LOGFILE Feature 01/2021

Digitalised Crisis Response for Pharmaceutical Production

by Felix Michler

The demands on manufacturers in the pharmaceutical industry are constantly increasing. Global competition and the international production and supply of raw materials and active ingredients increase the complexity of supply chains. At the same time, new regulations and guidelines for quality assurance of production processes, environments and plant inventories are constantly being added.

In the past, many companies have faced the growing demand for production data acquisition with a mix of paper documentation and self-developed tools. In the course of time, these in-house developments make it difficult to manage the change to a standardised and digital solution. However, the current pandemic is forcing companies to push ahead with the digitalisation of their processes.

Digitalised logbooks and protocols

Based on the superior data integrity, the deep integration capability and the functional richness of the application, a special equipment logbook for GMP production was developed. The changeover to a digital system that can also be used on tablets in the clean room offers clear advantages:

- Provision of multi-dimensional views with connection of data sets across several logbooks
- Illustration and documentation of all processes including time stamp
- Increase of data quality and simplification of searches and process control
- Reduction of the documentation effort
- Accessibility and transparency of all information
- Single Point of Truth (SPOT) while ensuring compliance and security conditions
- Digitalisation of equipment logbooks in compliance with applicable European and US regulations

Rapid Response Cycle for Active Pharmaceutical Ingredient (API) manufacturers

Companies have contingency plans for a variety of circumstances, but hardly anyone has considered a scenario like COVID-19. The new normality must include the digitalisation of communication processes. Although the pandemic may be an extreme case, any crisis

requires resilience, agility and commitment. Artificial intelligence (AI) is penetrating ever deeper into and through our companies and their processes. In the process industry, artificial intelligence will only thrive if human intelligence is included as part of the solution, especially in situations where dangerous and complex processes are operated by highly qualified and experienced experts.

Three main considerations are crucial for the operation of plants in the response to a crisis:

- **Maintaining production:** maintaining the availability of shift teams and reducing contamination from shift to shift
- **Remote team and asset managemen**t: Enable asset managers and process engineers to work remotely, yet effectively and efficiently.
- **Exceptional actions and contingency plans:** Be prepared to reduce your production team and initiate critical actions.

Emergency measures are crucial to solve a crisis. If these three considerations are properly addressed, plants will operate with greater agility and build up business resilience.

Water quality

In the manufacture of APIs, the process water must, at a mini-mum, meet the WHO requirements for drinking (potable) water quality. The minimum requirement here is therefore not – as re-quired for the manufacture of medicinal products – in the specifi-cation of the European Pharmacopoeia for purified water (Aqua purificata). However, if the WHO requirements for drinking water appear to be insufficient, the active substance manufacturer should establish tighter specifications for

- Physical and chemical attributes
- Total microbial counts
- Objectionable organisms and/or
- Endotoxins

If a non-sterile API is to be used for sterile medicinal products, water used in the final isolation and purification steps should be mo-nitored and controlled for total microbial counts, objectionable organisms and endotoxins.

Maintaining production

The employees in production are of elementary importance in order to be able to guarantee the maintenance of the production processes. We all learned about the "social distancing" through COVID-19 as the first and most effective measure to reduce the spread of the virus and to reduce contamination from shift to shift. As the process industry consists of many hazardous processes, many levels of protection depend on human cooperation.

Reduce contamination from shift to shift - replace face-to-face communication

The shift handover is a very vulnerable point in plant operation. It is based on a combination of the transfer of information in written and oral form from one shift to the next. The oral exchange of information can best be done in the form of a personal meeting, which is why shifts overlap in continuous processing plants. However, a joint presence at handover meetings could allow the COVID 19 virus to infect other colleagues. Personal communication must therefore be replaced by a telephone or video conference. The operating conditions during a pandemic mean that the outgoing shift must be better prepared than before.

Emergency procedures include the following steps:

The leaving team will communicate the data and all necessary information in writing. The departing team leaves the production environment and carries out any hygiene protocols that may be in place before the arriving shift team enters the room. Both the outgoing and incoming shifts ensure that there is no physical contact - never. In any verbal exchange, both shift supervisors:inside should follow the same digital protocol - ensuring a single source and version of the truth.

Establishment of best practices

Beyond the implementation of communication protocols, a good practice would include shift transfers in two completely separate rooms that do not share ventilation systems. Each room would contain tables and chairs, an office computer, two large screens and video conferencing facilities. An appropriate handover management solution with structured protocols and procedures is essential and includes the following:

- Continuous preparation of the shift protocols
- Preparation of the shift handover
- Execution of a detailed and excellent shift handover
- Enabling remote teams to work effectively
- Establishment of a communication platform and knowledge organization

The challenges of COVID-19 require much more flexibility from management, engineers and shift teams. But security must be a priority. There is no excuse for allowing uncoordinated and undocumented changes even in a crisis.

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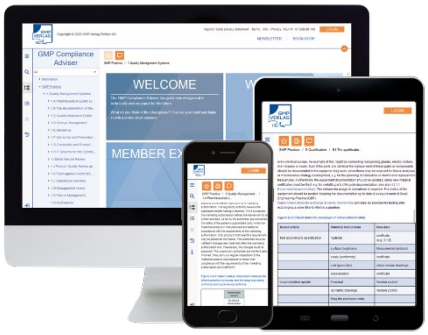

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