Digitalization of Batch Release Management

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The news went around the world: in the summer of 2021, a US pharmaceutical manufacturer was unable to deliver the promised quantity of Covid 19 vaccines. In a vaccine factory, several batches with a total of around 60 million doses had become unusable due to contamination. The company's share price plummeted dramatically. This is not an isolated case: there are around 100 product recalls every year in the USA alone. This shows once again how important the batch release is as a node in the value chain - and where the weak points currently lie.

Where there is a problem in quality management

Quality managers and qualified persons in particular have trouble with three points: Firstly, there are of course a lack of controls, which can lead to recalls. The second challenge is closely related to this: The high workload forces those responsible to focus entirely on collecting and analyzing data. In many large companies, quality managers have to go through a good dozen systems and paper files before approving them. A single approval takes between 40 and 500 hours, depending on the complexity of the product. This leaves little time to get to the bottom of errors and thus better prevent future incidents. The third weak point is the increasingly demanding and therefore more expensive compliance requirements.

How can a software solution simplify and digitalize the batch release process?

The entire batch release can be controlled centrally. All the data comes together in a single tool. The processes are standardized and largely automated – for all locations.

U-turn in quality management

Currently, the Qualified Person and their team spend almost all of their time on tasks that are not directly relevant to security or even add value: They manually collect data and compare information from different sources. There is no time to follow up on rejected batches. Everything is routine and reaction.

If the data is now automatically recorded and compared, these capacities are freed up and can be invested in quality management. An exception-based review becomes possible: Instead of checking batches as standard, the quality managers focus
entirely on exceptional cases, i.e. defective batches, and their causes. In this way, structural weaknesses in production can be completely clarified and the overall process can be continuously optimized. This means a 180-degree turnaround: The former cost center now actively ensures the quality of the batches.

A process that has often caused sleepless nights is even easier to manage - audits. In the case of audits, the documentation in the IT must be verified. With the software solution, all information is in one place instead of in distributed systems and files. In addition, audit log files are automatically recorded for each process. It is always clear who initiated which step and when. If an authority requires specific approval lists, these can be generated directly from the system. This enables a compliance-safe procedure and saves companies a lot of time.

**Batches for cell and gene therapy - a challenge**

A final point concerns products for cell and gene therapies, which are currently the largest market opportunity for the pharmaceutical industry. They require new methods to monitor and formulate the differences between individual batches, for example when it comes to thermal stability or RNA contamination. This is where a software solution that simplifies all processes and decisions really comes into its own.

Pharmaceutical companies can save up to 50 percent of order preparation time and up to 50 percent of compliance risk management costs with the software solution. The entire approval process could speed up by a factor of 10. Last but not least, this reduces storage costs. In addition, errors caused by incorrect data entry, for example, are practically impossible, and the "Right First Time" rate increases.

The bottom line is that such a software solution addresses the three major challenges in batch release. The quality of the products increases which prevents product recalls. The employees have significantly more time to get to the bottom of errors and to optimize the overall process. And the compliance costs are also reduced.

Two international pharmaceutical giants have co-innovated with SAP to develop a batch release software solution. The solution is available since July 2022.