

The impact of a company's equipment maintenance strategy on its competitiveness

“There are no coincidences, but simply that the application of a systematic and methodological approach on maintenance processes management delivers the minimum quality requirements in the maintenance departments of pharmaceutical production sites.”

Keywords: KPI-based management • maintenance management methodologies • maintenance processes • planned maintenance pillar • quality right-first-time • TPM

The contribution of regulatory agencies to the continuous improvement of the equipment maintenance processes management

Pharmaceutical companies have followed the internal development process that regulatory agencies like US FDA, EMA or ANVISA, for example, have passed through on the last years. If, some time ago, their auditors were focusing more on product quality itself when auditing production sites, nowadays they want to see the quality mindset embedded in other areas of support like maintenance, logistics or human resources.

Also, their professionals currently have a skills set broader than they used to have in terms of out-of-the-pharmaceutical-box knowledge. It means that many of them know what to look for when auditing, for example, the quality of a maintenance plan, the skills matrix of a technician or even the root cause analysis of an equipment breakdown.

In this aspect, it is reasonable to say that the audits of these regulatory agencies are currently much more constructive because they focus not on finding issues, but on how the issues are systematically treated in order to avoid reoccurrence.

Then, when auditing maintenance departments, it's not a surprise that they want to see how the maintenance processes are managed, what established flows for normal activities

are in place and what treatment is given when deviations on these flows occur.

This 'push' is highly contributing to the development of a quality mindset inside maintenance departments and forcing pharmaceutical companies to see maintenance not only as the needed evil, but also as a strong contributor to make sure that the products will have the minimum quality standards.

The challenge is to deliver the activities needed by the maintenance processes in a way that the overall production costs will not be 'overloaded' by the quality needs.

The utilization of maintenance management methodologies in the pharmaceutical environment

There are good and well-known maintenance management methodologies available in the market, but the application of them is still a challenge in many pharmaceutical companies. It is very common to hear that they are purely theoretical or focused on other types of products/processes than medicines. Therefore, they are not used by many pharmaceutical companies and worse than that, several times they are not even better understood before someone says that it cannot be applied to pharma production sites.

Let us now do a quick analysis of the planned maintenance pillar of total productive maintenance (TPM) methodology with



Frederico F Giunchetti
Department of Global Engineering,
Lek Pharmaceuticals d.d. (part of
Sandoz, a Novartis Company),
Verovškova 57, 1526 Ljubljana,
Slovenia
frederico.giunchetti@sandoz.com

pharma eyes. The objective here is to sustain that a methodological approach in the maintenance management can deliver the proper balance in terms of equipment efficiency × maintenance costs × quality and health, safety and environment (HSE) compliance. Consequently, the requirements of the regulatory agencies in terms of maintenance processes management will be delivered, as well as competitive costs by the production site.

The maintenance methodology according to TPM applied in pharma

A simple definition of TPM: “TPM is a management process developed for improving productivity by making processes more reliable and less wasteful”. It is important to highlight that ‘more reliable and less wasteful’ is related to the quality costs too. This methodology consists of eight core pillars: planned maintenance, autonomous maintenance, focused improvement, training and education, early management, office TPM, quality maintenance and HSE.

Going deeper into the planned maintenance pillar, we have to consider six steps for the maintenance evolution, as follows:

Step 1: analysis of the present status

Objective: allow the maintenance personnel to understand that breakdowns do not happen without cause – there are reasons for them. Then, they will come to better understand the equipment functions and mechanisms.

Step 2: restoration & improvement of the deteriorated equipment

Objective: restore and improve the equipment whose troubles were identified in step 1. For this, careful breakdown analysis has to be performed in order to have their root causes identified.

Step 3: tentative standard for maintenance procedures

Objective: sustain the improved condition of the equipment by drafting standard maintenance procedures for performing maintenance tasks. First, start with periodic maintenance.

Step 4: total inspection of quality function

Objective: carry out maintenance in order to prevent quality defects by understanding the relation between them and the equipment parts.

Step 5: improvement of inspection & maintenance efficiency

Objective: add the quality functional parts of the equipment identified during step 4 to the standard

maintenance procedures drafted during step 3. Also, ensure reliable execution of preventive maintenance and reduction of maintenance man-hours.

Step 6: execution of predictive maintenance

Objective: optimize the maintenance period by monitoring the trend of the equipment deterioration status using diagnostic techniques.

These steps are nothing else than the execution of obvious activities and application of tools that can be customized and embedded as routine in the sites’ maintenance management. Some of the tasks that must be performed in the pharmaceutical environment and derive from this methodology are:

- Assessment of all equipment and instruments, tagging them accordingly;
- Development of master equipment inventory and master instruments inventory;
- Criticality assessment of these assets in terms of quality, HSE or business impact;
- Development of the maintenance strategy as consequence of the criticality assessment and failure mode, effects and analysis (FMEA) tool;
- Development of the maintenance plans and task lists;
- Creation of processes flows that allow traceability on the maintenance activities;
- Development of key performance indicators (KPIs) to measure the maintenance processes and perform routinely plan-do-check-act (PDCA) cycle (analysis of the KPIs), also based on Pareto graphics;
- Application of root-causes analysis tools (Ishikawa, 5 Whys and 5W+1H, among others) in the breakdowns with the objective to avoid reoccurrence;
- Development of skills matrix to all the maintenance different functions and roles, consequently determining the development plan for the associates;
- Development of a Q-M matrix (correlation chart between product quality defects and equipment defects);

These tasks are also requests that come from the regulatory agencies, normally in two different ways:

- Formal requirements clearly described in their standards;

- Actions that will deliver systematic checks and analysis that they want to see in order to understand the impact of equipment maintenance to the product quality in that specific production site.
- Increase the equipment availability for production by the simple fact that they will be more reliable.

Is it coincidence that the regulatory agencies ask for things that are described in the planned maintenance pillar of TPM?

The relation between quality compliance & maintenance management

There are no coincidences, but simply that the application of a systematic and methodological approach on maintenance processes management delivers the minimum quality requirements in the maintenance departments of pharmaceutical production sites.

Considering that the regulatory agencies are constantly increasing the minimum requirements in order to guarantee that safer and more efficient products will be delivered, the application of a maintenance methodology will be even more important in the near future in order to:

- Deliver the requirements in terms of quality on maintenance processes;
- Increase equipment reliability triggered by prioritization (Pareto graphics) and KPIs-based management that systematically analyze the results of improvement actions;

References

- 1 Hozen K, Nakano K. *Comprehensive Approach to Zero Breakdown – Planned Maintenance*. Japan Institute of Plant Management (2003).
- 2 ISPE. *ISPE Good Practice Guide: Maintenance*. International Society for Pharmaceutical Engineering, FL, USA (2009).
- 3 ISO. *ISO 55000 - Asset Management – Overview, Principles and Terminology*. International Organization for Standardization, Geneva, Switzerland (2013).
- 4 Japan Institute of Plant Maintenance. www.jipm.or.jp/en/index.html
- 5 International Society for Pharmaceutical Engineering. www.ispe.org
- 6 International Organization for Standardization. www.iso.org/iso/home.html

Equipment reliability and fewer breakdowns also mean less potential causes of quality defects, deviations and consequently, better costs related to quality right-first-time. Also, it means less potential of safety issues for operators and maintenance technicians.

There are still huge opportunities to apply these maintenance concepts, tools and methodologies in the pharma business. Consequently, the room for quality improvement linked to equipment reliability increase is enormous, of course linked to the overall cost reduction.

This will be a strong competitive advantage in the next few years that will impact on many of the current pharmaceutical companies financial health. It's just a matter of time that they will decide to look maintenance management based on methodologies as one pillar for quality [1-6].

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending or royalties.

No writing assistance was utilized in the production of this manuscript.