What's New in Update No. 4/2018?

Dear Reader of the GMP Compliance Adviser,

we all trust in numbers – and in the end, numbers are decisive for the batch release by the Qualified Person: the analytical results of the final product tests must be "in spec". But do we all know the basics of determining numerical test results? What about truncated and rounded values? How many digits are significant? The matter gets even more complicated when the question arises if single or multiple testing is required, or if single values have to be within the specification when the average is specified. Markus Veit examines the complex field of dealing with numbers for pharmaceutical quality control and explains how reportable results are generated.

SOPs are a key element of Pharmaceutical cGMP: everybody knows them, everybody needs them. What makes up a "good" SOP? Read the chapter on Standard Operating Procedures and learn about the correct use of language, format and layout to make your SOPs easy-to-understand. You will also find practical guidance on all aspects of the SOP lifecycle – from compilation to archiving.

The EMA "Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities" gave reason to a lot of questions on how to implement the requirements in the pharmaceutical industry. A draft Q&A-document was then published which caused, however, a lot of discussions. Now, finally, there is a revised version of the Q&A document that covers 13 questions and answers relating to this fervently discussed subject.

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GMP in Practice		
Chapter 14 Laboratory Controls	14.N	Determining and reporting numerical test results in pharmaceutical quality control
Chapter 15 Documentation	15.D	Standard Operating Procedures (SOPs)

GMP Regulations		
Chapter C	C.5	EU GMP Guide Part II: Basic Requirements for Active Substances used as Starting Materials combined with GMP for APIs: "How to do" Document by APIC/CEFIC Interpretation of the ICH Q7 Guide
	C.8.6.1	Questions and answers on implementation of risk-based prevention of cross-contamination in production and 'Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities' (EMA/CHMP/CVMP/SWP/169430/2012)

Read the short summaries below to get a perfect insight into the new contents at a glance:

GMP in Practice

Chapter 14 Laboratory Controls

14.N Determining and reporting numerical test results in pharmaceutical quality control

It might sound surprising, but the very extensive body of regulations dealing with pharmaceutical quality control does not provide clear guidelines on how numerical test results are to be determined, reported and/or used for conformity testing. At first glance, the subject appears to be straightforward, but questions soon arise when averaging and rounding are addressed. This chapter explains how reportable results are generated. In addition, the differences are highlighted with regard to reporting in different documents such as certificates, stability and development reports and the product quality review (PQR). The different ways of processing the initial test results (raw data) are examined along with methods for presenting them in a form that is appropriate for reporting and/or for conformity testing. Also included is an interpretation of the current regulatory requirements. (Markus Veit, PhD)

Chapter 15 Documentation

15.D Standard Operating Procedures (SOPs)

SOPs are work instructions. For this reason, they should be written in a language that is to the point, precise and understandable. The addressee of an SOP is the staff member who requires instructions and/or guidance on how a specific procedure is to be carried out. SOPs are also used to demonstrate internally (e. g. in-house auditors) and externally (e. g. official inspectors) that processes are carried

out in a targeted and specific way. Certain prerequisites must be met to ensure that SOPs can be used in a meaningful and effective way. The SOP must be created, put into effect, trained and understood. A clear structure and uniform format and/or layout of all SOPs improve readability and understanding. SOPs must be regularly monitored throughout their entire life cycle and their content adjusted to suit changed conditions when necessary. An intelligent system of identification facilitates the management of SOPs. SOPs are an integral part of GMP documentation and must be archived. (Christine Oechslein, PhD, Cornelia Wawretschek)

GMP Regulations

Chapter C EU Directives and Guidelines

C.5 EU GMP Guide Part II: Basic Requirements for Active Substances used as Starting Materials combined with GMP for APIs: "How to do" Document by APIC/CEFIC Interpretation of the ICH Q7 Guide

The APIC/CEFIC has updated its "How to do"-Document in the light of recent regulatory requirements. It aims at helping pharmaceutical manufacturers with the implementation of the GMP Guide for APIs and describes current practice.

Take a look at the editorially combined text of "How to do" with Part II of the EU GMP Guide. It provides you with a valuable interpretation tool directly related to the regulatory text.

The following chapters have been revised:
- Chapter 5 Process Equipment
- Chapter 9 Packaging and Labelling of APIs and Intermediates
- Chapter 14 Rejection and Reuse of Materials

C.8.6.1 Questions and answers on implementation of risk-based prevention of cross-contamination in production and 'Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities'

The EMA "Guideline on setting health-based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities" gave reason to a lot of questions on how to implement the requirements in the pharmaceutical industry. A draft Q&A-document was then published which caused, however, a lot of discussions. Now, finally, there is a revised version of the Q&A document that covers 13 questions and answers relating to this fervently discussed subject.

We have summarized the most important changes to the draft version for you in our news post of 2nd May 2018 (**https://www.gmp-publishing.com/en/gmp-news/gmp-aktuell/ema-qa-pde-guideline.html**).

Service

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