GS1 Ireland Research Analysis: Are You Serialization Ready?

- **How Does Your Organization's Efforts Compare With The Other Major Pharmaceutical Manufacturers?**

- **Do You Face The Same Challenges**?

In collaboration with their partners GS1 Ireland, global serialization implementation consultants, Enterprise System Partners (ESP) carried out an extensive industry survey to establish the status of the industry in relation to the impending serialization deadlines which are facing the industry in the coming months and years. This survey was carried out in conjunction with a joint webinar on global serialization regulations in May 2016 carried out by GS1 Ireland and ESP.

Pharma IQ sat down with ESP's Serialization Director, Liam O'Riordan to gain a greater insight into the findings of the survey:

Question	Answer
ESP in collaboration with GS1 Ireland* recently completed an extensive industry survey on the subject of serialization. How did the idea for the survey come about?	In May 2016, ESP and GS1 broadcasted a live webinar updating its audience on the very latest updates to the serialization regulations in the major markets across the globe. In the lead up to the webinar, we were hearing common concerns and challenges that certain companies were facing and so we decided to establish how the wider industry was tackling serialization in general by conducting and industry-wide survey.
What were the objectives of that survey and who, within the industry, were approached?	We approached manufacturers, consultants, solution providers and wholesalers/distributors involved in serialization across the bio-pharmaceutical industry in Europe, the US and the wider global community
	With regard to the objectives, in my experience serialization can be a difficult journey full of changes and uncertainty. In an effort to help our clients make good strategic decisions we believe it was very important to get some sound evidence based data about where the industry is at right now in terms of the global implementation of serialization. Also we hoped that the placing of these results and conclusions in the public domain will help focus effort in critical bottle neck areas and thereby help facilitate a more efficient implementation of serialization across the industry.
What was the overall readiness picture in terms of being able to meet upcoming serialization regulations?	The majority, 81% of respondents believe they will meet their regulatory deadlines. While this is a high figure, there is however, obvious concern about the

	almost 1 in 5 organizations that believe they will not be fully compliant with these mandatory requirements when the time comes.
What is the typical time required to serialise a packaging line?	This will vary depending on the following factors; • Level of complexity on the line • Range and variation of product being packaged • Whether it is unit level serialization being implemented or full aggregation and indeed also the number of levels of aggregation. • Whether or not a core model is employed. A core model gives very significant benefits when a large number of very similar lines are to be deployed and validated. However in general 60% of respondents believe it takes 6 to 12 months to serialize a typical line.
Are most organizations planning to do full aggregation on all packaging lines?	This varies by region, influenced by both regulatory and distributor requirements, but approximately one third of all respondents plan to aggregate on all sites irrespective of specific requirements.
What is seen as being the key challenge	Without a shadow of a doubt uncertainty surrounding changing deadlines and conflicting priorities are seen as the biggest challenges to serialization implementation. In fact 59% of our audience listed shifting deadlines as one of the most highly challenging aspects of serialization right now.
Aside from the challenges, does the industry recognize that serialization may bring non-regulatory benefits from the implementation of a serialization program?	With such tight regulatory deadlines right now in the bio-pharmaceutical industry, it is not surprising most organizations are focusing on regulatory compliance. However, 72% of respondents did recognize that serialization will bring benefits to their organization other than regulatory compliance. These benefits are; • Safety • Security • Anti-Counterfeiting • Brand Protection • Preventing Product Diversion • Better Recall Management • Improved Supply Chain Management From my own perspective, over the past 20 years or so,

	I have been involved in serialization project across many industries such as electronics, mobile phone and more recently the bio-pharmaceutical industry. The drivers for implementation in these industries have varied and while all are valid, what I have found is their relative importance changes depending on the nature of the business.
How does this problem of regulatory uncertainty impact project implementation?	Regulatory uncertainty has two main impacts. Firstly it results in project scope change and secondly it results in legitimate reluctance from organizations in investing in meeting requirements that may not be fully clear or subject to future change.
What is the cost of implementing serialization on a packaging line	The cost of serialization is significant - running up to $0.5M per line depending on the level of standardization and increasing further if site controllers, aggregation and enterprise level integration are required.
What resources are required in implementing a serialization project	The report highlighted the need for a multi-disciplined team. On the packaging line the following resources are required; • Project Management • Packaging Subject Matter Expertise • Packaging Engineering • Automation Engineering • Validation • Quality For the Site server and EPCIS systems; • Project Management • IT Technical Skills • Computer System Validation • Quality Other Resources; • Program Management • Artwork & Labelling • Regulatory • Planning • Commercial • Logistics

In summary, how do you feel the industry is prepared for a new serialized world?	Firstly, we were enthused by the level of response of this survey. This reflects the high priority that serialization is now being given at corporate level now that deadlines are rapidly approaching. However, the unprecedented access to the status of serialization projects that this survey provides us with highlights the industry's continued concerns over the uncertainty surrounding shifting regulatory requirements. ESP is continuing to support the industry to prepare for deadlines in all major markets and to assist our clients in capitalizing on the commercial benefits that serialization brings.

Enterprise System Partners is a global consultancy specializing in the complementary disciplines of MES and Serialization exclusively within the life science industry. We have worked with many of the early adopters within the industry since 2007 and continue to develop and execute serialization strategies across the supply chain for bio-pharmaceutical companies so they are internationally compliant for the future. A copy of the GS1 Ireland/ESP Serialization Industry Readiness Report is available to view online.

ESP will be presenting on the latest regulations in the top 10 markets this November at the IQ Pharma Serialization and Traceability Summit, Geneva.

About the ESP - GS1 Ireland partnership

As a global standards organization, GS1 standards facilitate the delivery of serialization programs in a clear structured and coherent way. ESP's philosophy in the execution of a serialization program is very similar in that a successful execution requires a structured global approach to both strategy development and execution. As with GS1 standards, these have been proven over many years of industry use. This commonality of philosophy made GS1 Ireland an obvious partner for ESP in implementing our serialization programs across our many bio-pharmaceutical clients.
This partnership helps both parties to work collaboratively in the development and delivery of excellent anti-counterfeiting solutions based on GS1 standards.