White Paper

Methods and Solutions

for Controlling Product Quality

Deviation Management in Practice

METTLER TOLEDO

White Paper

All production industries need to define the quality of their products and control their production processes accordingly. Uncontrolled deviations in the production process have a negative effect on the quality of the product. Compliance with specifications, legislation and regulations is mandatory. Failure to observe this can lead to official warnings, complaints from customers or, in the worst case, even detriment to the health of consumers. Whatever the circumstances, this invariably leads to significant additional costs for the producers and potentially also perceptible damage to their reputation. A practical and easy to use "deviation management system" can help stabilize production processes and bring considerable cost savings here. METTLER TOLEDO has been developing and marketing comprehensive system solutions to meet these requirements for years.

Alongside observing legal and regulatory requirements, achieving optimum price-performance takes top priority for a production company.
This can be kept under control, provided the resources and equipment on hand work consistently and as desired. However, both technical systems and the people that operate them can change their behavior over time or based on their situation.
Operator actions can be laid down in instructions or SOPs (standard operating procedures) to ensure that the desired consistency is met. However, machines and production systems are subject to constant change. This also applies to the materials being processed which, despite commitments on the part of the suppliers, are themselves subject to deviations in terms of quality, composition and consistency. Despite comprehensive quality control and strictly governed specifications, certain aspects can still fail to be given proper consideration and then develop into a costly problem.

CAPA as an integral part of deviation management at companies

Since process deviations are hard to avoid, even in well organized enterprises, it makes sense to implement an effective and easy-to-use system of deviation management here. And such systems are today increasingly being conceived based on the rules of CAPA (corrective action – preventive action).
The purpose of the CAPA process is not just to determine and correct deviations (→ corrective action), but also to define and execute steps/measures to prevent such issues from occurring in future (→ preventive action).

The pioneering role of the pharmaceutical industry for other sectors

The pharmaceutical industry is subject to strict and regular examination by the US FDA (Food and Drug Administration). Any deviations from legal stipulations are recorded in publicly accessible warnings sent to the producers. In 2006 and 2007, warnings issued due to a lack of preventive processes ranked among the top 10 of all written warnings issued to industry, which further underlines their importance. To protect themselves from potential damage to their reputation and the costs associated with this, companies should undertake to securely prevent this through the introduction of appropriate measures.
The importance of this subject is further reinforced by the fact that the ISPE (International Society for Pharmaceutical Engineering; www.ispe.org) dedicates a whole chapter to CAPA in its GAMP Guide (Good Automated Manufacturing Practice). It portrays the CAPA process in simplified form in a flow chart (Figure 1).

CAPA for all sectors of industry

Massive cost pressure and the growing demand for traceable processes are making deviation management, together with CAPA, an ideal quality and cost control tool in all production industries.
In contrast to their colleagues working at pharmaceutical enterprises, the manufacturers of less strictly regulated consumer goods are being subjected to ever more critical examination by their consumers. Loss of reputation can have devastating effects on the success of a business here. So having a tool that not only detects and eliminates faults, but also helps prevent these from occurring again in future will protect the reputation of production companies and their position in the market.

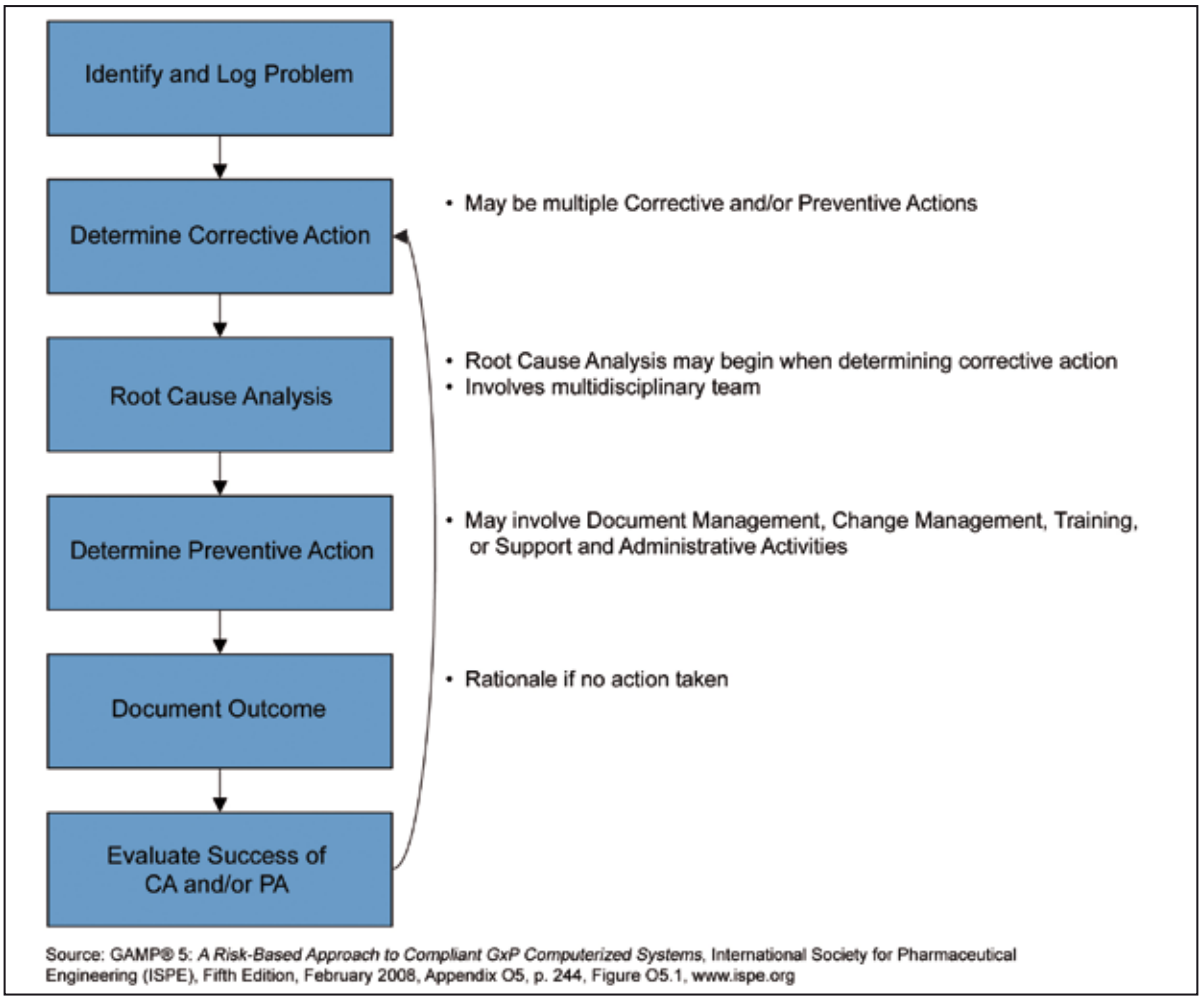
There are also many other processes critical to health that have to be controlled and monitored in other industries. Examples in the food industry include the addition of ingredients such as vitamins and flavor enhancers or complete process chains such as milk or meat processing.
An important aspect and advantage is the data trail that comes about with this process - making detection, elimination and prevention of issues traceable.

Major distributors have themselves set about implementing controls within the production chain using their own standards, such as IFS (International Food Standard; www.ifs-online.eu), BRC (British Retail Consortium; www.brc.org.uk) or SQF (Safe Quality Food Institute; www.sqfi.com), and have put into force similar requirements to the ones familiar from the pharmaceutical industry.

Practical solutions for implementation of deviation management

Software systems simplify detection and analysis of process deviations to achieve the necessary quality and cost control.
Employing networked systems which enable consistent recording of production parameters directly at the production site ensures that the data captured is available seamlessly.
This raw data forms the basis for a comprehensive analysis. All data captured is checked against specified limit values. Any violations can then be detected immediately and displayed to the operator/user. Necessary counteractive measures are defined and then implemented while the process is running, thereby ensuring that the production process can continue to run.
The frequency of the counteractive measures taken is an important indicator of the need for preven-

Figure 1



Source: GAMP® 5: *A Risk-Based Approach to Compliant GxP Computerized Systems*, International Society for Pharmaceutical Engineering (ISPE), Fifth Edition, February 2008, Appendix O5, p. 244, Figure O5.1, www.ispe.org

tive intervention in the process. As such, this provides a tool for quality assurance that secures the stability of the process and the constant quality of the product in the long term.

Software systems for quality assurance in production industries

With its FreeWeigh.Net® software system for statistical quality control, METTLER TOLEDO offers a comprehensive solution for production industries.

This system offers everything required to implement comprehensive deviation management. It permits implementation of quality assurance processes such as CAPA, but can also be a valuable addition to and complement Six Sigma (6σ). It also allows the part of the process chain it covers to be set up as fully traceable using electronic recording.

Specialized functions for fast and sustainable process interventions, such as the "Errors & Interventions" module, have been specifically developed for the requirements of long-term process optimization. Users are informed of any faults/errors that have occurred in the production process immediately via an online display on the terminal after data entry. Corresponding masks, which are defined as product-specific when making preparations, then prompt users to enter the reason for the error. The steps/measures taken on the production line are also recorded on the system in the same way.

This method ensures that production can continue to run efficiently without having to accept compromises in the quality process. The objective of this approach is to detect all weaknesses in the production chain over time and then stabilize these by taking appropriate steps in such a way that deviations become increasingly unlikely.

A stable process not only secures optimum product quality. Thanks to its controllability, it also has a significant effect on the costs and efficiency of production. This also helps prevent official warnings.

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Literature:
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- GAMP 5: A risk-based approach to compliant GxP computerized systems, ISPE, 2008, ISBN 1-931879-61-3

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