What's New in Update No. 10/2017?

Dear Reader of the GMP Compliance Adviser,

once more the year is coming to an end – time to have a short look back and to give an overview of the upcoming year.

In 2017….

- We reduced the time lag between the updates in order to keep you always in the loop of actual developments around GMP:
  you received 10 Updates instead of 4!
- What happened in the GMP in Practice Part?
  6 new chapters were introduced and 12 chapters were revised!
- What has changed in the GMP Regulations Part?
  9 regulations were added and 11 documents were updated!
- Beyond that you've got 8 Member Extras providing additional information!
- And last but not least: The GMP MANUAL has got a new name:
  GMP Compliance Adviser!

In 2018…

your GMP Compliance Adviser will continue to provide frequently updated GMP knowledge in a unique and extensive data base – always striving to support you in reaching GMP compliance!

Now let us take a brief look at the last update in 2017:

Drug manufacturing needs a clean environment – this is a well-known GMP-requirement. Efficient cleaning and disinfection are prerequisites for reaching the targeted hygiene level. What has to be considered when choosing cleaning agents and disinfectants? Which techniques are appropriate for applying them? How can the cleaning of premises be organized? Read about this in the chapters *Production Hygiene* and *Hygiene Plan*.

Login and check out the new content of your GMP Compliance Adviser!

GMP in Practice	
Chapter 11 Production	11.C Production hygiene 11.D Hygiene plan

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

GMP in Practice

Chapter 11 Production

11.C Production Hygiene

Personnel is not the only source of contamination during manufacture. Other sources include the premises and facilities, starting materials, packaging and aids, as well as gases, ambient air and the processes themselves. For this reason, the cleaning and disinfection of the machinery and premises using suitable agents in accordance with defined validated processes is extremely important. Effective training of certain aspects of cleaning and disinfection is important when establishing robust processes. (Christian Gausepohl, PhD)

11.D Hygiene plan

The hygiene plan is used to define the hygiene measures that are required in the workplace. The hygiene plan contains personnel hygiene plans and assigns the individual rooms of the manufacturing site to specific cleanliness classes. Cleaning and disinfection plans are also included. They regulate what is cleaned and/or disinfected, how often, using what and how the actual processes are carried out.

The hygiene plan deals exclusively with the cleaning of rooms and surfaces that do not come in contact with product. The organisation of room cleaning begins by assigning the production rooms to the individual hygiene zones or clean room classes. The limit values permitted for each zone must be specified. All authorised cleaning and disinfecting agents must be specified in a list. This also applies to the aids that are used. The details affecting general room cleaning can be summarised in a table. The room cleaning documentation should ensure that the cleaning status of a room can be checked at any time. The person(s) who carried out the cleaning and/or disinfection process, and when and how it was carried out should be clear from the documentation. It should also facilitate the traceability of the activities before cleaning was carried out.

During the periodic evaluation of the overall status of a room, monitoring data should be examined along with the room documentation. The rooms should be inspected on a regular basis using hygiene checklists. (Christian Gausepohl, PhD)

Service

We thrive to continuously improve the GMP Compliance Adviser.

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