What's New in Update No. 8/2017?

Dear Reader of the GMP Compliance Adviser,

analytical data are the last resort when deciding upon the quality of a drug product – and they play a key role for the market release. The quality of analytical results depends on several factors – one of them is the laboratory equipment. Read about the alpha and omega of qualification, calibration, management and maintenance of this important equipment. You will find examples, checklists and practical tips for implementation as well as routine operation.

Do you need additional clarification for the selection and justification of starting materials according to ICH Q11? Or do you have further questions on which information should be provided in marketing authorisation applications and Master Files? Newly included in the regulatory section you will now find the Question and Answer Document to ICH Q11. The 16 Q&As might help to clarify your open questions!

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GMP in Practice		
Chapter 14 Quality Control	14.D	Laboratory Instruments

GMP Regulations		
Chapter E ICH-Guidelines	E.11.1	ICH Q11: Q&A Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)

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

GMP in Practice

Chapter 14 Quality Control

14.D Laboratory Instruments

This chapter deals with four important aspects regarding laboratory equipment: qualification, calibration, instrument management and maintenance.

The *qualification* can be divided into four phases: DQ, IQ, OQ and PQ. The scope of qualification has to consider the complexity of the instrument and its intended purpose. Instruments and their respective control software should be qualified together as a system, and not individually. Qualification plans and qualification reports must be created. Acceptance criteria must be included in the plans. When changes are carried out that affect the instrument configuration, a change control process must be initiated which normally results in a requalification. The maintenance of a qualified status should be checked periodically. Requalification must be carried out on a regular basis and when changes are made to the configuration of the instrument.

All of the instruments used during analytical work must be calibrated. Instrument-specific SOPs must be created for the *calibration*. The scope of calibration must be determined for each instrument individually. Individual calibration intervals are defined for the different instrument groups. The calibration status is attached to the instrument. The period of validity of the latest calibration must be indicated. The documentation must be carried out in accordance with general GMP requirements.

Some basic rules for *instrument management* are introduced, such as instrument designation or the roles and responsibilities of instrument owners and users. Relevant documents such as master list, instrument folder or logbook are presented. In order to sustain the operational condition and prevent failure, a preventative *maintenance* plan should be in place. The chapter is completed by some examples for qualification and calibration of laboratory equipment. (Josef Künzle, Wolfgang Nedvidek)

GMP Regulations

Chapter E ICH-Guidelines

E.11.1 ICH Q11 Q&A Development and Manufacture of Drug Substances (Chemical Entities and Biotechnological/Biological Entities)

The ICH Q11 Q&A reached Step 4 of the ICH process in August 2017. Initiated already in 2014, the Question and Answer document on the development and manufacture of drug substances provides additional clarification for the selection of starting materials (section 5 in ICH Q11) and on the information that

should be provided in marketing authorisation applications and/or Master Files. The focus of the Q&A document is on chemical entity drug substances. The scope of the document follows that of ICH Q 11.

It is emphasised that designation of starting materials should be based on process knowledge for the intended commercial process. All of the general principles in ICH Q11 Section 5 should always be considered holistically, together with the clarifications in this Q&A document, rather than applying a single general principle or Q&A clarification in isolation.

The 16 Q&As are complemented by a decision tree in Annex 1 to serve as a pictorial exemplification to apply to all ICH Q11 general principles for the selection and justification of a starting material.

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