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Published
February 2019

What are the key challenges to serialisation implementation and how do you overcome these?

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Pharmaceutical serialisation is the application of unique information in human readable form and / or a 2D matrix bar code or a linear bar code to each saleable drug product unit to facilitate traceability through its entire supply chain. The aim of serialisation is to prevent falsified medicines entering the supply chain and to provide the patient / end-user with confidence that the drug product has not been tampered with.

Based on my experience, below is brief insight into my top 3 key challenges to implementing serialisation and how these can be overcome to ensure a smooth serialisation process.

Challenges

1. Investment

Firstly, depending on your needs and current production set-up, investment both in terms of money and time will be significant. By either updating current packaging lines with new technology or adding standalone solutions, serialisation infrastructure can be costly, especially when you think of the number of packaging lines you have across all your facilities.

In addition, you will need to incorporate the necessary software and data connections.

With regards to time, a vast amount of time will be required to train employees, not just your production operators but serialisation will impact your entire organisation from operations such as manufacturing / packaging and logistics right through to support functions of QA, validation and packaging design. Significant time will also be required in updating and drafting new operating procedures and work flows.

2. Packaging

The addition of a 2D barcode / human readable coding to your drug product pack in itself poses a challenge, as many commercial product packs will need to be redesigned to incorporate this information. As a direct consequence of redesigning artwork, it may also be necessary to alter the product packaging itself as more space will be required to accommodate the additional overprint. Keep in mind too that with any change to the product and or its packaging, regulatory approval will be needed from the relevant authorities, again lengthening your adaption process.

3. Data Management

Implementing a serialisation strategy company wide, generates a vast amount of data and in my opinion, the management of this huge data set requires a specialist 3rd party software solution as there are certain key data activities that need to take place including:

- ERP interaction/connectivity: captures processing orders and master batch data/ lot information alongside allocating serial numbers for each batch/requesting new serialisation numbers.

- Serial Number Management: With varying country serialisation requirements, you need to process different coding structures such as SGTIN, SSCC and custom serial numbers, as well as barcodes such as GS1 Application Identifiers, Chinese E-Code, Brazil IUM, Data Matrix, etc. Serial numbers may also need to be allocated in different ways either sequential, random, pre-randomized or shuffled.

- Serialisation Reporting (EPCIS): The data of each serialised batch across all packaging lines needs to be sent to a serialisation database or corporate EPCIS repository at Level 4. At differing time points you will also require various reports, for example reconciliation, performance, inspection, batch, audit so having a single management system eases the retrieval of all serialised information and ensures reporting consistency.

- Central Point of Configuration: Having a single system to configure, generate and collate data from all internal lines / facilities and any contract packaging provider(s) is invaluable.

Solutions

Plan Ahead

Think about what products you have, how they are manufactured / packed, at what facilities or with which contract service providers. So for example, your portfolio of commercial products could be manufactured / packed across 5 of your sites and you may have products outsourced to contract service providers. All of a sudden, you have multiple internal packaging lines which will need assessed to determine the most suitable serialisation solution from the fully automated to the manual application of the serialisation data and tamper evident feature. At the same time, you need to ensure your serialisation software solution can be tailored to manage the complexities of data transfer at your internal packaging sites and external contract service providers to enable data to be consolidated with your chosen Level 4 provider.

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Specialist Project Team

Serialisation projects are complicated and take a long time so having a dedicated serialisation team is beneficial. A cross-functional team that not only understands the global requirements of serialisation but have an appreciation of the impact it will have on operations, QA, IT, packaging design, supply chain and your contract service providers is vital to ensure cohesion between all of the key functions involved.

About the Author

Gary has a BSc in Business Studies with Computing along with a Diploma in industrial studies. Gary isresponsibe for the successful management and timelyexecution of a variety of business projects within Almac Pharma Services. Such projects include; Serialisation, process improvement, equipmentinstallations and facility upgrades across sites in Europeand America. Gary has been part of Almac PharmaServices' dedicated Serialisation team since 2017 and has aided in the delivery of serialised productsas per FMD and DSCSA regulations to all Almac clientsglobally.

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