LOGFILE Feature 03/2020 – Selection and procurement of cleanroom construction components

5-7 Minuten

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1.3 Selection and procurement

1.3.1 Which factors influence component selection?

In selecting the construction components, important factors to consider are

- the process and product-specific requirements to be derived from the manufacturing processes,
- the resulting specified cleanroom classes,
- the desired flexibility (single or multi-purpose) and
- the intended detergents and disinfectants.

National and international guidelines also require risk assessments when designing plants and when determining the scope of qualification/validation.

This gives rise to special hygienic and cleanroom requirements for components. Different requirements also result from the intended type of usage. Administration, research and laboratory buildings have different requirements than production rooms. The

requirements for production areas and clean rooms used for pharmaceutical purposes have a higher standard than other buildings, even if these components are not in direct contact with pharmaceutical products. An example of a risk-based assessment of surfaces in connection with their proximity to the product and cleanability is discussed in chapter *1.9 Example of a risk assessment for surfaces*.

1.3.2 How do the requirements put on rooms for pharmaceutical use differ from the requirements put on other building types?

Special operational requirements can also include measures for ergonomic workstation design that is well accepted by the operating personnel (e.g. colour schemes for surfaces, etc.)

The need to provide greater heights and thus increased space for the room-air installations above the cleanroom ceiling and their accessibility for maintenance is also an essential factor in the shell construction.

In the following chapters, the design options for pharmaceutical cleanroom construction of GMP classes A–D are described. The requirements for non-sterile production are not as high. Solutions for non-sterile production and also temperature-controlled areas (cooling rooms, incubation rooms, etc.) are not explicitly dealt with here, but can be applied analogously.

- Higher sealing requirements for external façades. A maximum specific façade leakage of < 0.3 m^3 x h-1 × m-2 at a static pressure of 500 Pa to minimize the rate of incursion of particles from outside [1]
- Higher seal effectiveness requirements for the surrounding surfaces of a cleanroom (increased seal effectiveness can also

lead to problems regarding control of room pressures – see also 3.I.12.4 Room Pressure Differential Control)

- Smooth surfaces free of pores, free of cracks and uncontrolled dead spaces which are not easy to access for cleaning
- Not susceptible to accumulate or release particles or release gasses from component materials (“molecular contamination”)
- No materials which could serve as breeding grounds for microorganisms
- Resistant to intended detergents and disinfectants and cleaning procedures
- In certain cases, properties impacting electrostatic charges are a criterion (e.g. when processing powders, during media transfer into plastic tubes)
- Other installations (pipes, air ducts, electrical installations) should be installed in a manner conducive to cleaning – cladding all the way up to ceiling or assurance of a minimum distance according to the cleaning procedures
- Simple and properly sealed incorporation of various installations such as airflow vents (inlet, exhaust, cross flows), lighting installations, smoke detectors, sprinklers, etc.

[1] From Report No. 6, Particle transport through leaking façades (Partikeltransport durch undichte Fassaden), Dohm Pharmaceutical Engineering, Dr.-Ing. Wolf Ziemer, DI(FH) Mike Urack, May 2009, www.dphe.de

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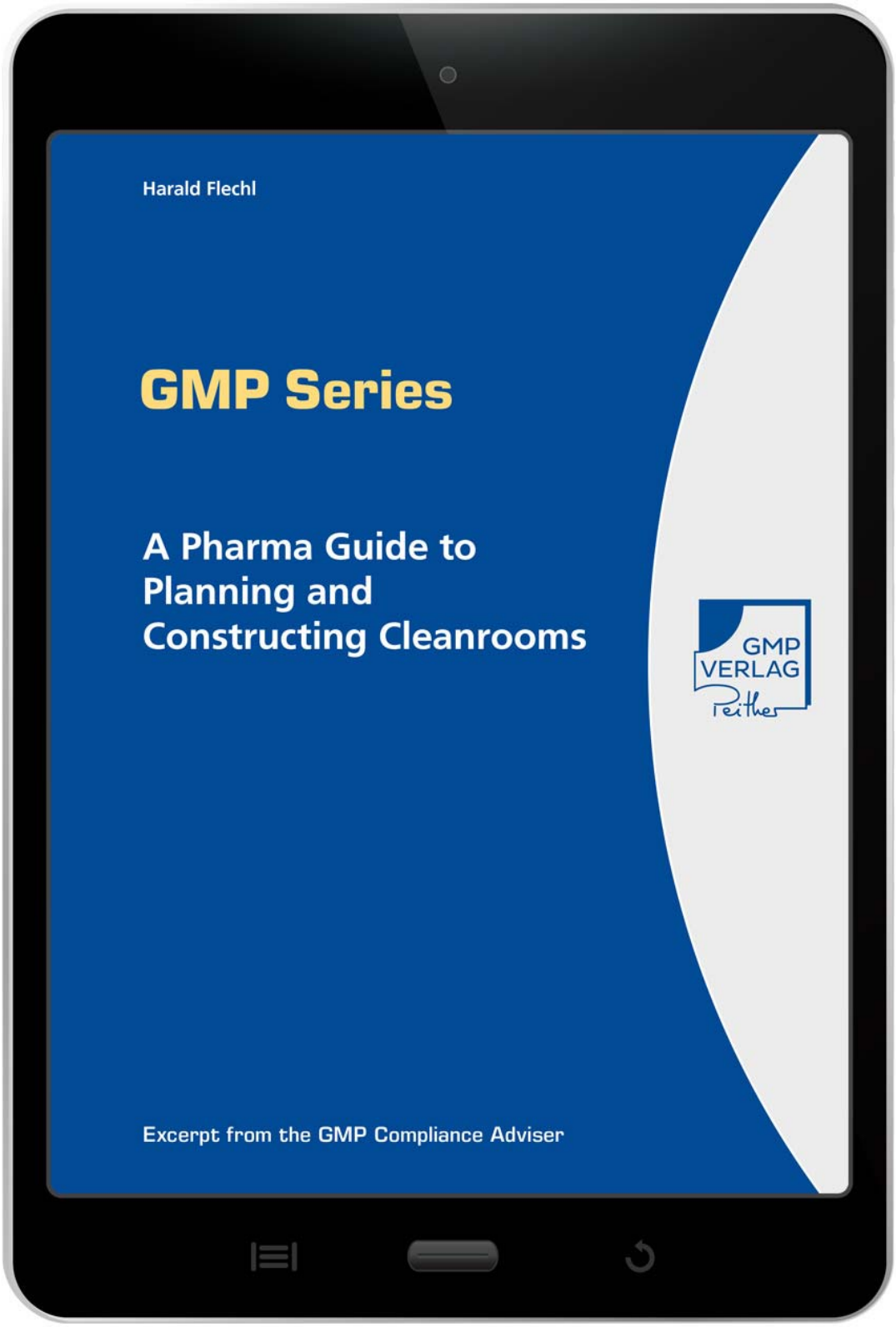
***An excerpt from the e-book** A Pharma Guide to Planning and Constructing Cleanrooms*



Planning and constructing cleanrooms is a complex task. Get to know how to successfully get through all steps of planning and construction.

The e-book offers expert knowledge on:

- Laws, rules and guidelines
- Selection and procurement
- New technologies for project planning
- Wall and ceiling systems
- Windows and doors
- Floor systems
- Application areas of construction components for different cleanroom classes
- Example of a risk assessment for surfaces

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