

ENGINEERING AND MAINTENANCE IN THE PHARMACEUTICAL SECTOR

1. Introduction

Today, it is unquestionable that maintenance in any industrial sector is fundamental for the short and long-term performance of our facilities and investments.

In the pharmaceutical sector, any incident can affect the environmental conditions of the process (which must be continuously monitored) and can even invalidate production.

In this article we are going to share our experience as a company that installs clean rooms, commissioning, maintenance and qualification services on the importance of integrating the maintenance department in the different phases of the construction of an installation (from design to its entire useful life).

2. Detailed design phase of new facilities

In this detailed design phase we propose to involve the maintenance department in at least the following tasks.

- The maintenance department must have and deliver from the beginning its URS (User Requirement Specifications) on all types of installations, specifying materials, standardisation of spare parts, brands and finishes to the installer who is executing this phase. This measure avoids cost overruns.
- Validate the design of the elements to ensure that the cost of their subsequent maintenance (in terms of time, intervals, spare parts) will remain within the budget allocated to them.
- Collaborate in the revision of the detailed, executive project, supervising accesses, sectorisations, records for inspections, necessary to facilitate subsequent maintenance tasks.

3. Completion of new works or modifications to existing installations

It is interesting that the maintenance department can supervise and validate the work carried out by the different subcontractors, especially at the beginning and end of the work. Specifically:

- Ensure that the "As Built" documentation (drawings, diagrams, technical data sheets, commissioning and qualification dossier) is exhaustive.
- We must also ensure that the maintenance plan and procedures are delivered and incorporated into the CMMS (Computerized Maintenance Management System) system itself. The maintenance department must verify that it has the necessary tools and protection systems to be able to carry out its future interventions quickly and safely.
- When the subcontractors complete their installations, the different finishes, the identification of circuits, wiring and regulation elements will be supervised.

- After completion of new construction or modifications to existing installations, training of personnel is initiated. This training must be appropriate in content and adapted to the professional profile of the staff to be trained. It shall include all installations.

By involving the maintenance department in all phases of the design and execution of the works, we facilitate the handover of the facilities under the responsibility of the maintenance department.

Today, the possibilities provided by Industry 4.0 are enormous. Having all the information about the systems in a practical and secure code-based form makes maintenance work easier. A balance has to be struck between the work required to maintain and update such a database and its application in daily practice.

4. Phase prior to the planned intervention

In order to be successful in future intervention, the following preliminary work should be taken into account:

- Analysis of all the interventions carried out "correctively", to determine why the equipment has deviated from its initial "optimal" setting.
- The study, by multidisciplinary teams, of possible improvements to the installation and optimisations (energy consumption, process performance, quality, ...)
- Periodic inspections will be carried out by expert technicians (also SAT of the equipment manufacturers) in which all the elements of each installation, different parameters (consumptions, pressures, flow rates, humidity) will be checked. Indicators on filters, pumps, gates, control system and the general condition of the installations shall be checked. Predictive tools such as thermographic analysis, vibrations, fluid analysis, ... are inexpensive and can be of great help in detecting abnormal situations.
- "Intrusive" inspections are foreseen to be carried out while systems are down during planned interventions.

The result of the work detailed above will be attached to the preventive plan, added to the specific actions to be carried out for modifications in other departments, and passed on to planning. Planning is a very complex activity, involving time, material and personal resources. Tools such as ERP plant maintenance modules become indispensable in order to ensure:

- Availability of spare parts and consumables. Organised, well-timed shopping can lead to savings. Availability of extraordinary handling equipment.
- Availability of staff (own and subcontracted), with appropriate and verified competencies. Safety documentation, plant-specific training.
- To arrange, transmit and verify the plan and protocol of the maintenance to be carried out to the professionals in charge of carrying them out
- Fitting all actions together in time, including the final phases of:
 - Commissioning, which consists of testing, regulating, adjusting and adapting all the parameters and elements that belong to each of the installations, in order to achieve the required conditions in each area.
 - Cleaning, sanitisation and disinfection.
 - Qualification and validation. It is very interesting that the same team that carries out the maintenance can carry out the qualification in order to optimise the interventions and, in the event that they occur, not to prolong the resolution of non-conformities.

5. Intervention

It is in this phase, when the installation is down, that we carry out the maintenance we have planned/planned.

The aim is to complete the work on time. It is important that someone in authority in the department monitors and coordinates the progress of the work and can make decisions to increase resources or modify the planned maintenance schedule.

6. Post - Intervention

This phase should include analysis of the interventions carried out, in order to:

- Propose improvements in maintenance protocols or facilities to facilitate future interventions. Reflect them also in the company's standards and URS.
- If work has been left to be carried out during the first few days with the installations in place, identify it and ensure that it is completed correctly.
- Re-plan future necessary interventions either because they have not been carried out according to plan or because they have become evident from the intrusive inspections carried out.
- It is now time to analyse the outcome of the intervention, in terms of costs, material and human resources. This will justify decisions regarding future investments and improvements.

7. Conclusions

The Pharma sector's huge investments in R&D (for both product and process), without good maintenance of the facilities, may not pay off in the foreseen timeframe. It is necessary to invest in the current tools available and to dedicate human resources in order to be able to work in the way proposed in this article. Maintenance managers must have the necessary skills to make these resources cost-effective and be able to demonstrate this with objective data.

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