What's New in Update No. 1/2019?

Dear Reader of the GMP Compliance Adviser,

Did you know that the **chapter "Premises"** is one of the most read in your GMP Compliance Adviser? How fitting that this chapter is the focus of our first update in 2019!

Let's start with the **revised Chapter 3. C. "Airlock concepts"** which now features information about various concepts for the separation of cleanrooms, layout schemes and gowning procedures for personnel airlocks, and a description of different design options for material locks.

What else is there to highlight? **The new version of chapter 3.E "Cleanroom construction components"** addresses the challenging task of planning and constructing premises for pharmaceutical purposes. Our expert Harald Flechl, Senior Engineer, has compiled an overview on floors, wall and ceiling systems, window and door elements. The chapter not only represents the current state of the art but also includes special considerations for detailed design execution based on various construction examples.

And if you are more into the topic of furnishing the **new chapter 3.M "Furniture and furnishings"** could be your favorite one:
What has to be considered when purchasing furniture and furnishings? Which materials are appropriate for which cleanliness grade? Get answers to these questions and take a look at the GMP compliant design versions for tables, chairs, shelving systems, computer cabinets and other items.

Stay current and simply login and check out the new content!

GMP in Practice		
Chapter 3	3.C 3.E 3.M	Airlock concepts (revised, formerly chapter 12.B) Cleanroom construction components (rewritten) Furniture and furnishings (new topic) The sequence of chapters 3.A to 3.M has been changed for editorial reasons.

GMP in Practice

Chapter 3 Premises

3.C Airlock concepts

For economic, technical or process-related reasons, high-cleanliness areas are enclosed or surrounded by areas of low cleanliness grades. This allows the areas with the highest cleanliness requirements to be reduced to a minimum, thus saving costs and minimising the risk of contamination.

Material transport and personnel movements between different clean areas increase the risk of contamination. Therefore, the planning of a detailed layout and the appropriate pressure cascade system must be executed carefully. Airlocks must have the same cleanliness grade at rest as the higher adjacent cleanroom area. Air leakage flow areas in the airlocks are only necessary to maintain pressure levels in the working areas. The simultaneous opening of more than one door should be prevented by an interlock or a visual and/or audible warning signal.

Generally, an airlock separates two successive clean room grades. In exceptional cases, it is possible to omit an intermediate cleanroom grade if the room qualification justifies this. Incoming and outgoing gowning procedures and material handling procedures in airlocks must be validated. As a rule, a sit-over bench divides the personnel airlock into the areas of the adjacent cleanliness grades. Gowning procedures are carried out in accordance with a written work instruction (SOP). (Ruven Brandes)

3.E Cleanroom construction components

When planning and constructing premises for pharmaceutical purposes, building law, operational and GMP requirements must be taken into account. Good Engineering Practice offers a systematic approach to the implementation of these different requirements in practice. When selecting wall and ceiling systems, window and door elements as well as floors, the intended cleanliness class of the rooms concerned must be taken into account. A risk analysis and the documented assessments as well as selected measures for risk acceptance are to be used for the selection of the components. The current state of the art and special considerations for detailed design execution are presented based on construction examples. (Harald Flechl)

3.M Furniture and furnishings

When purchasing furniture and furnishings for the pharmaceutical production area, care should be taken to ensure that the materials correspond to the intended purpose and are suitable for the intended cleanliness grade. In general, furnishings should be easy to clean and disinfect. In addition, they should not emit any particles or gases. The surface finish should not exhibit any roughness. (Harald Flechl, Wolfgang Mahl)

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