Annex 1 - 2022 Comparison Summary:

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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:

2008		2022
General instruction/guidance on the manufacture of sterile goods.	→	Emphasis on risk based management. Identifies Quality risk management (QRM), contamination control strategy (CCS) and pharmaceutical quality system (PQS) as appropriate mangement systems.

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Grade Level Detail:

2008		2022
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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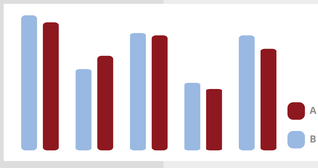

Grade B Sample Frequency:

2008		2022
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:

2008		2022
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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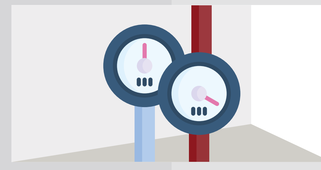
Personnel:

2008		2022
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.

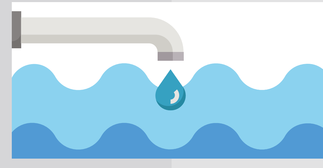


Pressure Differential:

2008		2022
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.

Equipment:

2008		2022
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.



Water Treatment:

2008		2022
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

2008		2022
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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