What's New in Update No. 1/2018?

Dear Reader of the GMP Compliance Adviser,

we continue to follow the line of frequent updates in 2018 – it shows that the rate of regulatory change is not going to slow down any time soon:

One of the hot topics this year that will challenge pharma manufacturers is the new draft version of **Annex 1 Manufacture of Sterile Medicinal Products**. The comprehensive revision is intensively discussed at present and open for consultation until 20 March 2018.

Also to keep in view: The **GMP Guidelines on ATMPs**. The "stand-alone guidelines" were strongly criticised by PIC/S for leading to an internationally non-harmonised approach to the implementation of GMP for ATMPs. Meanwhile, the guidelines are finalised and listed under EudraLex Vol. 4 as a new Part IV.

And last but not least we have added the **FDA's CGMP for Non-Penicillin Beta-Lactam-Drugs** as a result of a customer request that reached us over the **Ask our Experts** button.

Login and make yourself familiar with the new requirements!

GMP Regulations		
Chapter C EU Directives and Guidelines	C.6.1.1	Annex 1 – Draft Manufacture of Sterile Medicinal Products
	C.22	Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products
Chapter D USA: CFR and FDA Guidelines	D.26	Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination

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

GMP Regulations

Chapter C EU Directives and Guidelines

C.6.1.1 EU GMP Guide Annex 1 Draft – Manufacture of Sterile Medicinal Products

On 20 December 2017, the European Commission has published the long awaited draft of Annex 1 of the EU GMP Guide. The comprehensive revision includes a focus on Quality Risk Management (QRM) and PQS (Pharmaceutical Quality System) as introduced with the implementation of ICH Q9 and ICH Q10.

Some of the further key changes in short:

- Single use technologies
- Aseptic operator qualification
- Application of quality risk management
- Cleaning validation for cleanroom surfaces
- Water systems – biofilm strategy
- Pure steam
- Utilities
- Cooling systems
- Compressed gasses
- Closed systems.

A public consultation period will run until 20 March 2018.

C.22 Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products

On 24 November 2017, the European Commission has published the final version of the document. The term "Advanced Therapy Medicinal Products" (ATMPs) is used to designate gene therapies, somatic cell therapies and tissue engineered products.

According to the European Commission, the 90-page document shall facilitate the development and authorisation of these products as they offer groundbreaking new opportunities for the treatment of diseases and injuries. They are particularly important for severe, untreatable or chronic diseases for which conventional approaches have proven to be inadequate.

The new guidelines adapt the European Union GMP requirements to the specific characteristics of ATMPs and address the novel and complex manufacturing scenarios utilised for these products. The guidelines foster a risk-based approach to manufacture and testing of such products. They shall ensure that these novel medicinal products are consistently produced and controlled according to high-quality standards, for the benefit and the safety of patients.

It is particularly emphasised that the guidelines are specific to ATMPs. Other documents developing GMP requirements for medicinal products which are

contained in Eudralex Vol 4 are not applicable to AMPs, unless specific reference is made.

Chapter D USA: CFR and FDA Guidelines

D.26 Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination

This guidance

- describes the importance of implementing manufacturing controls to prevent cross-contamination of finished pharmaceuticals and active pharmaceutical ingredients (APIs) with non-penicillin beta-lactam drugs.
- provides information regarding the relative health risk of, and the potential for, cross-reactivity in the classes of sensitising beta-lactams (including both penicillins and non-penicillin beta-lactams).
- clarifies that manufacturers generally should utilise separate facilities for the manufacture of non-penicillin beta-lactams because those compounds pose health risks associated with cross-reactivity.

It is intended for manufacturers of finished pharmaceuticals and APIs, including repackagers.

Service

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