Collaborating with Lilly Spain to increase productivity through planned professional maintenance – Part 1

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The User

Operating since 1876, Eli Lilly and Company is one of the largest pharmaceutical companies in the world. Their site in Spain alone has more than 1,200 employees working in a variety of areas including therapeutics, bio-medicines, oncology and animal health.

Lilly's considerable success has been built on its R&D activities, promoting and supporting their corporate vision of making a significant contribution to humanity by improving health in the 21st century. Specifically, Lilly Spain is one of the manufacturing plants owned by Eli Lilly and Company around the globe.

FIGURE 1: Eli Lilly, Spain

The Challenge

Pharmaceutical companies are constantly regulated, both internally and externally, to ensure they are in compliance with good manufacturing practices. – This entails providing a complete audit trail of all machinery and equipment used. Lilly Spain previously used a tool management system to comply with regulations. However, the software is now an old US-based system that is no longer supported and maintained. Furthermore, key requirements, such as traceability features for individual punches, are unavailable without costly and time consuming, advanced technical support and guidance.

The Solution - I Holland Tool Management System

The I Holland Tool Management System (IH-TMS) is a standalone tooling management system that has been developed to allow proactive monitoring of tool rotations, tooling inventory and tooling maintenance. The system, which is 21 CFR Part 11 compliant, also keeps a record account of tablet quantities by number of tablets, work order or batch information, all of which is completely flexible to the user's needs.

Goals and the Decision Process

Monitor Tooling Life
When choosing a new management system, Lilly Spain identified four main goals that the software should help it achieve. The first is the ability to monitor tooling life starting from when it receives the tooling set from the manufacturer until the time the set is disposed of and no longer in use. The benefit of this is to accurately predict when new tooling will need to be replaced and to not lose any time and/or money on tablet press downtime.

IH-TMS was chosen for its ability to record and report production problems associated with a specific set of tooling during its life cycle, which then allows the forecast of potential future issues in production. This feature is particularly helpful with problems such as localised wear or sticking issues to the punches and dies that may indicate the need for repair work, cleaning or replacement.

Traceability
The second goal centres on the traceability of individual punches and dies within a set. This includes which room and cabinet the tooling is stored in, what maintenance actions have been carried out on them throughout their life and what machines the tools have been used in.

IH-TMS also includes the capability to store tooling and tablet drawings and take pictures of detected tooling problems (such as knocks, corrosion, burrs, etc.) which means that Lilly Spain can easily send the pictures to tooling experts, helping their trusted supplier give expert advice and find a solution. Additionally, ongoing monitoring provides the ability to constantly observe current actions and, therefore what can be done more efficiently to ensure longer tooling life. This could include changes to existing maintenance procedures and even predicting when new tooling needs to be ordered to decrease tablet press downtime.

Regulatory Compliance
The third goal Lilly Spain looked at was the reporting abilities of the different management systems available in the market place. The aim was to properly understand and identify areas of potential improvement in the company's tablet production system. Specific reporting requirements include; audit reports, maintenance action reports and inventory and product reporting.

Not only can IH-TMS generate 9 different types of reports, another benefit that supports Lilly's regulatory compliance goals is that IH-TMS is fully 21 CFR Part 11 compliant. This means that once reporting has been issued, the documents cannot be altered, leaving no room for queries by auditors. Reports can also be saved locally to the computer and sent to higher management for review, without time consuming manual entry and the potential for error. Furthermore, the system supports free type commenting on issues the production engineer/user deems necessary, providing a full audit trail throughout the entire life of an individual tool.

Ongoing Technical Support
Lastly, Lilly Spain required a new software supplier that was able to produce the assistance and technical support its previous systems manufacturer could no longer provide. Therefore, a key consideration when buying a new management system was ongoing trust in the supplier and the confidence that guidance would be provided by I Holland staff whilst Lilly learnt to use the software. IH-TMS satisfied this goal with the use of modern 64 bit Windows 10 technology that will be supported for years to come.

FIGURE 2: Testing the IH-TMS

Implementation

As part of the installation service, I Holland visits the customer site where the tool management system is to be situated. This takes place over a three or four-day programme designed to set-up IH-TMS exactly as the users require. The onsite training and implementation enables I Holland engineers to completely understand the exact needs of the customer and the process provides assurance to the company that IH-TMS is tailored to their objectives. At the end, there is also certainty (for both I Holland and the customer) that the system is set up in accordance with on-site standard maintenance procedures, and that users of the system are fully trained to customise the software to their requirements if they should change in the future.

Pablo Poza, Maintenance Coordinator at Lilly Spain, said: "The whole system will be very useful, it is very complete and more intuitive than any other system we have seen. We have been very happy with the installation process and have learnt a lot."

Liam Preston, Sales and Service Engineer for I Holland, added: "I really enjoyed meeting everyone involved in tablet production at Lilly Spain and helping them to set up the software to fit in with existing operating procedures. I look forward to hearing the benefits they reap from IH-TMS in the future.

IH-TMS®

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