What's New in Update No. 8/2018?

Dear Reader of the GMP Compliance Adviser,

Quality Management is one of the TOP-Priorities for each Pharmaceutical Company. It is also the TOP-Priority of this update: chapter 1 of your GMP Compliance Adviser has been completely revised! Here you will find new chapters as well as quality-related topics which were located in chapter 19 "Quality Unit" up to now. Chapter 19 is now dedicated to Quality Risk Management (formerly chapter 10).

Read about the objectives and key elements of a *Pharmaceutical Quality System* in the new chapter 1.A. It offers practical recommendations on how to phrase a quality policy and how to define quality objectives. Chapter 1.B presents an oversight on the *documentation of the pharmaceutical quality system (PQS).* It provides answers on questions about documentation hierarchy and the creation of a quality manual. One of the biggest challenges regarding a quality management system is to align the individual processes in such a manner that all QM processes perfectly work together. Electronic systems can make quality management processes more efficient, more transparent and more secure. The new chapter 1.H summarizes how to proceed when implementing and using *IT systems for the optimization of quality management processes.*

Heating, ventilation and air-conditioning (HVAC) play an important role in ensuring the manufacture of quality pharmaceutical products. *The new chapter H.19* reflects the view of the WHO on this topic. The guideline forms Part I, containing the recommendations that are to be considered as good practices in design, management, control and qualification over the life cycle of HVAC systems. The WHO has already drafted Part II which will supplement the first part with examples, clarifications and drawings.

Do you want to know more about this? Then simply login and check out!

GMP in Practice	
Note:	Chapter 1 *Pharmaceutical Quality System* (sections 1.A–1.I) has been completely replaced by a new chapter 1 *Quality Management Systems* (sections 1.A–1.N). The new chapter includes the former content of chapter 19 *Quality Unit* and is completed by the following topics:

GMP in Practice	
Chapter 1	1.A Pharmaceutical quality system (PQS) 1.B The documentation of the pharmaceutical quality system (PQS) 1.H IT Systems for the Optimisation of Quality Management Processes
Chapter 19	The former content of chapter 19 *Quality Unit* has been relocated and is now part of the new chapter 1 *Quality Management Systems*. The former content of chapter 10 *Quality Risk Management* is now provided in chapter 19 *Quality Risk Management*.

GMP Regulations	
Chapter H	H.19.1 WHO: Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products (Technical Report Series, No. 1010 (2018), Annex 8)

GMP in Practice

Chapter 1 Quality Management System (PQS)

1.A Pharmaceutical quality system (PQS)

The primary objective of the pharmaceutical quality system (PQS) is patient safety. The holder of a Manufacturing Authorisation is obliged to manufacture safe and effective medicinal products in compliance with the marketing authorisation. The PQS is used to guarantee this. Key factors are adequate resources (premises, equipment, and personnel), a sound quality policy with appropriate quality objectives and the documentation of all processes in the form of instructions and records. Various tools of the PQS are used to ensure its efficacy and continual improvement, including the processes for deviation management, change management, complaint management and CAPA management. In addition, self-inspections and audits are carried out and the PQR and management review are used as evaluation tools. Other key PQS elements are quality risk management (QRM) and knowledge management. (Senior) management plays a responsible leading role in the planning, implementation and continual improvement of the PQS. Important tasks of management include the description of the quality policy, the determination of quality objectives, the provision of appropriate resources, the definition of tasks and responsibilities, the promotion of communication and the implementation of the management review. The instructions and records of the PQS are used to control and verify the quality-

related processes carried out during the manufacture of the medicinal product and thus implement the relevant regulatory requirements. (Stephanie Blum, PhD)

1.B The documentation of the pharmaceutical quality system (PQS)

Documentation is the mainstay of the pharmaceutical quality system (PQS). The *instructions* provide the specifications for all quality-related activities, the *records* document their instruction-compliant implementation and appropriate *reports* summarise and evaluate the results. A pharmaceutical plant cannot operate without documentation. As a result, the documentation system is extensive: the required documents apply to processes in all areas of the company including Purchasing, Warehousing, Production, Quality Control and Sales, including the interfaces to all processes that are outsourced, and the company's own quality management system.

The quality manual contains a description of the PQS and as a minimum, in accordance with ICH Q10, the quality policy, the scope of the PQS and the designation of all PQS processes including their relationship to one another, and finally the respective management responsibilities. The quality manual can be defined as the sum total of all the quality-related instructions of a company (that are not product-related). Alternatively, it can be combined with the site master file or created as an individual document. In the latter case, its structure can be based on the EU GMP Guidelines. (Stephanie Blum, PhD)

1.H IT Systems for the Optimisation of Quality Management Processes

An electronic document management system stores not only the documents themselves, but also their attributes (metadata) and the relationships between users and documents. In order to operate electronic document management systems, a number of functional and non-functional requirements must be met, such as the design of search and display functions, version control, audit trail and electronic signatures.

While an EDMS focuses on the document, an EQMS is mainly focused on the management of processes such as change and deviation management or CAPA. An EDMS is in effect a part and prerequisite of the EQMS. When working with an EQMS, key functions such as documentation, routing, substitute rules, deadline monitoring etc. play a central role. The application of an EQMS is demonstrated based on the CAPA process. By combining EDMS and EQMS, many advantages can be gained for the execution of quality management, e.g. the targeted querying of data for reviews (APR, PQR, Management Review), the statistical evaluation and trend analysis of deviations, complaints and recalls, etc. However, this requires that all necessary data is available in the system in a retrievable form. Important prerequisites for the successful implementation of IT systems to optimize quality management are, in addition to the competence and experience of the supplier, a clear requirement specification by the user (URS), realistic resource planning, support by management and, last but not least, acceptance by the future users. (Thilo Gukelberger)

GMP Regulations

Chapter H WHO Guidelines

H.19.1 Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products

Heating, ventilation and air-conditioning (HVAC) play an important role in ensuring the manufacture of quality pharmaceutical products. A well-designed HVAC system also provides for protection of the environment and the operators. These guidelines were first published in 2006 and revised in 2011. Consideration of various comments and questions related to *GMP for heating, ventilation and air-conditioning (HVAC) systems* led to the proposal to revise the document again. After wide public consultation, and taking into account comments received, the document and comments were discussed during an informal consultation in Geneva in April 2017.

In accordance with the recommendation made during this consultation, the guideline has been rewritten in two parts. The present document is the first part and contains the recommendations that are to be considered as good practices in design, management, control and qualification over the life cycle of HVAC systems.

The second part will contain non-binding examples, clarifications and drawings in support of the guidelines in the present document and has already been drafted.

Service

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