

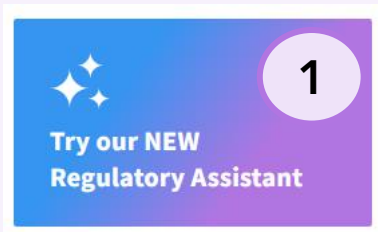
Comparing two document versions

Cortellis Regulatory Intelligence



Because Cortellis includes valid and previous versions of authority documents you can **easily compare two versions directly within Cortellis**. This helps you quickly pinpoint updates, additions, and revisions between versions, including draft and final releases. Request a comparison from the Regulatory Assistant page, the Sources of a Regulatory Assistant response or a Reference Document.

*Example: Provide an executive summary of the differences between **Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 22-Aug-2022 and the previous version Volume 3**.*



1. **Access the Regulatory Assistant** on the Home screen next to Quick Search OR from any Cortellis Regulatory Intelligence screen via the black ribbon at the top.

- 2. **Select "Compare versions" task tile.**
- 3. **Request the version comparison** as shown in the example.
- 4. Select the **Search arrow**.

Hi Beth, what is your regulatory question?

Let me find answers from our high-quality, comprehensive, and verified regulatory data

What changed between Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 22-Aug-2022 and the previous version Volume 3?

You can currently ask me to...

Understand a requirement

For example: "What is the requirement for retaining records in clinical trials in the US?"

Find a document

For example: "Find me a document about the distribution of drug samples in Canada"

Summarize a document

For example: "Briefly summarize the FDA's press release announcing completion of the first AI-assisted scientific review"

Compare versions

For example: "What changed between the latest EU Guideline on the Chemistry of Active Substances and the previous version?"

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What changed between Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 22-Aug-2022 and the previous version Volume 3?



Answer

How was this generated? ▾

I've found the following documents that match your description. Select the document you want to compare to another version by clicking the 'Version comparison' button

Source documents ▴

1 [C\(2022\) 5938 final: Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 22-Aug-2022](#)

Guideline • EC • European Union • Last updated 05-Jun-2026 • More info • Summarize **5** Version comparison

2 [Volume 4 Annex 3 of the EU Guide to GMP: Manufacture of Radiopharmaceuticals, 01-Sep-2008](#)

Guideline • EC • European Union • Last updated 05-Jun-2026 • More info • Summarize Version comparison

3 [Volume 4 Annex 5 of the EU Guide to GMP: Manufacture of Immunological Veterinary Medicinal Products](#)

Guideline • EC • European Union • Last updated 05-Jun-2026 • More info • Summarize Version comparison

Type your follow-up message

AI-generated content: check for accuracy • About Regulatory Assistant • Legal

5. Select the document you want to compare to another version by **clicking the Version Comparison button**.

6. **Select the versions you'd like to compare** in the pop-up.

7. **Click Compare**.

Version comparison

Select the two versions you want to compare

	Title	Status	Version	IDRAC	Authority acceptance	Coming into force
☒	C(2022) 5938 final: Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal...	Valid	Final, Revision	352081	22-Aug-2022	25-Aug-2023
☒	Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products (Corrected...	Outdated	Revision	89903	25-Nov-2008	01-Mar-2009
☐	Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 14-Feb-2008	Outdated	Final, Revision	80156	14-Feb-2008	01-Mar-2009
☐	EMA/INS/GMP/318222/2005: GMP Annex 1: Proposals for Amendment to the Environmental Classification...	Outdated	Draft, Revision	53902	28-Oct-2005	-
☐	Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 30-May-2003	Outdated	Revision	39022	30-May-2003	01-Sep-2003
☐	Volume 4 Proposal for Revision of Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 23...	Outdated	Draft, Revision	36196	23-Oct-2002	-

2 of 2 selected

Cancel

7

Compare



Answer

8

Here's a summary of the key updates in the 2022 version of the C(2022) 5938 final: Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 22-Aug-2022, compared with the 2008 version of the Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products (Corrected version), 25-Nov-2008.

Key Updates in the C(2022) 5938 final: Volume 4 Revised Annex 1 to EU Guide to GMP: Manufacture of Sterile Medicinal Products, 22-Aug-2022

1. Introduction of Contamination Control Strategy (CCS)

A comprehensive CCS is now required, integrating all contamination control measures across the facility, including risk assessment, monitoring, and continual improvement.

2. Emphasis on Pharmaceutical Quality System (PQS) and Quality Risk Management (QRM)

The 2022 version explicitly requires a PQS tailored to sterile manufacturing and the application of QRM principles throughout all processes.

3. Expanded Scope and Application

The scope now includes guidance for certain non-sterile products where contamination control is critical, and clarifies application to investigational and veterinary products.

4. Detailed Requirements for Premises, Equipment, and Barrier Technologies

There is significantly expanded guidance on facility and equipment design, including the use of isolators, RABS, and closed systems, with specific requirements for their qualification, operation, and background environments.

5. Enhanced Personnel Requirements

Personnel qualification, training, gowning, and hygiene requirements are more detailed, including annual requalification, disqualification criteria, and specific gowning protocols for each cleanroom grade.

8. An **Executive Summary of the key updates** appears, helping you quickly identify and understand changes between versions and assess the potential impact of regulatory updates.

6. Comprehensive Environmental and Process Monitoring

The monitoring program is now more prescriptive, with detailed requirements for routine and qualification monitoring, alert/action limits, trending, and investigation of excursions.

7. Aseptic Process Simulation (APS) Requirements

APS (media fill) requirements are expanded, including design, execution, acceptance criteria, and investigation of failures, with a focus on risk-based approaches and operator qualification.

8. Detailed Guidance on Utilities

There are new and more detailed requirements for water, steam, gases, and vacuum systems, including qualification, monitoring, and maintenance.

9. Specific Guidance for Production Technologies

Sections on Blow-Fill-Seal, Form-Fill-Seal, lyophilization, closed systems, and single-use systems are significantly expanded, with technology-specific contamination control and validation requirements.

10. Updated Cleanroom Classification and Qualification

Cleanroom classification and qualification requirements are aligned with ISO 14644, with clarified definitions for 'at rest' and 'in operation' states, and new requirements for requalification and documentation.

11. Expanded and Updated Glossary

A comprehensive glossary is added, defining key terms such as CCS, RABS, isolator, APS, and others, to ensure clarity and harmonization.

12. Increased Focus on Data, Trending, and Continuous Improvement

There is a new emphasis on data-driven decision-making, trend analysis, and the need for ongoing review and improvement of contamination control measures.

Source documents ▾

- 1 CNIL Deliberation No. 2026-050 of 19-Mar-2026 approving a Reference Methodology relating to the Processing of Personal Data Implemented in the Context of Health Research requiring the Consent of the Person concerned for Participation in the Research (MR-001) and repealing Deliberation No. 2018-153
 Legislation • Legifrance • France • Last updated 12-Jun-2026 • More info • Summarize Version comparison
- 2 CNIL Deliberation 2018-153 on the Approval of a Reference Methodology for the Processing of Personal Data Implemented in the Healthcare Research Context with the Consent of the Person concerned for Participation in the Research (MR-001) - Repealing Decision No. 2016-262 of 21-Jul-2016, 03-May-2018
 Legislation • Legifrance • France • Last updated 29-May-2026 • More info • Summarize Version comparison

9. In the **Sources of any Regulatory Assistant response**, choose any official document with a previous version to run a comparison.

10. You can also **access AI-powered Version Comparison directly from any valid Reference Document** that has a previous version and follow the same workflow outlined above.

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Decree of 26-Jan-2026: Adopts the National HTA Programme for Medical Devices 2026–2028

Valid 433515 Italy Reference Document Legislation Translation: Machine Translation

Medical Devices and IVDs

No specific Specialty

Legislative Framework Pricing Reimbursement HTAs

AI summary Version Comparison Side by side Save & alert Download

1. Summary
 2. Document
 3. Reason For Update
 4. Mentioned Documents
 5. Mentioned By

Summary

Abstract

This decree establishes the National HTA Programme for Medical Devices for the years 2026–2028.

The primary objectives of this programme are to produce HTA assessment reports and to facilitate the transfer and implementation of their findings within the National Health Service.

To achieve these goals, the technical document for the National HTA Programme for Medical Devices 2026–2028 outlines the principles, responsibilities, and key activities of the various stakeholders involved in different phases of the programme. It also builds upon and updates the National HTA Programme for Medical

Previous version
 Decree of 09-Jun-2023: Adoption of HTA National Program 2023-2025

For more information contact Customer Care at LSH.support@clarivate.com