

Collaborating with Lilly Spain to increase productivity through planned professional maintenance – Part 2

“Without any doubt, it is a great management system, easy to use, really useful and very visual.”

Pablo Poza, Maintenance Coordinator at Lilly Spain

The User & Challenge

In 2018, a leading pharmaceutical manufacturer, Eli Lilly and Company, contacted I Holland to help their Spanish manufacturing plant implement a new tool management system. The site was already using basic software to monitor tooling; however, it operated an old US-based system which was no longer supported and maintained.

Lilly's main aim for implementing a new system was to proactively monitor tooling and maintain a full audit footprint, a key feature required by pharmaceutical companies to ensure that they are following good manufacturing practices. It was important for the new system to contain features that aided with traceability for individual punches, as well

as the ability to record complete audit trails of all tooling, maintenance and measurement methods used.

Overall, Lilly Spain had four main goals they wished to achieve with a new tool management system.

1. The ability to monitor tooling life, commencing from when a tooling set is received from the manufacturer, until the tooling is disposed of and no longer in use.
2. To easily trace individual punches and dies within a set. This included where the tooling is stored, maintenance actions that have been carried out during its lifetime, and what machines the tools have been used in.
3. For the system to understand and identify areas of potential improvement in the company's tablet production system. This needs to include audit reports, maintenance action reports and inventory and product reporting.
4. To have access to assistance and technical support when necessary.



FIGURE 1: Eli Lilly, Spain

The Solution and its Implementation

With over 70 years of tablet compression knowledge, I Holland developed the innovative Tool Management System (IH-TMS). The software has been specifically developed to maintain efficient, well organised and in-depth monitoring tooling life and tablet production, giving manufactures a complete transcript of tooling usage and maintenance. The system allows tablet manufacturers to keep a record of tablet quantities by number of tablets, work order or batch information to ensure that production is running efficiently. It also incorporates an in-depth guide to tooling specification and troubleshooting so that any problems flagged up by the IH-TMS can be rectified or further investigated. In addition, it has the capability to archive tablet and tool images/drawings. The system also has alarms to alert the users of any problems including over compression, tooling replacements or when maintenance is required.

After a thorough assessment of the all the key goals required by Lilly, they were clearly achievable using IH-TMS. The software was installed onsite at Lilly's plant in Madrid during a four-day visit. I Holland used the time to train Lilly's key stakeholders, explain the benefits of the software and how to get the most from the system toward their stated goals. All training was provided before validation commenced, entering real data in parallel with the old system. This meant that after validation had finished, Lilly could enter the data in an "easy and quick way" making the training "really useful".

Working with Lilly's skilled engineers, I Holland fully customised the system so it would integrate seamlessly into current manufacturing processes. Users were taught how to adapt the system for future change, making it a sustainable monitoring system capable of evolving to meet any eventuality. This included translation and changing the system language to Spanish once the initial set up had taken place.

How Did IH-TMS Help with Lilly Spain's Goals?

As soon as the I Holland Tool Management System was validated, Eli Lilly saw advantages when comparing it to their former system. Pablo Poza, Lilly's Maintenance Coordinator said: "The system is working as we expected, and it has fulfilled the expectations we had with our requirements."

Monitor Tooling Life

A core feature of IH-TMS is the ability to keep track of maintenance features that tooling has undergone, thus being able to monitor tooling life from when the set is first received, to when they are disposed of. The correct maintenance is critical in obtaining the maximum life from punches and dies as problems can be detected before they impact on production. If followed correctly, a maintenance procedure allows the person in charge of managing the tool room to prioritise maintenance activity by creating a work-to list.



For a highly efficient company like Lilly Spain, the ability to accurately predict when tooling will need to be replaced, so as not to lose any time and/or money on tablet press downtime, was essential. The control provided by the management capabilities of IH-TMS allows Lilly to “get the maximum yield of tools and establish replacement planning for buying new tools before problems start to appear.”

Additionally, one of the most important features of IH-TMS that Eli Lilly use for monitoring tooling life, is the ability to measure tooling and for data to be easily transferred into the system. As a good general rule, tooling measurement should be carried out at regular intervals, even if repair has not been necessary, to check for natural wear occurring during the compaction process. It is important to ensure that critical tooling dimensions have remained within tolerance. Lilly reported that their metrology activities were much faster following the application of IH-TMS. The software has enhanced the department’s productivity by enabling staff to keep an overview of several jobs as the system easily records and displays the information required.

Traceability

Within tablet manufacture, the importance of knowing where tools are and what condition they are in, should be a priority. Without this information, either unnecessary tooling replacements are made, or punches are deployed when they should be in maintenance or replaced. Unnecessary replacement of punches or scheduling the use of un-fit tools for production reduces productivity in the long run and can make a difference to the bottom line – a concept which Lilly fully understands. Traceability of tooling is, therefore, a necessity in tablet manufacture and a key requirement for a driven company like Lilly Spain.

When tooling arrives on site and a batch campaign is started, Lilly first record and issue the tooling onto the system. From there, they are now able to store all the relevant data they need from the beginning, when tools have been ordered from their trusted suppliers, to the end of the tooling life. Within the tool management

system, they can see what activity each individual tool has gone through, what tablet batches the tooling has provided, any images/ drawings associated with the set or individual tool, and all measurements. In fact, Lilly’s most used feature of IH-TMS is the ability to issue and return tooling to and from production. This enables them to know exactly where all tools are during any one given time and is especially useful during shift change.

Regulatory Compliance

Examining and reporting on location, maintenance procedures and tolerances, in-keeping with accepted standard operating procedures (SOPs) for regulatory requirements, was also an important objective for Lilly Spain. IH-TMS has been developed to allow proactive monitoring of tool rotations, tooling inventory and tooling maintenance. The system, which is compliant with protocols like the FDA’s Code of Federal Regulations – 21CFR Part 11, can generate nine different types of reports, including audits, maintenance actions, inventory and product reports. These all support Lilly’s regulatory compliance goals and are used for regular updates to all key staff.

Because the system can easily produce these reports, reporting has not only been more manageable, but also allows Lilly to check and monitor tooling effectively and on a regular basis. This in turn can be “translated into more actions, easily and quickly”, helping to increase productivity to their current processes.

Ongoing Technical Support

The last requirement for Lilly was assistance and technical support that the previous system’s manufacturer could no longer provide. From implementation of the system through to the current day, I Holland has been on hand to assist with any challenges Lilly may have faced. Mr. Poza highlighted: “The I Holland technical support for any questions/doubts is much better than the one we had with our previous supplier.” This increase in technical support is accentuated by a good working relationship with the highly motivated staff at Eli Lilly.

Conclusion

Software like I Holland's Tool Management System can identify maintenance issues or poor handling problems by auditing all tooling and its respective processes. A professional tooling procedure audit is a simple way to directly detect and rectify this, ultimately saving many hours of reduced production through unplanned tooling maintenance and replacement.

Overall, the system has met or exceeded Lilly's four main objectives; monitoring tooling life, traceability, regulatory compliance and technical support and they are already seeing a difference in production following the implementation of IH-TMS. Furthermore, the simplicity, ease of use and features of the system mean that the team at Lilly have been able to unify different activities onto one system, a feature which they could not do before. This includes measuring tooling, taking/storing photographs and creating/analysing reports.

Final words from Pablo Poza: "Without any doubt, it is a great management system, easy to use, really useful and very visual. The comments have been positives, especially for the easy management and for being very intuitive, managing all the information easily."

Liam Preston, Sales and Service Engineer for I Holland added: "I am excited to see how IH-TMS helps Lilly's tooling maintenance productivity. The more they use the system, the more they will appreciate the different features that will help with their existing processes. Overall, it has been a very enjoyable and fulfilling experience working with Lilly to help meet their goals with IH-TMS."