Annex 1 - 2022 Comparison Summary:

EU GMP Annex 1 Revision

Annex 1 of EU GMP provides specific guidance on the manufacture of sterile medicinal products.

The outgoing version of Annex 1 was last revised in 2008, so an update was much overdue. The 2022 version has expanded considerably in length. We have pulled together a comparison of differences between the two versions, highlighting some key areas of focus, with links to further supporting content. While this is not a comprehensive account of every single update, we hope you find it useful.

Page Number Comparison:

Annex 1 - 2008:
16 Pages

→ Annex 1 - 2022:
59 Pages

Change of Emphasis - Keywords Chart:

General instruction/guidance on the manufacture of sterile goods. → Emphasis on risk pharmaceutical quality system (PQS) as appropriate mangement systems.

2008 — Download Chart — 2022

Grade Level Detail:

Grade A recommended limits for microbial contamination stated as an average of less than one cfu.

Brief descriptions around premise and Grade A - D facilities. → Grade A Maximum permitted microbial contamination is zero cfu.

Greater level of detail describing requirements and guidenace on operations in Grade A - D facilities.

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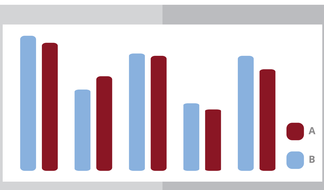

Grade B Sample Frequency:

States that clean air monitoring sample frequency in Grade B can decrease. → Expresses that Grade B monitoring frequency should be similar to Grade A.

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Aseptic Preparation:

Products prepared aseptically should be subject to sterilisation or filtration sterilisation.

Discusses Ointments, creams, suspensions and emulsions. → Aseptic preparation of products should be clearly defined, with risks associated and control measures in place including monitoring and review, well documented.

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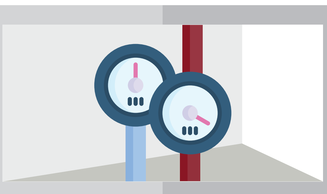
Personnel:

Personnel in critical areas should be kept to a minimum and be trained appropriately - including basic microbiology, manufacturing and gowning for each area A-D. → Personnel should receive appropriate training, including manufacturing processes and this must be documented and validated. All manufacturing personnel are responsible for cleaning and maintenance.

2008 — 2022



Pressure Differential:

Guidance on pressure differential between different graded rooms can be between 10 - 15 pascals. → Guidance on pressure differential between different graded rooms should be a minimum of 10 Pascals.

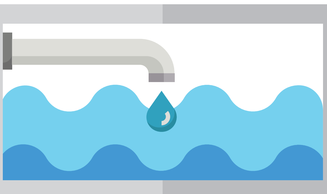
2008 — 2022

Equipment:

Equipment; designed with maintenance, repairs and operations in mind.

Cleaned and sterilised to appropriate levels. → Equipment; detailed description, design and monitoring requirements all documented; plus greater detail on the cleaning and sterilisation of equipment.

2008 — 2022



Water Treatment:

Water treatment falls under equipment section specifying reliable supply and refers to the requirements for water for injection (WFI). → Water systems has an entire section, which also refers to the Pharmacopoeia requirements, biofilms and WFI.

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VHP

Limited section on sanitisation, disinfection and fumigation → Cleaning is referred to throughout and now mentions vapourised hydrogen peroxide (VHP) as part of fumigation.

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