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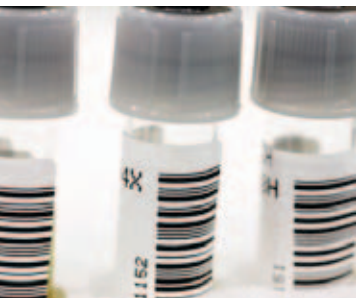

Serialisation isn't optional... this is patient care delivered by Supply and operations

Protect your patients, Product Revenue and Brand Reputation along your Supply Chain through serialisation. The need to protect drug products globally is increasing. Stakeholders across the world are struggling to understand how to transform their increasing complex global supply chains to address the need for traceability of drug products. We believe two things are certain: The revolution is coming. And it starts and ends with the patient.

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Why is it important?

- Life Science Supply chains are increasingly complex with manufacturers expanding their operations on a global scale. This requires a common approach and set of rules to ensure the integrity and traceability of the product.
- Fake Medicine seizures in the EU increased by over 700% in 2011, confirming that risk of counterfeit drug products has increased significantly – driving global regulators to enact legislation.
- New regulations, new trading partners, and perhaps new contract manufacturers and suppliers, increase the value of developing a serialisation strategy.
- Life Sciences companies that increase control, visibility, and traceability to safeguard and secure their supply chain in the interest of all stakeholders - most importantly the patients – will earn trust and retain brand integrity.

Where is the industry heading?

Counterfeit pharmaceutical products and diverted shipments in the life sciences industries are increasing the risks to patient safety and also resulting in lost revenue and poor brand image for the manufacturers. According to the latest UPS "Pain in the Chain" survey, product security has once again emerged as one of the top issues cited by senior healthcare executives, IDC Health Insights, a provider of Life Sciences market research and advisory services, also estimates major pharmaceutical companies lose as much as 4.5% of their revenue due to lack of such product visibility.

As federal and regional governments around the world have introduced legislation to detect and prevent counterfeiting. Longer term, pharmaceutical environment will become even more stringent. With more and more regulations in place and first experiences on serialisation gathered, safeguarding and securing the health care supply chain is now ready for a next step i.e. Value creation. Life sciences companies needs to bring together the appropriate strategy, technology and processes.

In order to combat this challenge, Deloitte recommends that life science companies must:

- Increase control, visibility and traceability in their global supply chain.

- Adapt a proactive approach - to maximise value rather than a reactive approach - which often leads to a fragmented, uncoordinated and, in the end, costly set of individual solutions, varying from region to region. A proactive approach will not only help you achieve regulatory compliance, but will also position you to improve your brand image, operational efficiency and, above all, patient safety.

The best course of action for a pharmaceutical firm is to **'Act Now'** to gain visibility and derive value rather than a last minute rush to be compliant with the legislation. The benefits of doing so outweigh the investment.

What is Deloitte's approach?

- Prepare a strong business case. Find the value that will drive adoption of serialisation, do not just focus on compliance.

- Define and develop a clear strategy and objectives for serialisation adoption – Begin with the end in mind. Prioritise markets, products and facilities and position strategically to take advantage of downtime and turnovers and use the business case to understand impacts. Collaborate with trading partners, suppliers and regulators to mitigate risk and maximise efficientcies.

- Develop a detailed and flexible implementation roadmap, aligned to global compliance requirements, revenue generation and operational feasibility. Run through scenarios and leave room for the expected and unexpected – new products, new markets, M&A and new laws. As part of this effort, conduct a process study and gap assessment vis-a-vis the current and potential future market regulations.

- Conduct due diligence and an impact assessment of adoption of serialisation to processes and systems including any third party logistics providers (3PL).

- Design and deploy a serialisation and track & trace system, initially launching a closed loop, then trading partner pilot before rolling out on a larger scale.

- Ensure that governance, program management and quality assurance are forefront in any effort.

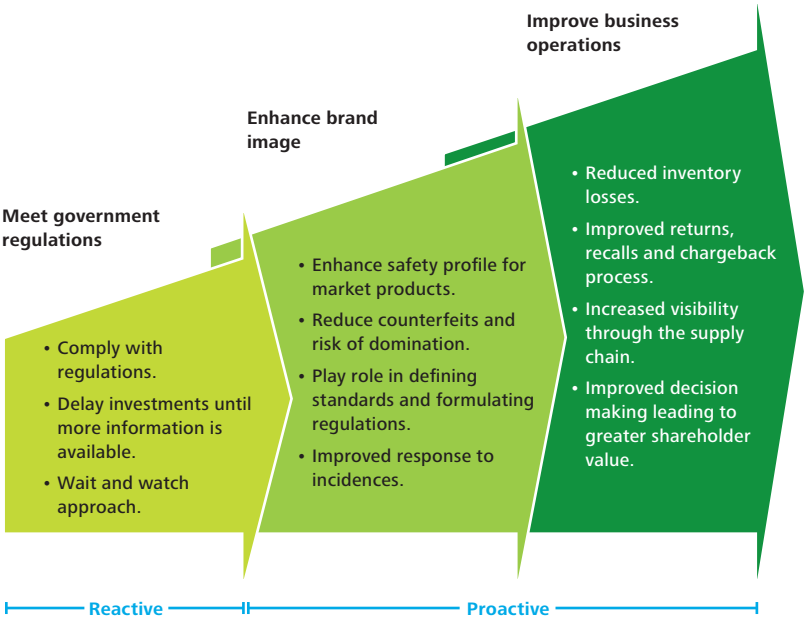
What are the outcomes?

The outcomes of moving beyond compliance to value creation are in line with what organisations seek for their business every day. Patient safety, satisfaction, accuracy and efficiency are clear benefits that can be realised through the implementation of serialisation. These benefits multiply when collaboration with trading partners and suppliers occurs.

The use of serialisation has the potential to transform the pharmaceutical industry by providing additional data and capabilities, and therefore insight, into the drug supply chain. Some companies who execute strategically will gain significantly, while others could face major challenges.

We believe two things are certain: The revolution is coming. And it starts and ends with the patient.

Move beyond compliance to value creation



About Deloitte's Life Sciences & Healthcare practice

Deloitte's Life Sciences & Healthcare industry comprises of over 5000 professionals in over 50 member firms. Deloitte works with all of the top 10 largest medical equipment manufacturers, 8 out of the 10 largest biotechnology companies and all of the 15 largest pharmaceutical manufacturers.

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