Six steps to secure product safety in pharma filling

When it comes to pharmaceutical product security the baseline is complying with the most stringent global standards. Companies producing medical devices, over the counter products, and prescription drugs need to install and verify a consistent approach with the production process. Securing product safety in sterile pharma filling is all about repeatedly minimizing risk. Here are the six checkpoints towards securing product safety in pharma filling:

1. The supplier follows the country specific regulations

Having the correct validation process in place during pharma production ensures no end user will come to harm due to a mistake during the manufacturing of the product. As technology has advanced – particularly with the advent of automation – the rules and regulations required of the pharma industry have kept pace, becoming more and more stringent in order to ensure safety and security during production. Those rules and regulations differ from country to country, so suppliers have to ensure that the packaging machines are compliant to country-specific markets.

2. Using safe materials and evaluating the pharma production equipment

In order to comply with the various rules and regulations you first and foremost perform what is called 'installation qualification', which includes the selection of the correct materials for the machine, such as what is used inside the pump or inside the nozzle. Your supplier also verifies that the machine is built correctly, looking at the specifications and drawings, comparing and confirming that the machine is built for the intended purpose.

Building the machines and ensuring there is no deviance or error that could lead to some kind of harm to the product which could cause harm to the end user is key – and the initial steps with which your machine supplier is helping. Creating an audit trail is the next step, because changing any parameter in the machine is a pharmaceutical risk that could lead to unforeseen risk circumstances.

3. Tracking the production process step-by-step

"The audit trail is a log that registers any changes made in the machine by a user. Having an assessment as far as what kinds of changes is critical from a pharmaceutical standpoint," says Norden's Automation Engineer.

"This might be the temperature for sealing the tube, the fill volume, the code you read, print, or verify".

This allows the manufacturer to act accordingly if there is a risk – which is critical, because if something goes wrong you can pinpoint exactly where in the process it happened.

The audit trail creates a chain of responsibility, where any changes are written into the database of the machine, such as who made the change, when it was made, what value it has, etc.

Image: Tube with UV-laser printed digits and letters.

4. Securing the operations with multi-national pharmaceuticals – and local pharma companies

Labelling is also part of the audit trail and a critical step when it comes to pharma. When you apply a label in a pharma production environment, you have a bar code on it, which you verify is correct and allows you to track the product from beginning to end. While multi-national pharmaceutical companies have been in the game for a long time, small or new players or sub-contractors would probably need to hire someone to verify installation qualifications and operational qualifications.

***GAMP guidance aims to achieve computerized systems that are fit for intended use and meet current regulatory requirements, by building upon existing industry good practice in an efficient and effective manner.*

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5. FDA approvals – demanding the strictest standards by registering a production user-directory

CFR 21 part 11 is an extension of the audit trail. In order to meet full FDA (The Food and Drug Administration) compliance you need to not just fulfil CFR part 11 but also meet a number of other demands, such as handling your users and local logins.

In the standard setup you have local users in the operator's interface and in order to maintain a secure environment you need to have a password. But to reach full CFR part 11 compliance you need to connect the machine to an active directory where you handle all the users. You also need to back up all the records to an external server, as well as have Internet timestamps. Norden is fully compliant in all of these areas.

6. Seek help from the software experts

Product security also includes having the expertise when it comes to software. Norden follows all the major standards, such as those set out by Gamp 5**, using verified PC software that runs the control system, operator interface, and the automation equipment in the machine. It's critical that the software verifies that the machine is consistent and delivers the same result every time – and if something goes wrong that it's handled correctly.

"Software verification is done by us," says Norden's Automation Engineer. "We don't share our source codes with third parties, so testing of the source code is done in-house at Norden, which ensures optimal security."
When it comes to pharmaceutical product security the baseline is complying with the most stringent global standards. Norden does this by ensuring the design specifications of the machine, verifying that everything works the way it should for consistent results, while also using verified software that follows Gamp 5 standards. We also ensure our customers are in full compliance with CFR part 11, allowing you to operate anywhere in the world.
"Norden Machinery has been building machines that meet the requirements of pharma for more than half a century," says Norden's Automation Engineer. "
Norden follows the strictest standards in order to ensure its machines are globally compliant, providing pharma solutions and validation. □

Contact us at sales@nordenmachinery.se to learn more about Norden filling and packaging equipment.