AG Solution
Process Automation & Industrial ICT

Discover the benefits of implementing an EBR in the Pharma Industry

Introduction

Making sure each manufacturing batch record meets regulatory requirements is a challenging task. This is because in today's pharmaceutical manufacturing environment, production runs are shorter, product complexity is increasing and quality expectations are greater.. Discover how a well-designed EBR solution can help you overcome the main challenges of the Pharma Industry.

Let's start defining an MBR

The MBR (Master batch record), also known as Master Recipe, is the document that contains the main and most common manufacturing instructions and processes. It can be used as a general recipe, which can be adapted depending on the family product. The MBR is used as the basis to generate the Batch records, which are related to specific batches. The MBR contains details regarding:

- √ Product specifications – BOM's and other product-related information.
- √ Standard operating procedures.
- √ Activities diagrams or workflows – including processes steps and task definition, including Quality ones.
- √ Definition of Critical Process Parameters

All critical data is written, allocated in the right context (steps and processes). Once the batch is completed, this documentation is used for Quality assurance. It is also used by regulatory agencies to prove that the batch has been produced according to validated specifications and GMP standards.

So what's an EBR?

EBR stands for Electronic Batch Record. It is a system that digitalizes and substitutes the batch records based in paper.

The EBR allows to digitally design the product specifications, the SOP's workflows, and the definition of parameters. It is an easy way to support them, having a unique and maintained source of truth for MBR. Data integrity is granted because as an EBR system may support the requirement for an audit trail.

By using an EBR, paperless manufacturing is enabled. However, this paperless production can present different maturity levels:

Instructions in digital format.

The instructions are shown to the operator in a digital platform, where the data has to be manually collected (tablet or similar).

Automated instructions in digital format and integration with control systems.

Integrating the EBR with the Control System layer, allows to automatize the capture of data coming from the production processes, avoiding the use of paper and saving a lot of time and possible errors.

Main capacities of an EBR

An EBR software has a lot of characteristics, tools and widgets. However here we are not talking about software but about a solution, the EBR.

In any case, an EBR **provides** manufacturing **context** to each task that has to be executed during every production process:

- √ In terms of resources, it is specified who needs to execute each task.
- √ In terms of asset or equipment, it is defined where each task has to be executed.

The EBR is not only used to design the manufacturing guide in a digital format, it is also used to follow that guide during the execution of the different manufacturing processes and tasks.

This allows to avoid any variability in the processes because the execution of those is supported by a platform that ensures that everything is being done -by the operators or the machines- according to the previously designed guide.

The work order management is also improved with an EBR solution. The orders can be executed much faster and can be integrated with the control system.

It is finally possible to enable the report by exception. This means that only those batches that do not meet all requirements should be analyzed. The majority of the batches will not need any control beyond the control supported by the EBR in a digital platform.

These main capacities lead to a paperless factory, ensuring a faster and safer data acquisition and achieving an improved management and control of manufacturing operations.

Challenges of the Pharmaceutical industry

One of the main challenges of the Pharma Industry is the constantly growing cost pressures and the new regulations that the agencies establish for the different markets. The European Union is recognized as highly regulated, also concerning the price for medicine. In the US, even though the manufacturers can freely set these prices, the Medicare has derived into a single purchaser with great power over these prices.

In this scenario, Pharmaceutical companies are forced to move forward and reduce costs and manufacturing efforts. In this article, we highlight 4 areas of improvement:

1. **Reduce labour costs**

There is a way of reducing labour costs by doing the same but in a more efficient way. This can be achieved by reducing the workload for quality assurance teams, or reducing the time spent on batch record preparation and maintenance.

Thanks to different kinds of automation, it is also possible to reduce the time spent on capturing information from production and the time spent on consulting that information contained by multiple sources.

All this efficiency will lead to a reduction in the time required to release the batch, while achieving an enhanced flexibility.

2. **Reduce reworks**

Another big challenge for Pharma manufacturing is the need to reduce reworks of production. Reworks are very common when something has gone wrong during production. In some cases, rework is not an option and production needs to be discarded. Many of the problems that lead to a rework are caused by human errors and by deviations during the production process.

Reducing the possibility of having these human errors and variabilities in production should be an important step to accomplish this challenge.

3. **Reduce investigation time**

When something goes wrong, even if the issue is not critical, it has to be investigated: comparing between batches, going deeper into the problem, etc. It should be a priority to widen the capacity for an early detection of the problems, which will lead to a reduction of reaction times. Furthermore, proper systems for data collection, would facilitate investigations and minimize the time spent on them.

4. Challenges of a regulated environment

The pharmaceutical and biotechnology industries have been bound by strict regulations for a long time. At a batch level, this implies the need for transparency and traceability.

The information contained in the Batch Records can be accessed during assessments and it is used to confirm that the appropriate procedures are followed, that the material inventory is controlled, that the operators' identities and training levels are verified and, finally, that the Quality checks have been properly performed.

Therefore, it means a big challenge to meet these strict requirements and standards without any human mistake.

What manufacturing issues should an EBR solve?

Taking all these challenges into account, why should a Pharma company implement an EBR solution? The answer is very straight: because an EBR solution will help them to accomplish the following:

- √ Eliminate all the non-added value QA activities
- √ Reduce the time investment for recipe maintenance
- √ Avoid variabilities that are currently resulting in reworks
- √ Reduce the time to market by optimizing the production

Main benefits of an EBR

Let's take a look at the main benefits of an EBR solution, which will show us how the previously mentioned Pharma Industry Challenges can be accomplished with the help of such a system.

1. Review by exception

With the help of a digital platform such as the EBR, only the batches that have had performance problems during its execution, or that are outside the specifications of the MBR, must be checked by QA.

2. Unique source of information

The EBR assumes the role of the unique digitally maintained source that contains production specifications:

- √ What has to be done?
- √ Where has it to be done?
- √ Who has to do it?
- √ How does it have to be done?

With an EBR, there is a consolidation of all the operations that must be done (manually or semi-automatically) in only one source of truth.

3. Traceability

The EBR gives a full traceability of actions, activities and processes, making it very easy to respond to the authorities.

There is also a traceability of every CPP (Critical Process Parameter), which will speed up investigations that may be necessary after production.

4. Resistance to error

A native integration with the Control Systems and the EBR proactivity will secure the production resources (personnel, equipment and material) and will reduce the variabilities of all the processes and activities that must be done.

With the right level of maturity, the EBR will be a proactive system, capable to detect anomalies and to potentially predict them.

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