QUALITY EXCELLENCE SERVICES

Quality Excellence Services
18 Maple Avenue, Ste. 148
Barrington, RI 02806
United States of America
+1 (401) 246-3204 · +1 (401) 252-9653
mweeden@qesisbest.com · https://QESisBest.com

STANDARDS & GUIDANCE BRIEF · EUROPEAN UNION · EU GMP ANNEX

EU GMP Annex 1

Manufacture of Sterile Medicinal Products

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ISSUED BY	European Commission (with PIC/S)	PREPARED BY	Conner Davidson
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INDUSTRIES	Pharmaceutical	ONLINE	qesisbest.com/standard-eu-gmp-annex-1.html

IN FORCE The revised edition, published August 25, 2022, has applied since August 25, 2023; the lyophilizer loading provision followed a year later.

What It Covers

GMP for sterile medicinal products, built around a contamination control strategy and quality risk management, covering facilities, utilities, personnel, equipment, environmental and process monitoring, aseptic processing and sterilization.

Who It Applies To

Manufacturers of sterile medicinal products for the EU market, and by extension PIC/S member inspectorates.

Key Requirements

- A documented contamination control strategy (CCS) across the facility and process.
- Cleanroom grades, qualification, and environmental monitoring designed from risk.
- Aseptic process simulation, personnel qualification, and gowning.
- Sterilizing filter integrity testing, including pre-use post-sterilization testing where applicable.

What an Auditor Asks to See

- The contamination control strategy and how it is reviewed.
- Environmental monitoring trends and the actions on excursions.
- Aseptic process simulation results and interventions.

Where Systems Fall Short

- A CCS written as a document rather than used as a system.
- Environmental monitoring locations chosen by habit rather than risk.

How QES helps. A contamination control strategy tied to the monitoring data and the deviations it is meant to prevent. See the gap assessment: qesisbest.com/services.html#gap-assessment · +1 (401) 246-3204 · mweeden@qesisbest.com

Sources, checked October 24, 2026. European Commission — EudraLex Volume 4, EU GMP guidelines — health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en.

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