cost

Concerns highlighted by participants revolving around cost include:

- Training and down time which involves a lot of costs.
- Fully understanding the costs to serialisation and potential ROI beyond simple compliance.
- A high cost outlay for manufactures with limited numbers of licensed products leading to a lack of prioritisation for smaller scale manufacturers.

Planning

An interesting area of concern highlighted was planning and timelines, with some participants noting the struggles of implementing serialisation and track and trace simultaneously. Most areas in this vertical focused on not being capable of adhering to requirements in time and not understanding all the variables in order to implement in a timely fashion.Reliable partners were a key pain hotspot.

One respondent specified that struggles are experienced with their cross-departmental communication and strategy being a difficult area to master, adding that; "We continue to work in a vacuum and then crash together as due dates approach."

Recent report conducted by Tracelink (2) reported that some CMOs are not moving fast enough for serialisation deadlines in the US. This is concerning as the future lifeblood of CMO business with pharma rests largely on their serialisation capabilities, A lack of compliance is likely to equate to a loss of business to competitors. A pain point with SMEs is the fear that CMOs will not be compliant in time as some of their work is outsourced to these firms.

Jim Cummings, Vice President of Adents (Americas):

Once you begin to implement a plan, you will see the wrinkles in your plan. The more upfront planning that is done, in my experience, the more frequently wrinkles occur. My advice is to plan to solve those problems that you have. Protracted planning has a tendency to introduce problems that may or may not need solving.

As far as effort, again plan solve the problems you have. This will prevent extraneous effort that will ultimately produce solutions to be redone or completely undone.

A well thought out phased approach plan will reduce both effort and cost. Selecting the right vendor for your implementation will completely mitigate the hurdles. Those vendors that are too quick to say yes to every question asked of them, are probably the vendors you want to avoid. Experienced implementers will discuss your questions in detail with you to understand your organization's unique needs and work with you to arrive at an appropriate solution.

Remember, there will be hurdles. When overcoming these hurdles, it is critical to ensure your chosen vendor has the depth and breadth of experience to handle these hurdles. OpEx, and therefore, TCO can grow wildly out of control with the selection of the wrong vendor or the attempt to plan everything upfront.

SAVE YOURSELF FROM COUNTERFEIT DRUGS. EMPOWER YOURSELF WITH OUR APP.

In the Life Sciences industry, we are seeing new and stronger government regulations driving drug safety and security across the world. With thousands of requirements driving the change in the market, the entire supply chain is collaborating towards the delivery of an end to end tracking mechanism for all drugs manufacturers and sellers to secure their products and serve their customers better.

At Cognizant, our domain champions, technologists, digital and data scientists, and cloud specialists are transforming the way pharmaceutical supply chain meets the DSCSA and global regulations for serialization, before their deadlines.

By building strong partnerships with stake holders and technologies companies that will fuel this change, we offer a wide range of products and platforms to that cater to your entire supply chain, assisting you in exceeding your goals and discovering the value of serialization beyond compliance.

Cognizant

Lessons from the field: Business strategies to take the sting out of serialisation

Pharma IQ Editor Chanice Henry speaks to Pari Sanghavi, Senior Director at Cognizant Technology Solutions to find out how pharma firms can look to smoothly implement their serialisation projects and the areas in which they can start to unlock returns.

How does one keep on top of all the rapidly evolving serialisation regulations and addressing them with a streamlined approach?

Pari: "Our first recommendation is that you partner with a global systems integrator that's committed to staying abreast of these global regulations and can also help you interpret those regulations based on what others in the industry are doing. So it is not enough just to know what the regulations are or when they are changing, it is equally important to know how they are being interpreted by others in the industry.

"The other way to do that is to leverage your solution provider. So if you have chosen a solution provider already, as a serialisation product vendor, these firms have no choice but to invest in R&D budgets to keep abreast of these regulations and to also enhance their software solutions.

"We also recommend participating in industry forums, webinars and conferences where a lot of good information is shared and exchanged. Of course, most importantly, you need to engage your local regulatory and supply chain teams in those markets. They need to take ownership of these regulations and also how they are being interpreted locally. In some cases, those local regulations are only printed in local languages, so you may not even have the ability to stay informed about regulations without local help.

"In terms of streamlining, use a global template approach for those core capabilities that can be standardised, very similar to how you would roll out an ERP system. In terms of country-specific regulatory reporting, we recommend that you leverage those country-specific packages that your solution providers should be actively building. Roll these out with a sufficient lead-time for you to incorporate that into your serialisation platform."

What measures would you advise for controlling costs in the implementation of a serialisation project?

Pari: "One model is to leverage systems integrators that can bring in experienced resources from lower-cost regions of the world, such as India and other countries in Asia. So a company like us has the ability to leverage local resources and take advantage of their extensive local serialisation experience.

"Another way of keeping costs controlled is to be very smart about which Country specific regulations you are actually going to comply with. A case in example is Brazil. The moment the regulation was published, the way it was constructed made it very obvious to any seasoned person in the industry that it was not going to be realistically complied with. The reason is that the regulation was very onerous and the infrastructure in that market was not ready to comply with it along the timeline suggested. Some large companies chose to not take that risk and they decided to spend a lot of money trying to comply with a regulation that was never going to be realistically be enforced within the targeted timelines.

"So we can help you interpret the regulations as they are published to see whether they are realistic and are going to be adopted across the industry. If you stay with the pack you will make sure that you do not commit dollars to markets that may not have realistically achievable regulations. It is very important to be smart about how, when and where you invest your dollars. Finally, for those who still have to choose and procure serialisation solutions, we can help you prepare a business case that looks at total cost of ownership rather than just picking the hottest product in the industry."

For those manufacturers that have already invested a significant sum into their serialisation programmes, are there any opportunities to start reaping returns from their investments?

Pari: "We at Cognizant have published a white paper called, Driving Value Beyond Compliance, that examines the various strategies to utilise the serialisation-related data generated and

continually updated. Some of our clients are starting to pilot enhanced supply chain visibility-type of projects using serialisation data. Once you start enabling your warehouse-level tracking and tracing, that will open up a whole slew of additional use cases for leveraging serialisation data for supply chain visibility.

"The wholesalers in the US, as an example, are going to require that their manufacturers start to provide serialisation data by approximately 2019 as they ship product to the wholesalers. This will cost the manufacturers to set-up the infrastructure so they can share the serialisation data.

"This is actually a great opportunity for the manufacturers to ask the wholesalers in return for data back from the wholesalers. So when the wholesaler is selling the product onwards on to their customers, manufacturers today do not have visibility on a lot of that information. However, with this new advent of data sharing from the manufacturer to the wholesaler, it is only reasonable for the manufacturer to ask the wholesalers for additional downstream data in return for providing serialisation data ahead of the regulatory deadline, which is not until 2023.

"Another promising area of opportunity is mobile app based validation and tracking to act as a first step towards a consumer facing app.

"All of this is ultimately leading to key benefits such as preventing product diversions from lower cost markets to more expensive markets. Additionally it will assist with returns verification as well as charge-back auditing. Millions can be saved from auditing the charge-backs submitted by wholesalers to manufacturers and rejecting those charge-backs that are not substantiated by the underlying serialisation data."

As a leading serialisation systems integrator that's currently deploying serialisation capabilities with multiple clients globally encountering a variety of platforms, what would you say are the current common challenges you are seeing?

Pari: "We are witnessing a lot of challenges around serialisation itself, integration, mass data as well as the regulations.

Serialisation

"Equipment process procurement lead times: Do not expect that once you have selected your equipment manufacturer you will receive it overnight. Lead times are averaging six months and will continue to stretch as more firms order serialisation equipment. So plan this into your advance planning roadmap.

"Diverse line level systems: When one packaging facility holds conflicting line-level serialisation solutions, some customers are struggling to have one site-level system handle the diverse line-level systems. If firms are planning to house multiple serialisation solutions at the line level in a packaging facility, we recommend choosing a site-level system that is product agnostic.

Integration

"EPCIS compliance: A lot of site-level systems today are not capable of integrating with the latest enterprise-level solutions using EPCIS. It is ideal to proactively upgrade site-level systems to be fully compliant with EPCIS . Also as you build your product mix, be sure to confirm that integration certification seal from both the enterprise- and line-level solution providers.

"EPR WM system integration: In terms of ERP and warehouse management integration, we are discovering the requirement to integrate with a variety of different ERP and WM systems. Only a few solution providers can offer out-of-the-box connectors to integrate integral serialisation solutions with ERP or WM systems.

Mass-Data

"Data permanence and clear ownership Without good data permanence and clear ownership of mass data harmonisation will be complicated as you will need to share across different packaging facilities and companies and countries. So we do recommend leveraging any existing MDM solutions or perhaps strongly considering deploying an MDM solution to keep all of your serialisation data in sync across your packaging facilities as well as your ERP and WM systems.

Regulations
Shifting goalposts

"Here, we are witnessing the constant challenge of trying to execute implementation against a serialisation roadmap that is constantly shifting according to the evolving industry regulations. Prioritisation will allow for flexibility in your roadmap as new regulations are published on an ongoing basis."

The main operation challenge our participants are facing is the optimum utilisation of existing technologies/machineries. Do you have any tips in regards to this challenge?

Pari: "Most lines would have commenced down the serialisation path and some serialisation equipment may exist on some packaging lines.

Strategies need to be deployed based on how to best mitigate risk, while not having a cacophony of different technologies.
"Build to align with your existing selections by adding onto that, and perhaps add one more player in the mix to mitigate risk, but not to the extent of each manufacturing site or packaging facility having bespoke line-level or site-level solutions. In some areas, funds can be saved from actively pulling out existing serialisation solutions and replacing them with something more standard to your organisation. It will certainly help to reduce support costs as well as validation effort."

What advice do you have for how industry firms should select the right serialisation solution and deployment partner for their needs?

Pari: "It is obvious that there is a lot of solutions on the market today with more jostling to enter. This makes it very difficult for a manufacturer to know which would be a good fit, plus the RP process itself can be expensive and time-consuming.

"By turning to an experienced consulting partner, like Cognizant, you gain access to extended industry knowledge of who the leading solution providers are and in some cases even bypass the RP process together. In cases, where internal governance processes require you to do an RFP process, we can bring a variety of tools and frameworks to the table to speed up the process."

"It is important to consider the fact that that one vendor, who is giving you their solution, may not have the scale for professional services to actually scale up and satisfy all of the various customers simultaneously purchasing their products.

"In tapping into an experienced systems integrator, manufacturers gain support in deployment as well as other aspects such as programme management, change management, validation and testing, contract packagers coordination, etc. A much more cost-effective and lower-risk way of deploying the solution of choice."

What will be the next serious focus in the serialisation journey for the manufacturers that have already serialised a significant percentage of their lines?

Pari: "A lot of packagers are taking a very short-sighted approach and not aggregating as they commence product serialisation. We strongly recommend that manufacturers aggregate as they serialise. One of the reasons being that if aggregation does not happen now, it will inevitably have to occur some point in the future. So manufacturers have to ask themselves which is more logical, to gamble and then have to bring the pack line down to introduce aggregation and revalidate the packaging process, or be proactive and sign up for aggregation upfront? Seemingly, the absence of significant costs due to aggregation upfront is allowing packagers to start to aggregate.

"Looking at the US, we foresee that a lot of warehouse-level tracking and tracing will start to get enabled – those internal and with 3PLs. Although 3PLs have not even begun to comprehend the impacts of serialisation to their existing infrastructure, processes as well as added operational costs. We are seeing a replay of the contract packager scenario where the 3PLs are essentially saying; 'We refuse to make an investment to serialise my warehouse. If you wish me to serialise and track and trace the warehouse, you as the client must provide the required investments.' Everyone is trying to see who is going to cave in first and as a by-product warehouse-level tracking and tracing has not really taken off. (Pull quote)

"Also in the US we shall soon see the sharing of serialisation data between manufacturers and wholesalers. By 2019, we are expecting that all three large wholesalers are going to acquire serialisation data along with products they receive in their warehouse. So these are areas that we recommend you start piloting and start to get ready to deploy them more widely.

"In the EU, we are starting to see clients aggressively serialise both their internal packaging lines as well as their outsourced packaging lines. This is a smart approach, because the deadline is right around the corner and it is going to hit before the industry knows it.

"European market players need make key decisions on aggregation, tamper-proof packaging, as well as product flows, since there are more complex scenarios when it comes to repackaging. We suggest that pilots start now with integrating national and EU databases as to address any surprises upfront.

"With the evolving regulatory markets like India, South Korea, China and Brazil, professionals must be aligned to the country specific regulations are and how they are evolving. Updates are published on a monthly or quarterly basis, being informed is directly linked to the ability to adapt. The same applies to emerging regulatory markets like Russia, Ukraine, Saudi Arabia, Jordan, who are only just finalising their regulations."

ADENTS

YOUR TRACK AND TRACE PAIN POINTS TACKLED

A range of hurdles were highlighted by respondents of Pharma IQ's 2016 Serialisation Industry Report. In light of these issues Pharma IQ Editor **Chanice Henry** speaks to **Jim Cummings,** Vice President of Adents (Americas) on how pharma firms can navigate regional compliance complications, cost considerations and planning problems within serialisation projects.

What is the best approach to adopt in the face of moving targets with implementation dates and compliance requirements in different countries?

Jim: "New regulations will continue to be enacted in different countries also these existing regulations will most likely change.

"So one needs to keep that in mind and look at systems that can most easily deal with change, enabling companies to add new regulatory requirements or change the existing quickly and easily."

In terms of having a global strategy, which the majority of our participants are choosing to follow, have you got any key tips to simplify the process and control costs with multi region compliance?

Jim: "The ideal is to have a serialisation solution that minimises change management, downtime for the packaging line, any revalidation cost and any IT governance required. When a solution requires a lot of change to the software system at each and every packaging line, then one has maximised their change management time/cost and the revalidation cost.

"It is my opinion that a centralised configuration management system where all of that work is completed in one location and the majority of the work can be conducted offline while the packaging lines are operating, is the most efficient and economical method."

How can firms work to fully understand the costs to serialisation and potential ROI beyond simple compliance?

Jim: "Just from the serialisation and compliance issue, most clients we have talked to and those I have interacted with at conferences are looking at this as a cost, because it's a compliance issue and had not actually entertained the idea of ROI. However, some are starting to think of innovative ways to use this data. One pharma company noted that they are beginning to have a better yield in their supply chain and are entertaining methods like mobile apps – which their consumers can connect to and check their medications. With those innovative approaches, one can build on these systems that are opening up the view of the supply chain and find ways to create ROI."

What would you say to smaller scale manufacturers which aren't prioritizing serialisation due to the high cost outlay for manufacturers with limited numbers of licensed products?

Jim: "Well, number one, everyone has to comply, so they need to just understand and buy into the programme. Now, let's just not just look at what has a big pharma company done. Yes, a big pharma firm may have spent a million dollars per line, but that does not mean the smaller companies need to go down that path. It should not cost that much, also, it should not take as much time as has been experienced in the last couple of years."

"All these companies, no matter their size, should ask an abundance of questions and keep their minds open to technologies that are available, but may not, in specific regions, be readily used yet. They should keep their minds open to methodologies that are different to those of the current market leaders, which can reduce the total cost of ownership of the system and decrease the time taken to implement.

"The companies just need to acknowledge they must do this and they must do it quickly now, because in the US the time is certainly running out."

"In my opinion not being fully invested may not be wise. The firms really need to understand what's going on in the marketplace and what their options are."

One participant in our research noted the complications with cross departmental communication:

"We continue to work in a vacuum and then crash together as due dates approach."

What are the potential consequences with this? What are the common mistakes made with communication in a serialisation implementation project?

Jim: "In regards to internal communications within a manufacturer's organisation, these issues are just problems leading to disaster, because these serialisation efforts are not a project, they're a programme. So many different departments need to be involved: the operational teams, the supply chain division, the IT technicians as well as the quality and regulatory units. If there is not a cross functional team coordinating communication, gaps may appear in understanding and so certain teams will not fully achieve the input that is required of them and there is probably not going to be a solution or a programme that will work efficiently for that client."

What is the best way for firms to neutralize the pain felt from the challenge of ensuring optimum utilization of existing technologies and integrating enterprise systems?

Jim: "In many cases when firms look at current market leaders they're looking at proprietary devices - printers, cameras, vision, scanners - and they're not looking at what they have currently and how this dictates what they may be able to use for their serialisation projects.

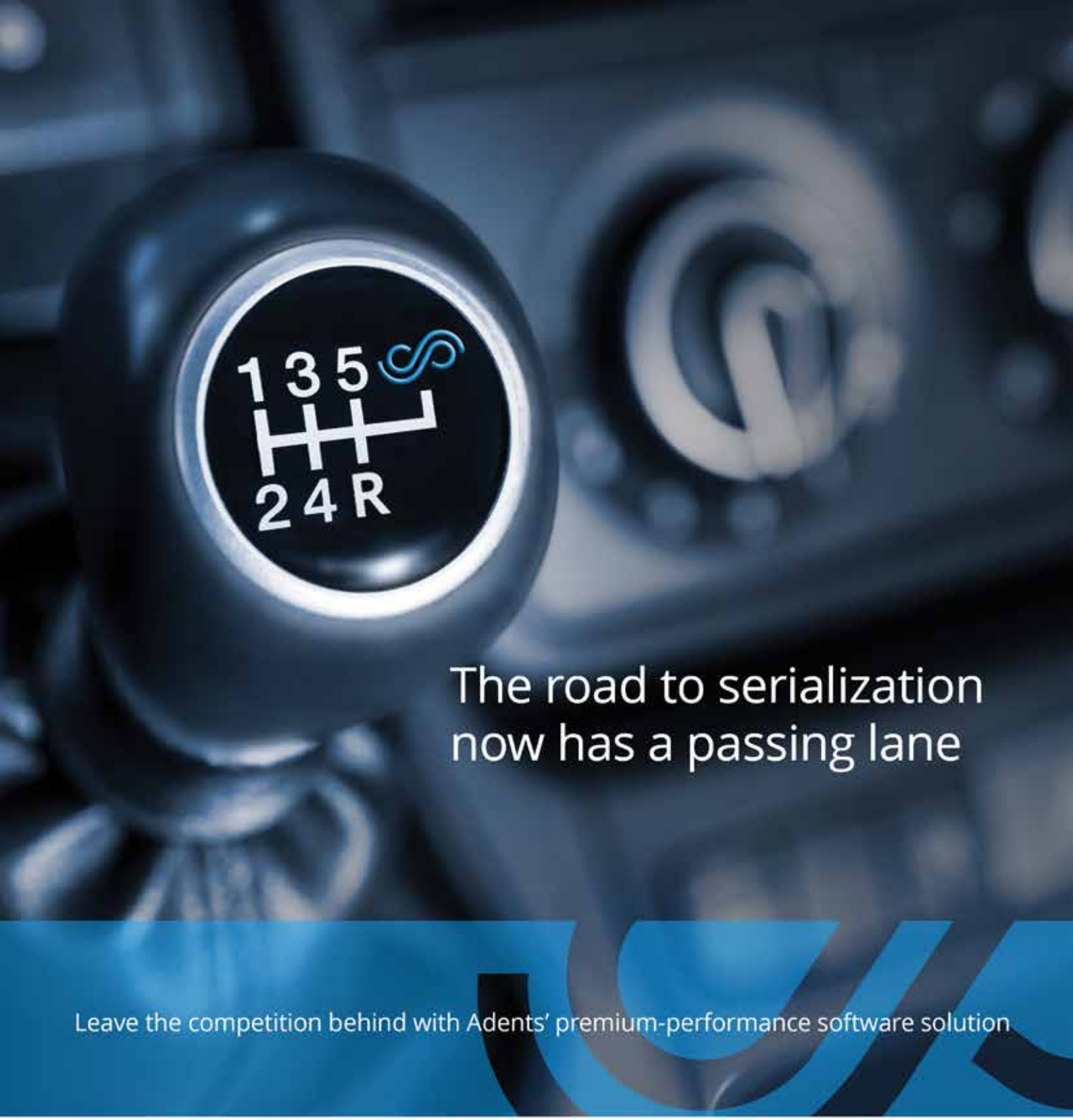
"Consider: are there any new devices that not only need to be supplied, but installed, wired and integrated? Or are there existing devices where a software solution could be put in place that is wired to these devices and integrated and so minimises the time to implement and the cost of implementation. In addition to this, during regular operations, utilising commercially available devices can reduce the cost of the serialisation programme and the total cost of ownership of the solution. Should a device like a camera fail you can also readily acquire a replacement.

"These are the elements that need to be assessed by these companies, because there are options where companies can choose not to go the proprietary hardware route and instead utilise devices they already own and already have standardised throughout their organisation and so in the process they can save themselves a lot of time, money and stress."

Any final remarks?

Jim: "Well, I know in IQPC Serialisation and Traceability forums and other conferences - the message that has been promoted to companies, manufacturers, is that the current group of vendors and resources that supply their serialisation solutions is limited; and to some extent this is true.

"There are other methodologies used by other vendors that allow them to scale as the market needs. This needs to be a critical consideration when companies are looking at their vendors. Although, many vendors are somewhat overwhelmed at the current time. If one does the math comparing time needed to deliver and implement a system versus the level of work left to do, one should be concerned."



The road to serialization now has a passing lane

Leave the competition behind with Adents' premium-performance software solution

Speed to deployment gets serialization to your lines up to 5X faster than other solutions

Easy configuration means exceptional modularity for existing hardware and multiple points of use

Maximum flexibility with easy, centralized changeovers

ADENTS

www.adents.com

Adents @adentsinfo.com

FINAL REMARKS

The 2016 results have shown that, in terms of planning, the consensus is that firms are choosing to adopt a global approach to serialisation. Regional challenges in terms of compliance are being experienced with Asia according to our research base. Less confusion is there in terms of the US and EU markets with added clarity being given via published regulations. However, this is paired with the time pressure regarding the execution of the expected procedures. With this in mind it may be surprising to some that a number of participants admitted to not thinking about serialisation at all as of yet.

The late adopters are going to be critically reliant on excellence in project execution to get their programmes in place and delivered on time. Any implementation project that is being kicked off now faces a daunting amount of complex capability that must be delivered in a very short time with little or no opportunity to practice before the deadline hits. A delayed surge towards vendor selection at a late point may cause prices to spike.

There has been a progression in consensus since last year which is positive. However, the industry must beware not to lurch into over-optimism on how successful the implementation projects are due to be and how quickly full serialisation will be obtained. A sense of very high optimism is implied within these results in regards to timelines to complete serialisation. With deadlines looming, the industry must equip itself with the maximum amount of time to ensure that it will not incur any costly mistakes.

ACKNOWLEDGEMENTS

The creation of this report would not have been possible without the input and views from a significant number of serialisation and traceability participants and stakeholders. Pharma IQ would like to thank those whom we have directly cited, in particular:

- **Mark Davison of Bluesphere**
- **Pari Sanghavi of Cognizant**
- **Bill Fletcher of Pharmalogic.**
- **Jim Cummings, Vice President of Adents (Americas)**

Resources

1. http://www.pharmtech.com/tracking-pharma-s-serialization-efforts
2. https://www.securingindustry.com/pharmaceuticals/cmos-still-not-stepping-up-to-serialization-challenge-poll/s40/a2803/#.V1A4sOlrLIU
3. http://www.in-pharmatechnologist.com/Regulatory-Safety/Recipharm-to-invest-40m-in-serialization-tech-ahead-of-EU-and-US-track-and-trace-rules