GS1 Ireland

ENTERPRISE SYSTEM PARTNERS

# Serialisation

## Industry Readiness Report 2016

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# Introduction

*I want to thank everyone who took part in our Serialisation Industry Readiness Survey. GS1 standards play an important role in the solutions being utilised by pharmaceutical manufacturers to meet the requirements of the Falsified Medicines Directive (FMD), and other regulatory requirements across the globe. We, in GS1 Ireland, have a role to play in providing support and relevant information regarding the implementation of GS1 standards throughout the serialisation process. It is helpful to us to receive your feedback from the survey, so that we can tailor our efforts to meet your needs.*

*With the majority of respondents utilising GTINs as their unique identifiers, and 68% of respondents planning on using GS1 standards-based methods to store and exchange serialisation data, GS1 standards are the clear industry choice. Companies utilising GS1 standards are approaching differing regulations in a singular manner, reducing complexities and costs, while increasing efficiencies. When dealing with the complex requirements of serialisation, GS1 standards should be included in the strategy development and planning phase. GS1 and ESP can provide support at this stage, and indeed, at any point of serialisation implementation. The European Commission's deadline for the requirement of unique identifiers on the packaging of human medicines within the EU is the 9th February 2019. With the weeks until compliance passing swiftly by, the time to act is now.*

**Siobhain Duggan**
Director of Innovation and Healthcare
GS1 Ireland

**Liam O'Brien**
Managing Director
Enterprise System Partners

*Producing this Serialisation Industry Readiness Report was an incredible opportunity to communicate directly with those affected most by serialisation in the industry – the manufacturers, wholesalers, solution providers and consultants. We were enthused by the response to the survey – reflecting the high priority serialisation is being given at corporate level now that deadlines are rapidly approaching. It was interesting to note in particular that while 58% of respondents are well underway in their serialisation implementation, the most pressing concern surrounds the potential for further regulatory changes as well as insufficient time, based on current deadlines. ESP are delighted to present these findings to you.*

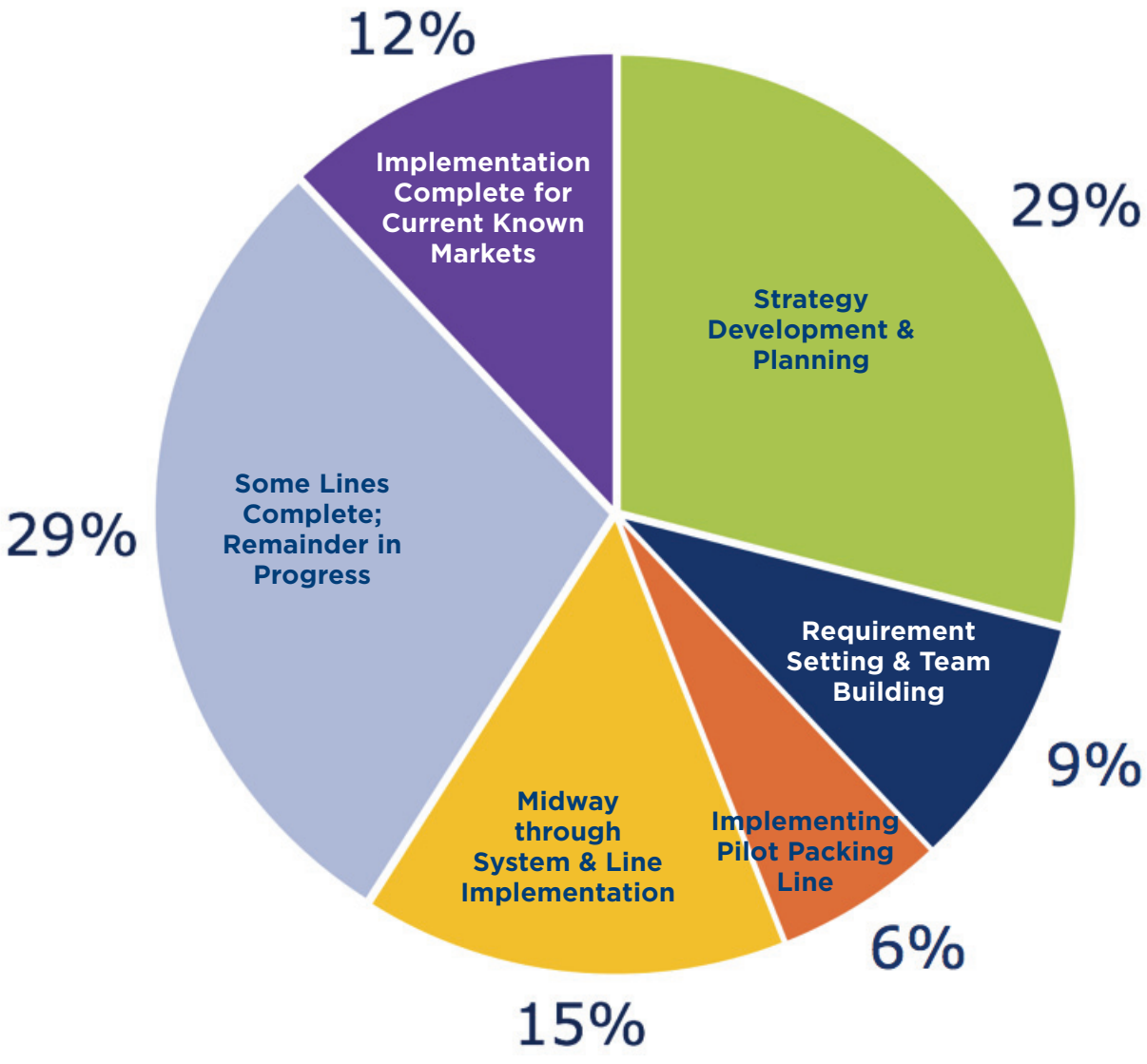
# About the Survey

This survey was carried out by GS1 Ireland & ESP in conjunction with a joint webinar on global serialisation regulations during May 2016. The majority of respondents were pharmaceutical manufacturers (59%), followed by consultants (15%), solution providers (15%), wholesalers/distributors (3%), and other (8%).

The aim of the survey was to measure the readiness for serialisation amongst respondents' companies. The majority (58%) have implemented or are implementing serialisation on their production lines. The joint GS1 – ESP webinar on serialisation regulations and global market requirements is available to view online at www.gs1ie.org/serialisationwebinar.

**Watch our Serialisation Regulations Webinar**

# Respondents' Current Stage of Serialisation Implementation



# Executive Summary – Key Findings

- The majority of respondents (81%) believe that they will meet their regulatory deadlines.
- Both the EU and US seem to be following the pattern of adoption of more mature Asian markets.
- 60% of respondents believe it takes between 6 to 12 months to serialise a line, with 27% believing that it takes under 6 months.
- The GS1 & ESP Serialisation Readiness Survey showed that most respondents had up to 10 lines within Ireland, but had between 50 and 100 globally.
- 68% of respondents will be using GS1 standards when storing and exchanging serialisation data.
- Approximately a third of respondents plan to aggregate on all sites (32%), in excess of regulatory requirement.
- A variety of GS1 standards are being used in the process of serialisation, showing how GS1 standards can bring even more value when used together.
- Information gathering about regulation changes has been highlighted as an issue for manufacturers.
- Changes in global regulations is ranked as one of the most critical resource issues, along with having insufficient time for the scale of the project, and competing projects and priorities.
- Approaches to serialisation appear to be multi-disciplinary, with serialisation teams drawn from across their respective organisations.
- The majority of respondents (72%) see value beyond compliance, including stock management, data analysis, supply chain visibility, and anti-counterfeiting. High cost and lack of resources were noted as hurdles in realising that value.

# Contributors

**Liam O'Riordan**
Serialisation Director and Senior Consultant Enterprise System Partners

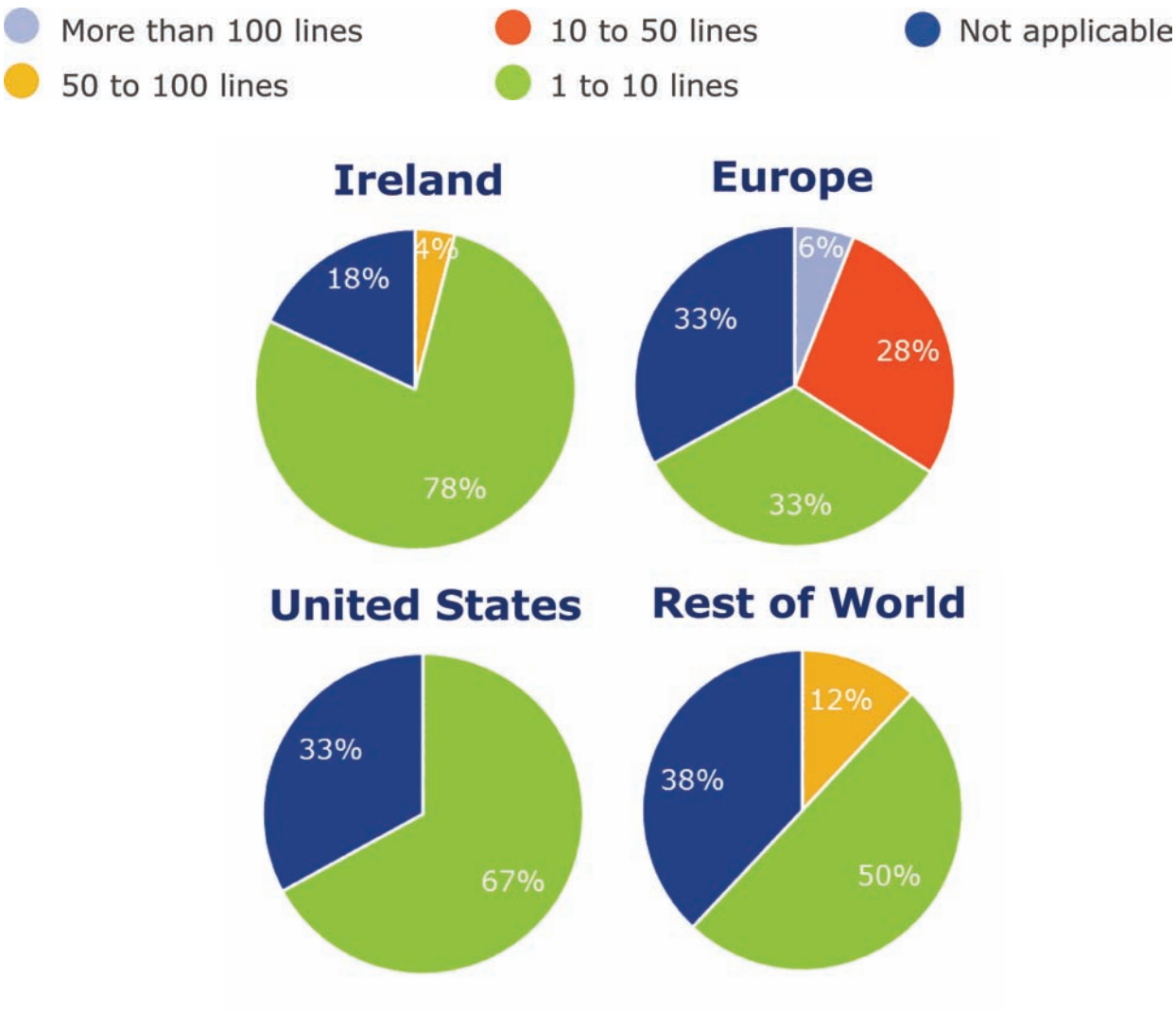
Liam is Serialisation Director and Senior Consultant with ESP, providing IT, serialisation and MES consultancy services. He has 25 years' experience working across a range of industries. He has managed serialisation projects in the electronics, mobile phone, automotive, medical device and pharmaceutical industries. This experience allows him a unique perspective on the impact of serialisation within the pharmaceutical industry.

**Alan Gormley**
Industry Engagement and Solutions Manager GS1 Ireland

Alan works as a liaison between industry and GS1 and supports initiatives to bring GS1 standards-based solutions to market, in line with industry needs. Collaborating with solution providers nationally and globally, Alan works in numerous industries such as healthcare, aerospace and retail to help implement GS1 standards for traceability, patient safety and efficiency-focused solutions.

# Response Analysis

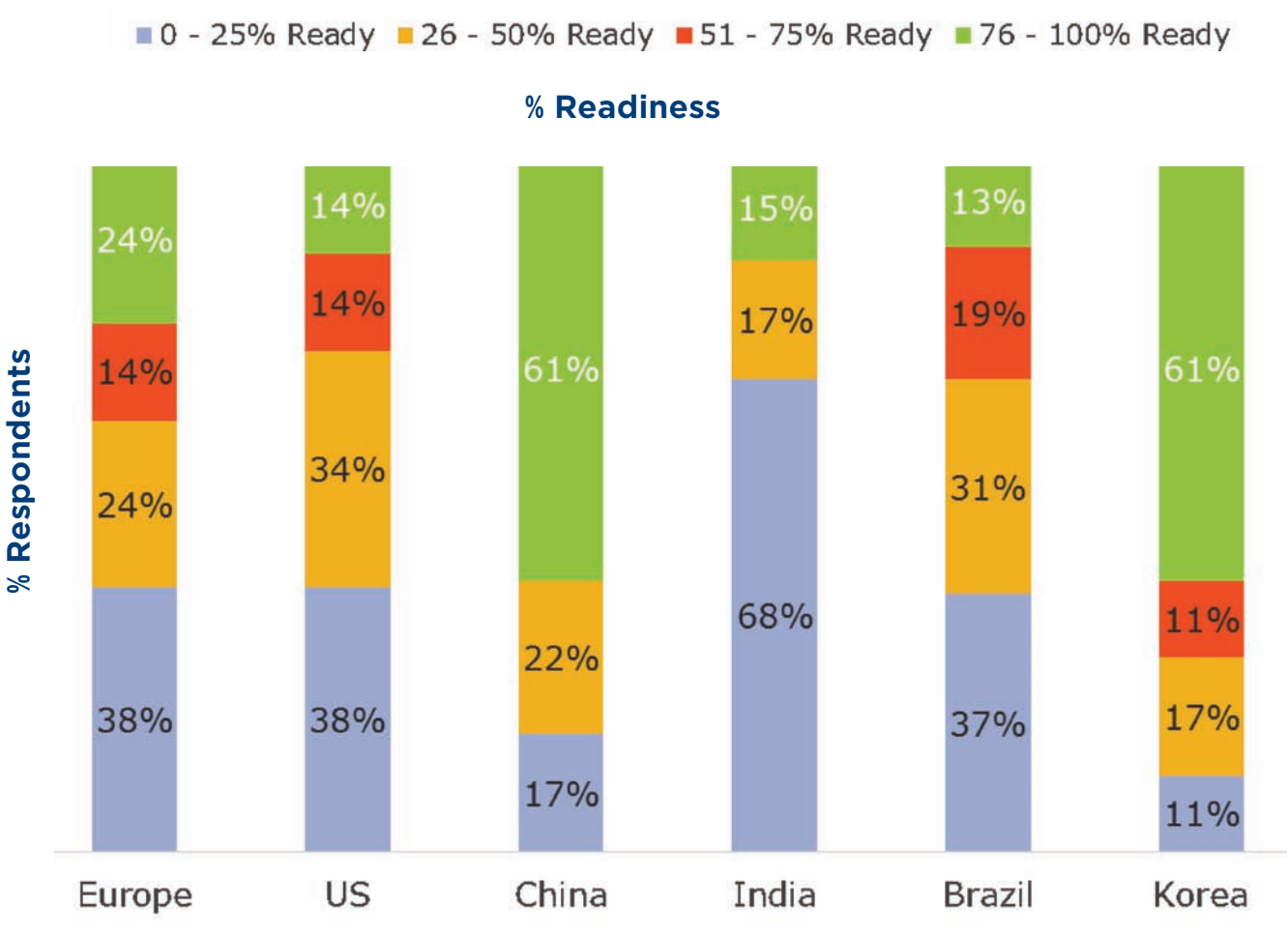
## 1. How many packaging lines will be impacted by your serialisation programme?




**% Respondents**

**Alan (GS1):** It's clear from the survey that there is significant work to be done in terms of global operations. With so many lines to be serialised in Ireland, there is an opportunity to copper fasten Ireland's reputation as a leader in complex manufacturing process in the biopharma industry through implementing best-in-class solutions, based on GS1 standards.

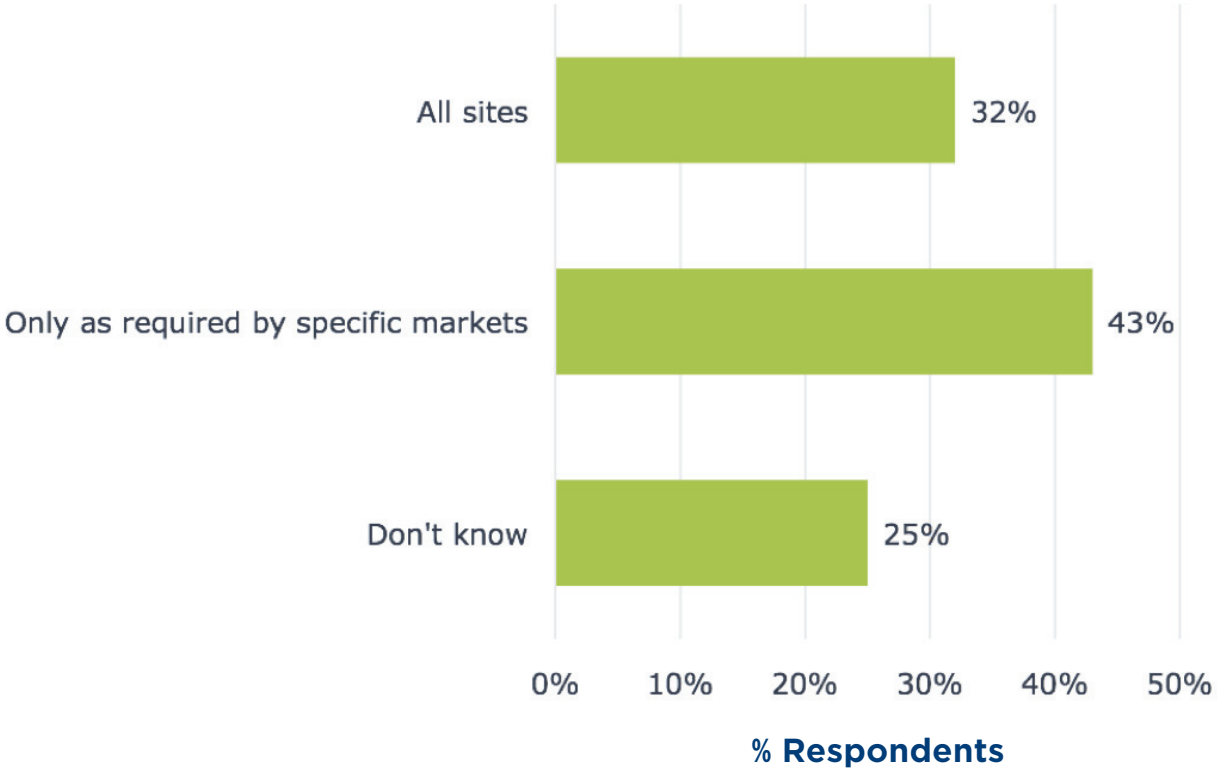
## 2. In terms of the markets you supply, how would you rate your level of readiness for each market?




## Market readiness is progressing as expected

**Liam (ESP):** It is reassuring to see that key regions such as US & EU are moving up a similar readiness curve to that of mature markets like Korea & China.

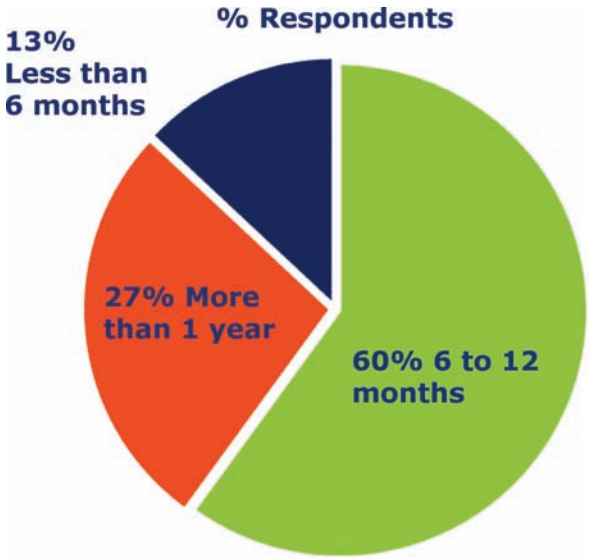
## 3. Are you planning to implement aggregation at all sites or just as required by regulations in specific markets?




**Liam (ESP):** An interesting result from our survey highlights that almost a third of manufacturers plan on implementing aggregation on all sites, regardless of statutory obligations.

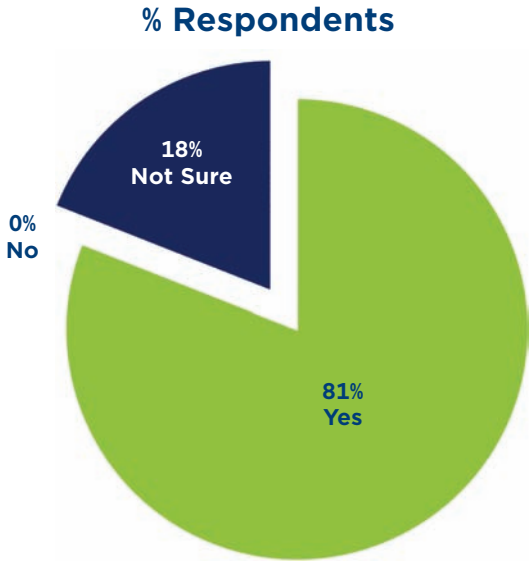
**Alan (GS1):** It's clear from the results that there are varied approaches to aggregation, be it for different markets, or different business processes. EPCIS is a GS1 standard that enables trading partners to share information about the physical movement and status of products as they travel through the supply chain, which is ideal for aggregation.

## 4. Based on your experience to date, how long does it take on average to serialise a packing line?




**73% Of Respondents Believe It Takes Less Than 12 Months To Serialise A Packing Line**

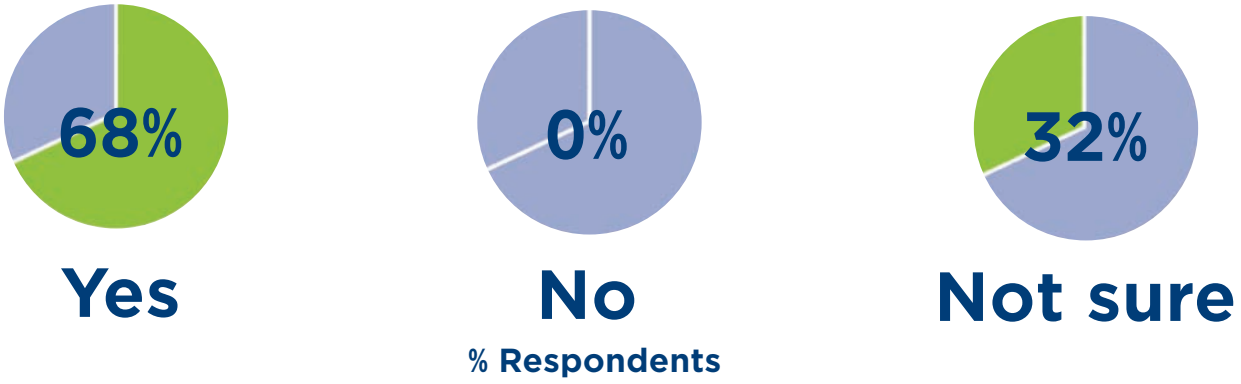
## 5. Do you believe you can meet the current regulatory timelines?




**81% Of Respondents Are On Track To Meet Their Regulatory Deadlines**

## 6. Which GS1 standards form part of your serialisation project?

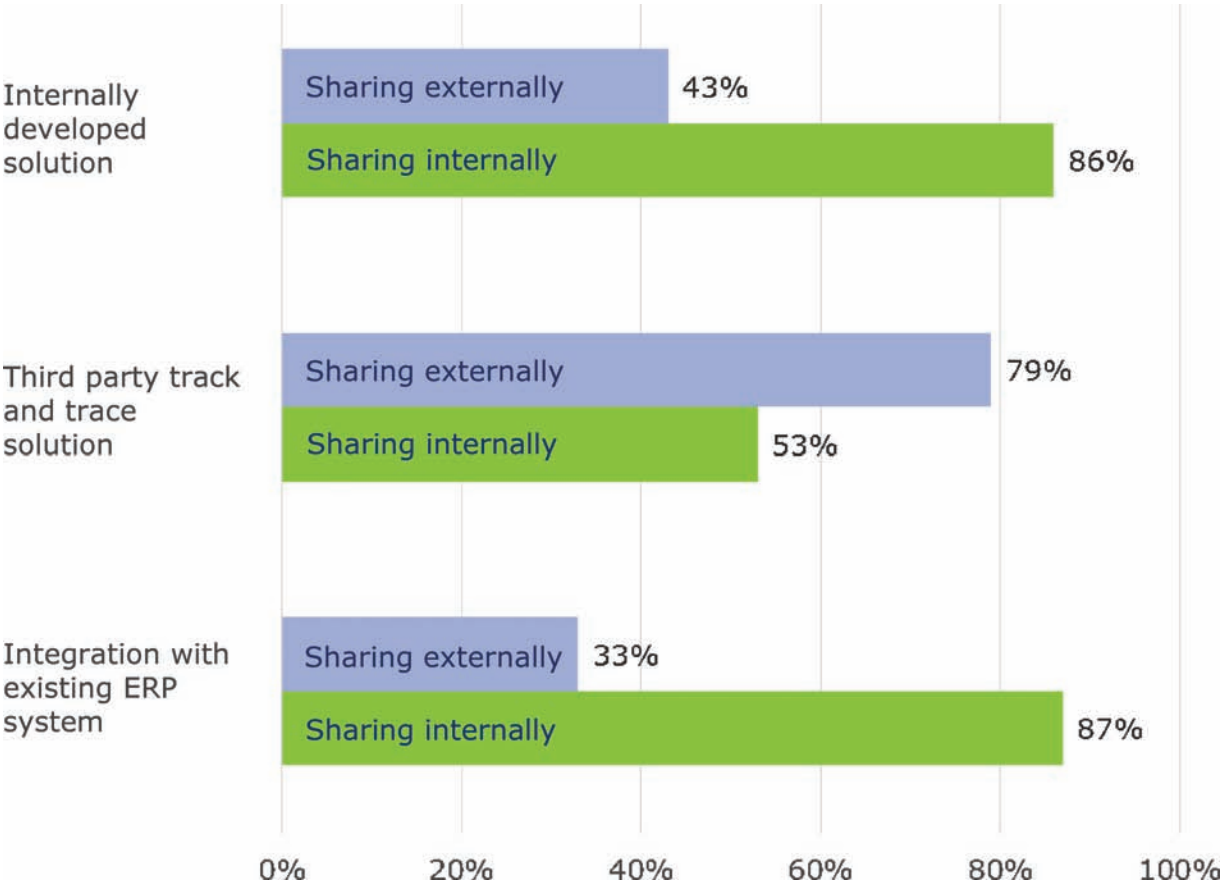

## 7. Do you plan to use GS1 standards-based methods to store and exchange serialisation data?




**Alan (GS1):** There is a clear recognition by industry that GS1 standards are core to their serialisation strategy. Working in collaboration with our solution partners, GS1 Ireland will be hosting an educational forum to help industry members understand how GS1 standards can support the storage and exchange of both serialisation and product master data.

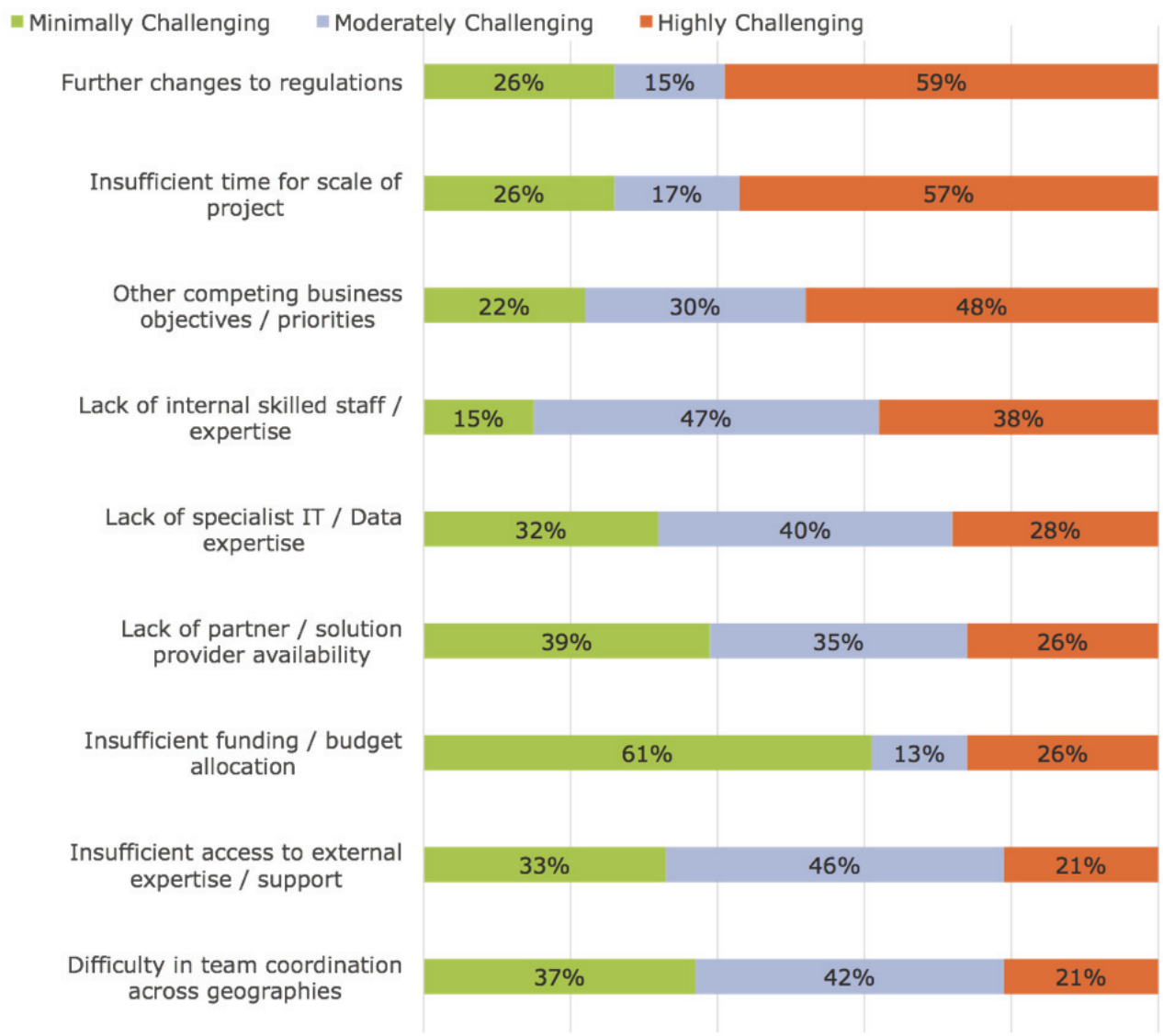
GS1 is a system of standards which is greater than the sum of its parts. An understanding of the interaction and co-dependency between standards is critical to exploiting business benefits beyond simple regulatory compliance.

## 8. How do you plan to exchange serialised data with your partners, internally and externally?




**Alan (GS1):** No matter how companies approach the exchange of serialised data with partners, the solutions that are chosen, or are developed internally, can utilise GS1 open standards such as EPCIS, which is now an ISO standard. Whether you are working with a solution provider such as ESP or are developing your own solution, one which is based on, or compliant with, EPCIS ensures interoperability, flexibility and scalability, for the long term in a changing landscape.

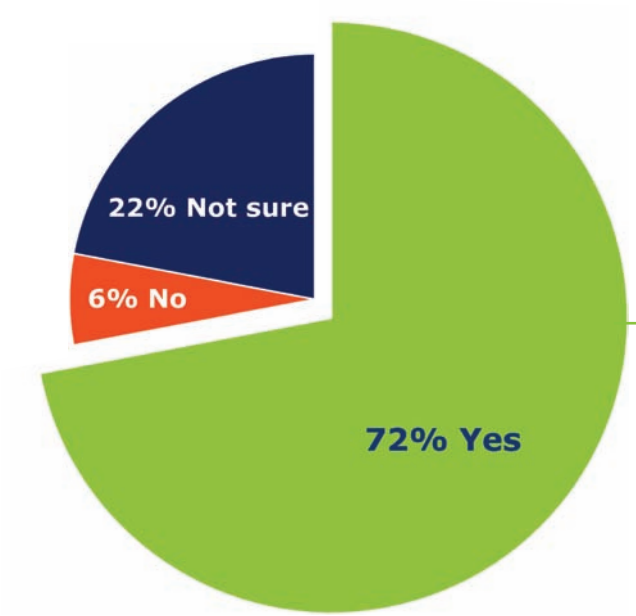
## 10. In terms of resource availability, which of the following do you feel presents the biggest challenge to meeting deadlines for serialisation?




**Liam (ESP):** Further changes to regulations emerged as the most significant challenge facing respondents when it came to keeping up with their deadlines. Furthermore, many respondents reported having no structured way of keeping up to date with the latest regulatory changes. It is clear that the majority of manufacturers surveyed are looking internally for updates on serialisation regulatory updates. It is critical, therefore, for teams to keep themselves fully abreast of the latest changes.

## 11. Do you see additional business value *beyond compliance* for implementing serialisation?

**% Respondents**




**Possible additional benefits beyond compliance for implementing serialisation**

- Stock Management
- Traceability
- Data Analysis
- Supply Chain Visibility
- Anti-Counterfeiting
- Stock Visibility
- Product Recalls
- Product Returns
- Improved Print & Check
- Control and Quality of Product Life Cycle
- Off-Site Control
- Product Data
- Improved Outcomes
- Parallel Imports
- Improved Operational Efficiency of Equipment

**Obstacles to achieving the identified additional benefits**

- Delays with Processing on Line
- Lack of Time & Resources
- Too Costly
- Impact on Operational Efficiency of Equipment
- Capex Cost

**Alan (GS1):** There is a recognition of the potential for serialisation to yield benefits far beyond regulatory compliance, including data analytics, supply chain visibility, and anti-counterfeiting measures.

There are also serious impediments to those benefits being fully realised, including impacts on operational efficiency of equipment, and a lack of time and resources. There is a challenge for businesses to be in a position to leverage these additional benefits, and GS1 and ESP are available to provide advice where needed.

## 12. Which of the following business areas are represented on your serialisation team?

| | |
|---|---|
| 90% | Packaging |
| 90% | Automation / Engineering |
| 87% | IT |
| 83% | Quality |
| 80% | Production / Operations / Manufacturing |
| 73% | Artwork / Marketing |
| 70% | MES / ERP |
| 60% | External Consultants |
| 37% | Sales and Commercial |

% Respondents

**Liam (ESP):** Serialisation impacts the entire business eco-system, from artwork to IT, manufacturing execution systems to automation and quality. It is essential to include the interests of all departments in your serialisation plans.

# Conclusion

The unprecedented access to the status of serialisation implementation projects that this report provides us with highlights the industry's continued concern over current regulatory deadlines and shifting regulatory requirements across some the worlds' most critical markets.

While legislative conformity is a key factor in implementing serialisation, to gain maximum return on investment, manufacturers need to approach their design strategy from a business and not a technical perspective and see serialisation as an opportunity rather than a regulatory necessity.

Serialisation aids in eliminating many of the gaps associated with traditional pharmaceutical production and distribution that leave manufacturers susceptible to product falsification. The biggest benefits of serialisation are seen in the areas of patient safety, supply chain management, business continuity and brand protection.

Once again, we would like to thank all contributors to this report.

## Upcoming Deadlines in the Top Global Markets*

| | |
|---|---|
| EU | Feb 2019 |
| USA | Nov 2017 (Lot Level) 2023 (Unit Level) |
| Brazil | Pending consultation from Anvisa (Sept 16) |
| Saudi | March 2017 |
| China | Regulations suspended. Clarification pending |
| India | Clarification pending |
| Philippines | By 30 June 2016 GTIN lot & expiry required. No serialisation regulation to date |
| South Korea | Serialization regulation in place |
| Russia | Jan 1st 2017 Critical Drugs, Jan 1st 2018 Vital Drugs, All medicines by Jan 1st 2019 |

**Please note that these deadlines are accurate as of the 15th August 2016, but are subject to frequent change*

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