

What's New in Update No. 3/2018?

Dear Reader of the GMP Compliance Adviser,

cleanrooms need clean air – behind this simple fact there is a highly sophisticated field: air handling technology. Be honest - are you familiar with the technical background, the various implementation options and the requirements placed on operating and maintaining air handling units?

The new chapter 3.I *Air handling technology* provides a broad overview on design and planning of cleanroom air handling systems, layout options and filter types. You will find guidance on cleanroom protection concepts as well as design criteria for the ventilation of rooms. A large number of illustrations explain the context in a comprehensible way.

Harald Flechl, the author of this chapter, is a senior engineer with more than 30 years of professional experience in planning, implementing and maintaining ventilation systems in the pharmaceuticals, electronics and health care industries.

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GMP in Practice	
Chapter 3 Premises	3.I Air Handling Technology

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

GMP in Practice

Chapter 3 Premises

3.I Air Handling Technology

The term air handling technology is subdivided into the two categories "air handling technology for rooms" and "process air technology".

In the field of pharmaceuticals manufacturing the basic types of air handling units used are:

- 100 % fresh air units
- Central re-circulating air or mixed air units
- De-central re-circulating or mixed air units with central fresh air conditioning
- 100 % re-circulation units

Ambient air is interspersed with different substances of various particle sizes and various types. This mixture of substances is to be removed using air filters to a degree that the specified cleanliness standards in a production are upheld.

When developing the design concept of an air handling system for a pharmaceutical manufacturing facility, the external conditions and situation of the site, the requirements placed on the rooms, the climate factors influencing the production process and the requirements associated with the layout must all be known.

During detailed design of the ventilation system the following criteria must be reflected:

- Air flow patterns in rooms
- Filter classes and filter stages
- Room environmental conditions
- Pressure differential stages

The reliable, effective and economic operation of an air handling unit is dependent upon an effective maintenance program.

The maintenance program includes various activities: inspections serve to identify and assess the current state of the equipment, planned maintenance serves to maintain the desired target conditions and overhauling is necessary to re-instate target conditions. (Harald Flechl)

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