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Reference project

Clean room monitoring

strengthen

Customer: Pharmaceutical manufacturer

Sector: Pharmaceuticals

Monitoring with usability and prediction

- ***Audit security through the introduction of a monitoring system***
- ***Recording and archiving of all relevant room data***
- ***Compliance with all national and international regulations***

In order for our customer's production facilities to meet the criteria for a clean room, continuous monitoring is required. The company must also be able to prove at all times that it is complying with all conditions – and thus requires reliable records of all measurement results. In the past, both definition and collection of data were done manually. This is a great responsibility for employees, and despite the many precautions in place, it is a perilous error source that could cost the company enormous sums of money – not to mention the immense amount of work for the personnel involved.

Qualification, implementation and validation of the system according to GMP specifications with Wonderware System Platform

Use of the standard onoff monitoring system

Integrated alarm management with escalation

Reporting

Compliance with guidelines according to FDA 21, CFR Part 11

Hardly any other industry is as demanding as the pharmaceutical sector. There are few specialized fields in which so many rules and regulations apply as they do here. Additional complications come from the regional differences: In the USA, for example, completely different rules apply to pharmaceutical production than in Europe or Germany. For companies that operate internationally, this is another challenge that must be mastered.

Strict guidelines stipulate conditions for a company's production facilities, for example. These include room temperature, humidity, air pressure, and the occurrence of irritating particles in the atmosphere. Precisely defined thresholds may never be exceeded or fallen short of.

An integrated solution

About ten years ago, onoff developed the first automated clean room monitoring solution for this pharmaceutical customer; today, this is one of onoff's standard services. Components of the system that were worth retaining were kept; the customer's existing concept was partly factored in and integrated into the new system (for example, its alarm management). This meant that no customer training was necessary. By switching from manual to automated monitoring, the pharmaceutical company saves costs and work time today, so that these resources can be invested more effectively. Employees who were previously mostly involved in monitoring the data now have time to analyze it, and to use this information to intervene in the processes with foresight and precaution. The company is thus being proactive instead of reactive and not limiting itself to mere compliance with norms, but rather exploiting real potential.

Safety is key

The established system provides the customer with a high degree of safety by providing timely and reliable warnings and intervention. The monitoring systems developed at the time are still in operation, with few disruptions or incidents. Even when the system was being expanded with new hardware components, or when the operating system was being updated, production processes were never affected or disrupted. The reason for this complete reliability is the configuration of a "hot standby," an identical (redundant) parallel system that takes over monitoring immediately in case of failure, so that there is no dead time. A failure would therefore not effect processes or information. By now, onoff has become a real expert in the pharmaceutical sector. Thanks to numerous experiences in other projects in the industry, onoff has solid knowledge of national and international regulations, such as those of the Food & Drug Administration (FDA), the Code of Federal Regulations (CFR 21), Good Manufacturing Practice (GMP) and Good Documentation Practice (GDP).

"Now we work proactively instead of reactively."

System operator monitoring on the customer side

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Would you also like to take advantage of all opportunities? We look forward to meeting you.

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