Introduction of Electronic Batch Records to Support High Volume Growth of Medical Devices Manufacture

Background
Batch records provided a step-by-step record of production-related tasks and activities and any associated information or data. They provide confirmation that Abbott Diabetes Care (ADC) manufactures quality product that is fit for purpose. Almost all countries have regulations in place to relating to the keeping of Batch Records. Often we must state labelling requirements on distributed product for traceability and compliance. It is important to maintain accurate records as it allows tracking and bracketing based on:
- Lot information and manufacturing dates
- Product/Process data for continuous improvement

An accurate and easily accessible batch record makes it easy to demonstrate compliance with applicable regulations and ensure product quality. Good records are also important for tracking shipment and distribution of product around the world.

Business Case
Keeping accurate batch records is a key process for all medical device manufacturers. There are many regulations in place that necessitate the tracking of product. 21 CFR 821 is a US regulation that outlines what a manufacturer must do to track their devices and is not limited to a paper system. Signatures are a key part of electronic tracking, thus it is necessary to ensure conformance with electronic signature regulation 21 CFR 11.

ADC began to investigate if an electronic system would be viable to reduce work effort producing and reviewing paper records whilst maintaining compliance with all requirements. The Electronic Batch Record (EBR) project was initiated with the intention to create built-in data validity checks to further reduce the number of reviews required. The added benefits would be:
- Faster Reporting from batch records
- Integration with production equipment
- Integration with production quality systems

Example: Manufacturing a Widget
The following is an example of a recipe to make, assemble and package a widget. The “Make Part A” Unit Procedure contains operations for key activities such as preparation of the work area and operation of the production machine. The user signs in at the beginning of the UP and the system queries the Training Management system to ensure they have fully up to date training on the associated procedure.

Expanding the “Start Machine” operation shows a number of phases that walk the user through the set-up activity for the production machine. Some of the phases will present a display to the user, however many of the icons represent automated processes (indicated by a *) which execute in the background on the application server.

Interfaces
Data is transferred between the MES system and external data systems by the exchange of delimiter separated values in a file shared to a common secure location via MQ TFE (secure file transfer). When a business event occurs, external systems are configured to construct a message following an agreed structure which is processed by the interface gateway and relevant MES database tables are then populated. Similarly, when an event occurs in the MES, transaction data from the event is captured, a structures message generated in the secure location and the file transferred to the destination system by MQ TFE.

Since August 2018 to End 2018...

- 6,000 Reviews not required
- 40,000 A4 pages saved
- 37.5 hours a week saved as no longer have to print
- 5,750 manual data entry hours to ERP saved!
- 84% decrease in batch record errors out of 130,800 weekly opportunities

With the large-scale manufacturing expansion, Abbott Diabetes Care have been required to increase their output of product substantially. The EBR system has enabled the manufacturing output to increase without recruiting additional workers for reviewing batch records. The system has been a huge help to the business and to patients worldwide.