Vereinstreffen der AQPA

15. Mai 2025

Der AQPA-Vorstand:

Georg Göstl, Obmann
Gabriela Schallmeiner, Obmann-Stellvertreterin
Regine Tomasits, Schriftführerin
Markus Thiel, Kassier

Winfried Chang
Klaus Hofstädter
Carina Rappel
Stefan Schneider
Richard Vasicek

Agenda

- 17:30 Begrüßungskaffee und Eröffnung des online-Meetings über MS-Teams
- 18:00 Begrüßung
- Präsentationen:
  - ICH Q5A „Viral Safety of Biotech Products“ Rev.2 *(Regine Tomasits/ViruSure)*
  - Allfälliges: Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
- Teilnehmerliste *(Regine Tomasits/ViruSure)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

Allfälliges

BASG/AGES neue FAQ zur erforderlichen Berufserfahrung einer QP:

Wie können die Voraussetzungen einer Sachkundigen Person gemäß § 7 Abs. 3 AMBO 2009 nachgewiesen werden?

„… Durchführung von **praktischen Tätigkeiten** in einem Qualitätskontrolllabor … **zweifelsfrei nachzuweisen**.
„… dokumentierte Nachweise der angewendeten Methoden, Geräte und Referenzen durch Stellenbeschreibungen, Schulungsnachweise, Arbeitszeugnisse, Tätigkeitsbeschreibungen, nachweislich durchgeführte Prüfungen, o.ä. vorzulegen.
Werden keine belegenden Dokumente übermittelt, hat das Bundesamt für Sicherheit im Gesundheitswesen vom Nicht-Vorliegen der Voraussetzungen auszugehen."

- ✓ https://www.basg.gv.at/fuer-unternehmen/bewilligung-und-zertifizierung/gute-herstellungs-/-vertriebspraxis-gmp/gdp/faq-meldepflichtige-fachpersonen

Österreich

- Bevorratungsverordnung (BevVO)
  - Seit 21.4.2025 in Kraft (für 3 Jahre)
  - Welche PZN: Anlage der BevVO
  - Basis: 4 Monatsbedarf (letztes Kalenderjahr)
  - Lager im Inland
  - Jeweils aktuelle Liste: RIS („Bundesgesetzblatt authentisch ab 2004“, Suchworte: „Bevorratung von Humanarzneispezialitäten“)
  - Neue Liste vom 28.Februar 2025 (zahlreiche PZN gestrichen)
  - 7 Unterschreitungsgründe, davon 3 meldepflichtig:
    - §3 (1) Z1: zumindest 25 % erhöhter Bedarf
    - §3 (1) Z2: Höhere Gewalt, nicht vorhersehbare Ereignisse
    - §3 (1) Z6: EU Solidaritätsmechanismus
  - Nicht meldepflichtig für BASG bekannte Gründe und kurze, geringfügige Unterschreitungen aufgrund rollierender Lagerhaltung
  - Jährlich bis 31. März hat MAH den Bedarf zu melden und
  - Unverzüglich eine beabsichtigte Unterschreitung (Höhe und Dauer)

Österreich

- BASG „All-in-one-Register“.
  - Das Informationsportal **"medikamente.basg.gv.at"** kombiniert in Zukunft Informationen aus:
    - Arzneispezialitätenregister
    - Vertriebseinschränkungsregister
    - BASG-Verlautbarungen: tagesaktuelle Informationen zu Verfahren und Bescheiden des BASG
    - BASG-Abstimmungen: tagesaktuelle Entscheidungen des BASG
  - Pilotphase bis Ende April 2025
  - Deutsch und Englisch
  - Feedback war bis Ende April möglich
  - FAQ-Seite:
    https://www.basg.gv.at/fuer-unternehmen/online-service/leitfaeden-und-faq/faq-basg-all-in-one-register

Draft GMP für Veterinärarzneimittel

- **COMMISSION IMPLEMENTING REGULATION (EU) …/... of XXX laying down good manufacturing practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council**
  https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13994-Veterinary-medicines-rules-on-good-manufacturing-practices_en

- **COMMISSION IMPLEMENTING REGULATION (EU) …/... of XXX laying down good manufacturing practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council**
  https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14388-Veterinary-medicines-rules-on-good-manufacturing-practices-for-active-substances-used-as-starting-materials_en

Draft GMP für Veterinärarzneimittel

Wichtig:

- Implementing Regulation (und nicht als Guideline) plus 9 Anhänge für Veterinärarzneimittel
- Implementing Regulation plus Anhang für Wirkstoffe für Veterinärarzneimittel
- Insgesamt: 205 (!) Seiten
- Feedback Periode: 22 JAN – 19 FEB 2025 (nur **4 Wochen**)
- EU-Kommission (nicht EMA)
- Commission Adoption planned for **Q4/2024**
- Inkrafttreten geplant: 20 Tage nach Veröffentlichung im *Official Journal of the European Union*
- Geplant nur 8 Monate Implementierung

Draft GMP für Veterinärarzneimittel

Wichtig:

- Obwohl GMP-Guide (EudraLex Vol 4) für Human- und Veterinärarzneimittel
- „shall“ statt „should“
- Auch neuer „Annex 1“ ohne Verweis auf QRM „in its entirety“
- Guideline: alternative Verfahren möglich
- Regulation: direkte Implementierung in allen Mitgliedsländern

Immerhin: *„This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.”*

Aber: werden die besten Kommentare die Kommission umstimmen können?

Allfälliges

EC launched a public consultation on the EU Medical Device and In Vitro Diagnostic (IVD) regulations

- ✓ Regulations 2017/745 and 2017/746 on medical devices and in vitro diagnostics
- ✓ Aiming to evaluate their effectiveness and efficiency from 2017 to 2024.
- ✓ The consultation seeks feedback from stakeholders on the regulations' impact on device availability, innovation, costs, administrative burdens, and alignment with other EU policies.
- ✓ It will also consider the potential for simplification and examine the regulations' coherence with environmental and digital policies.
- ✓ The targeted evaluation is now expected to lead to the introduction of stage two amendments to the EU's MDR and IVDR.
- ✓ Deadline for comments: **21 March 2025**.
- ✓ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14155-EU-rules-on-medical-devices-and-in-vitro-diagnostics-targeted-evaluation_en

Allfälliges

EU Critical Medicines Act:

- ✓ improve the availability of critical medicines in the EU
- ✓ protect the health of citizens by promoting the diversification of supply chains and strengthening pharmaceutical production within the EU
- ✓ proposal will now be submitted to the European Parliament and the Council for examination

https://www.gmp-compliance.org/gmp-news/securing-the-supply-of-medicines-in-the-eu-through-the-critical-medicines-act?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW13-2025-MEU

EU advancing research to reduce PFAS in healthcare sector:

- ✓ Goal is to minimize environmental and health related risks
- ✓ Reduce PFAS emissions and exposure
- ✓ Develop safe alternatives and make European healthcare sector more sustainable
- ✓ The project follows a two-stage application process:
  - Deadline for first phase is April 23, 2025
  - Deadline for second phase is October 14, 2025

https://www.gmp-compliance.org/gmp-news/pfas-in-the-healthcare-sector-innovations-for-a-sustainable-future-in-europe?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW11-2025-MEU

ECHA (European Chemicals Agency): Update on PFAS Restrictions:

- ✓ https://www.gmp-compliance.org/gmp-news/echa-update-on-pfas-restrictions?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW04-2025

EU GMP guide part II: Basic requirements for active substances used as starting materials: GMP compliance for active substances

3. Is an audit performed by a third party acceptable? H+V Apr 2025

9. What are the expectations for the content of written final assessment of third-party audit reports? H+V New Apr 2025

*"Manufacturers may contract with third parties to undertake relevant audits. If a third party is involved, the **arrangements should be subject to chapter 7 of the GMP guideline**. There should be evidence that the contract-giver has evaluated the contract-acceptor accordingly and the MIA holder should ensure that there are arrangements in place to assure that any conflicts of interests are declared.*
*The **QP has the ultimate responsibility** to ensure that **audit reports are properly evaluated** when the audit is performed by a third party. The **written final assessment** document should provide a comprehensible summary of this evaluation and should be readily available and shared with authorities, if requested.*
The assessment should include all expected elements of the auditing process and audit report(s) identified before, during and after the audit. In particular, this includes verification of contractual arrangements, scope and appropriate duration of audit, adequate competence of auditors considering the scope of the audit, planned audit frequency, and CAPAs whether adequate and how these are to be followed up. Any conflicts of interest identified should be discussed.
***QPs should ensure** that the written final assessment and approval of third-party audit reports includes an evaluation of a **declaration or absence of any conflicts** of interest made by auditors and/or the contracting parties. Conflicts of interest may come to light after the QP has relied upon a third-party audit report and it may be necessary for the QP to undertake a retrospective assessment."*

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers

Allfälliges

Q&A to QP declaration revised:

- ✓ CMDh/340/2015/Rev.8
- ✓ https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_340_2015_Rev.8_2025_02_clean_-_QA_on_QP_Declaration.pdf

EMA Q&A on how third party audit(s) should be reflected in part C of the QP declaration:

- ✓ 11 April 2025
- ✓ EMA/129980/2025
- ✓ If the audit is undertaken by the MIAH, the auditing body column should be left empty. If the audit is performed by a third-party body (*i.e.* contract acceptor on behalf of the MIAH contract giver), this should be detailed as reflected in the contract.
- ✓ In case the audit is performed on behalf of the MIAH by **different entity/entities belonging to the same overall company**, this should also be detailed in the auditing body column.
- ✓ The MIAH should always correspond to the contract giver (other contracted entities not directly involved in performing the audit should not be detailed in the table)
- ✓ MIAH site has the ultimate responsibility
- ✓ The same principles also apply in the case of sharing of audit reports between different MIAHs using the same active substance supplier
- ✓ https://www.ema.europa.eu/en/documents/other/questions-answers-how-should-third-party-audits-be-reflected-part-c-qp-declaration_en.pdf

Allfälliges

EMA comments on role of the QP in Supply Chain Traceability:

- ✓ Q&A published under Annex 16 on documentation of supply chain of active substances and the medicinal product

"To fulfil the criteria for the process of certification set out in Section 1 of Annex 16, the complete manufacturing and distribution supply chain of the medicinal product and its related active substance **up to the stage of certification, should be documented and available for the Qualified Person**. Supply chain records should provide adequate traceability and be available in a timely manner, to facilitate amongst others, quality defect investigations and product recalls as provided for in Chapter 8 of Part I of EU GMP, or requests of competent authorities. This means that these records should make it possible to identify, for active substances and medicinal products, all the entities, including suppliers and outsourced activities, involved in the manufacture of a specific batch of the drug product, **in line with the registered supply chain**.
In addition, and according to Chapter 1 and 5 of Part I of EU GMP, when establishing the supply chain traceability **the associated risks should be formally assessed and periodically reviewed with appropriate risk-mitigation measures determined to mitigate any risks identified.**"

- ✓ https://www.gmp-compliance.org/gmp-news/ema-comments-on-the-role-of-the-qp-in-supply-chain-traceability?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW48-2024

Allfälliges

EMA Q&A on “post-authorisation procedural advice for users of the centralized procedure”:

- ✓ 21 February 2025
- ✓ Revision 11
- ✓ 305 pages Q&A document
- ✓ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure-document-track-changes_en.pdf

EMA Concept paper on revision of Guidelines for the Plasma Master File (PMF):

- ✓ 17 MAR 2025
- ✓ Deadline for comments: 30 JUN 2025

https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-guideline-scientific-data-requirements-plasma-master-file-pmf-revision-1-annexes_en.pdf

Allfälliges

EMA Update of Q&A Documents for “Centralized Procedures”:

- ✓ October 2024
- ✓ Topics before and during the application (151 pages)
- ✓ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure-document-tracked-changes_en.pdf
- ✓ Topics after the authorization has been granted (307 pages)
- ✓ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure-document-track-changes_en.pdf

CMDh/HMA: Guidance Documents on Variation Notifications Updated:

- ✓ Chapters 3 and 6 of Best Practice Guide for Submission and Processing of Variations in the Mutual Recognition Procedure
- ✓ Update in January 2025

https://www.gmp-compliance.org/gmp-news/cmdh-hma-guidance-documents-on-variation-notifications-updated?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW11-2025-MEU

Allfälliges

EDQM and EU have signed new agreement to strengthen SoHO systems:

- ✓ SoHO (Substances of Human Origin)
- ✓ Through this agreement – which covers the triennium 2025 to 2027 – both organisations reaffirm the importance of making the best use of their respective strengths and resources and ensuring that these vital medical resources remain safe, of high-quality and available to those who need them, while protecting both recipients and donors.
- ✓ Through this agreement, the EU expresses its support to the EDQM in its new role by co-financing the development of standards to be included in the guides and their digitalisation.
- ✓ https://www.edqm.eu/en/-/strengthening-european-soho-systems-the-council-of-europe-and-european-union-step-up-co-operation

EU First Rules of the Artificial Intelligence (AI) Act are Now Applicable

On 02 February 2025, the first set of rules under the EU AI Act entered into force, requiring companies to ensure their staff have adequate AI literacy. The rules mandate that AI providers and deployers must ensure their staff understand AI systems based on their knowledge and training. While the rules are now in effect, enforcement will begin 02 August 2025. EC has also published examples of how companies are meeting the new AI training requirements and a draft guideline on prohibited AI practices.
https://digital-strategy.ec.europa.eu/en/news/first-rules-artificial-intelligence-act-are-now-applicable

Allfälliges

EMA Concept paper on revision of GMP for ATMPs:

- ✓ EMA/INS/GMP/48771/2025
- ✓ Deadline for comments: 08 JUL 2025
- ✓ Incorporate revised Annex 1, QRM, PQS, CCS and recent technological advancements with focus only on sterile manufacturing sections
- ✓ Plan:
  - Proposed date for release of draft guideline: September 2026
  - Deadline for stakeholder comments: December 2026
  - Adoption in GMDP IWG: March 2027
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-part-iv-guidelines-good-manufacturing-practice-specific-advanced-therapy-medicinal-products_en.pdf

EMA draft guideline on quality aspects of mRNA vaccines:

- ✓ EMA/CHMP/BWP/82416/2025
- ✓ Published 27 MAR 2025
- ✓ Deadline for comments: 30 SEP 2025
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-quality-aspects-mrna-vaccines_en.pdf

Allfälliges

EMA updated IRIS guide:

- ✓ “IRIS guide for applicants” update in December 2024 and January 2025
- ✓ Now version 3.6

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants-how-create-submit-scientific-applications-industry-individual-applicants_en.pdf

EMA consultation: guideline on risk management requirements for elemental impurities in veterinary medicinal products

- ✓ Comments until 31 JAN 2025

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-risk-management-requirements-elemental-impurities-veterinary-medicinal-products-revision-3_en.pdf

EMA Guideline on Quality, non-clinical and clinical Requirements for Investigational Medicinal Products for Advanced Therapies in Clinical Trials:

- ✓ comprehensive guidance on the structure and data requirements for clinical trials of ATMPs, including gene therapy products, cell-based therapies and tissue-engineered products.
- ✓ particular focus is on the requirements for exploratory studies, including first-in-human studies, as well as confirmatory studies.
- ✓ The guideline has already been approved by CAT and CHMP and will enter into force in July 2025.

https://www.gmp-compliance.org/gmp-news/ema-guideline-on-quality-non-clinical-and-clinical-requirements-for-investigational-medicinal-products-for-advanced-therapies-in-clinical-trials?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW13-2025-MEU

Allfälliges

EMA Guideline on the chemistry of active substances

- ✓ Revision 1, published for public consultation
- ✓ Comments until 31 JAN 2025
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-chemistry-active-substances-revision-1_en.pdf

EMA published update of Module a of eCTD:

- ✓ List of “Validation Criteria” updated to version 8.1
- ✓ From 01 MAR 2025 version 8.1 is mandatory
- ✓ https://www.gmp-compliance.org/gmp-news/esubmission-updates-of-validation-criteria?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW48-2024

CMDh/HMA: Updated Guidance Documents on Variation Notifications:

- ✓ Since 01 JAN 2025 Guidance Documents in the “Variations” section of HMA website are to be observed
- ✓ Including “Best Practice Guides” in addition to large number of other documents
- ✓ https://www.gmp-compliance.org/gmp-news/cmdh-hma-updated-guidance-documents-on-variation-notifications?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-MEU-KW05-2025

Allfälliges

EMA has published guidance on shortages prevention + mitigation:

- **Shortage prevention and mitigation plans**:

✓ Guidance for industry on implementing shortage prevention plans (SPP)
✓ good practices for industry for the prevention of human medicinal product shortages
✓ Guidance for industry on implementing shortage mitigation plans (SMP)

- **Templates** are available for MAHs to draft shortage prevention and mitigation plans:

✓ Medicine shortage prevention plan – template
✓ Medicine shortage mitigation plan – template

EMA is running a pilot shortage prevention and mitigation plans:

- EMA encourages MAHs to **participate in the pilot on a voluntary basis**
- will help prepare MAHs for the upcoming reform of the EU pharmaceutical legislation
- **Medicine shortage communication (MSC)**
- EMA is also **piloting** a medicine shortage communication template **until March 2025**. The template will come into effect after that date.
- Medicine shortage communication (MSC) – template

ESMP (European Shortages Monitoring Platform) now live:

✓ MAHs to routinely report shortages of centrally authorized medicines
✓ Verpflichtend seit 02 FEB 2025
✓ Je nach Liste von MSSG auch nicht-zentral zugelassene Produkte meldepflichtig
✓ https://www.ema.europa.eu/en/news/european-shortages-monitoring-platform-enables-better-monitoring-shortages-eu

Allfälliges

CMDh/EMA: Appendix 1 for Nitrosamines Revised:

- ✓ In February 2025, new substances were added to Appendix 1

https://www.gmp-compliance.org/gmp-news/cmdh-ema-appendix-1-for-nitrosamines-revised?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW13-2025-MEU

EMA Draft Reflection Paper on qualification of non-mutagenic impurities

- ✓ EMA/CHMP/543397/2024
- ✓ Public consultation until 30 APR 2025
- ✓ Focus: to provide alternative strategies to qualify novel impurities or to qualify higher levels of impurities that were previously qualified at a lower level
- ✓ Suggests alternative strategies to in vivo studies for qualifying novel impurities
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-qualification-non-mutagenic-impurities_en.pdf

End of Transition Period for Clinical Trials in the EU:

- ✓ As of 31 January 2025, all clinical trials in the European Union (EU), including ongoing trials approved under the previous legal framework, the Clinical Trials Directive (CTD), will be subject to the Clinical Trial Regulation (CTR)
- ✓ Only EMA's CTIS system is now mandatory a portal for submission and maintenance of clinical trials in Europe
- ✓ Transfer applications are no longer possible. Sponsors of ongoing CTD trials must submit a new applications via CTIS
- ✓ https://www.gmp-compliance.org/gmp-news/end-of-the-transition-period-for-clinical-trials?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-MEU-KW08-2025

Allfälliges

EMA CHMP issued draft document “Reflection paper on tailored clinical approach in biosimilar development:

- ✓ Discusses necessity of Comparative Efficacy Studies to demonstrate biosimilarity
- ✓ Deadline for comments: 30 SEP 2025
- ✓ https://www.ema.europa.eu/en/documents/other/reflection-paper-tailored-clinical-approach-biosimilar-development_en.pdf

EMA Considerations regarding implementation of ICH M13A on Bioequivalence:

- ✓ Bioequivalence for immediate-release solid oral dosage forms
- ✓ Published 26 FEB 2025
- ✓ https://www.gmp-compliance.org/gmp-news/ema-publishes-considerations-regarding-the-implementation-of-ich-m13a-on-bioequivalence?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW11-2025-MEU

EMA published first report on EU-wide sales and use of antimicrobials in animals:

- ✓ Data on both sales and use collected for the first time
- ✓ Annual surveillance report for 2023
- ✓ All 27 EU countries plus Iceland and Norway
- ✓ https://www.ema.europa.eu/en/documents/report/european-sales-use-antimicrobials-veterinary-medicine-annual-surveillance-report-2023_en.pdf

Allfälliges

EMA issued draft "guidance on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration":

- ✓ Deadline for comments: 31 MAY 2025

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-core-smpc-human-normal-immunoglobulin-subcutaneous-intramuscular-administration-scig-imig_en.pdf

EMA: Draft guideline on clinical investigation of human normal immunoglobulin for s.c. and/or i.m. administration

- ✓ Revision 2 published for comments
- ✓ Deadline for comments: 31 MAY 2025

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-clinical-investigation-human-normal-immunoglobulin-subcutaneous-or-intramuscular-administration-scig-imig-revision-2_en.pdf

EMA Q&A document on ICH Q8, Q9, and Q10:

- ✓ Released on 05 FEB 2025
- ✓ Guidance on quality by design, pharmaceutical quality systems, and impact of ICH guidelines on GMP inspection practice
- ✓ Removed outdated content and rephrased certain Q&As

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ich-guideline-q8-q9-q10-questions-answers-r5_en.pdf

Allfälliges

EMA published 2nd version of "Union list of critical medicines"

- ✓ 28 substances added
- ✓ Q&A on the list updated as well

https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/medicine-shortages-availability-issues/availability-medicines-during-crises/union-list-critical-medicines

New Q&As on Wholesaler Distributors and brokers and suspicious offers:

- ✓ 1.How will wholesale distributors and brokers know if they are given suspicious offers?
- ✓ 2.What should wholesale distributors and brokers do if they learn of suspicious offers?
- ✓ https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers

EMA updated a Q&A document on the quality of medicines

- ✓ Two new questions on the terms "granules in capsule for opening" and "oral powder in capsule for opening"
- ✓ Additional considerations for products that carry the terms
- ✓ https://www.ema.europa.eu/en/human-regulatory-overview/research-development/scientific-guidelines/quality-medicines-qa-introduction/quality-medicines-questions-answers-part-1

Gebühren für GMP-Inspektionen

Seit 1. Jänner 2025

https://eur-lex.europa.eu/eli/reg/2024/568/oj

2024/568

REGULATION (EU) 2024/568 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 7 February 2024

on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95

EUROPEAN MEDICINES AGENCY

NEW FEE REGULATION:

	Current Fee Regulation	New Fee Regulation
Fee GMP inspection	➢ Within EEA: 27100 EUR ➢ Outside EEA: 27100 EUR	➢ Within EEA: 30 300 EUR • Leading authority: 10 800 EUR • Supporting Authority: 6 500 EUR ➢ Outside of the EEA: 48 700 EUR • Leading authority: 20 900 • Supporting authority:12 600 EUR
Cancellation fee policy for GMP inspections **Cancellations attributable to the applicant.*	➢ Within or outside EEA: 13400 EUR	• If a scheduled inspection is cancelled **30 calendar days or less before the first day of the inspection: full fee.** • If a scheduled inspection is cancelled **more than 30 calendar days before the first day of the inspection: 1 000 EUR**
Other changes	For inspections outside the European Union, travel expenses shall be charged extra on the basis of actual cost.	The **supervisory authorities shall charge the applicant the travel expenses separately from the fee specified in this Annex, based on actual costs.** In case of a cancelled inspection, the applicant shall be charged for any travel expenses already incurred by the inspecting authority on the date of cancellation for which that authority is not able to obtain reimbursement.

Allfälliges

Neue EMA-Q&A (Feb 2025) zu „biological medicinal products“:

- When should Low Endotoxin Recovery (LER, also known as ‚endotoxin masking‘) be investigated?
- Should nitrogen be included in the finished product composition?
- Should suppliers of container closure systems for the finished product be included in the dossier?
- Where should prior knowledge be placed in the CTD?

https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/scientific-guidelines/biological-guidelines/questions-answers-biological-medicinal-products

Allfälliges

EMA draft of ICH M13B Guideline on Bioequivalence:

- ✓ Published on 09 April 2025
- ✓ "ICH Guideline M13B on bioequivalence for immediate release solid oral dosage forms - additional strengths - Step 2b"
- ✓ Public consultation until 09 JUL 2025
- ✓ https://www.gmp-compliance.org/gmp-news/ema-publishes-draft-of-ich-m13b-guideline-on-bioequivalence?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW17-2025

EMA draft reflection paper on linking to electronic product information (ePI) from EU medicine package:

- ✓ Discuss and outline considerations for getting effective PIs into the hands of customers when ePI is needed
- ✓ Published on 31 MAR 2025
- ✓ Deadline for comments: 30 JUN 2025
- ✓ https://www.ema.europa.eu/en/documents/other/draft-reflection-paper-linking-electronic-product-information-epi-eu-medicine-packages_en.pdf

EMA updated IRIS guide to registration and RPIs

- ✓ Preliminary requirements for all IRIS submissions, including substance and Research Product Identifier registration
- ✓ Version 2.17
- ✓ Published 28 MAR 2025
- ✓ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf

Allfälliges

EMA-Link zu aktuellen Q&A zu GMP und GDP:
Neue Q&As in 2024/2025 zu:

- Annex 1 (Keimzahl-Limits, Rapid method, Isolator, Parametrische Freigabe)
- Annex 8 (DEG/EG contamination)
- Annex 16 (Supply Chain Traceability)
- Wholesale distributors/brokers (suspicious offers)

https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers

EMA-Link zu allen aktuell offenen Konsultationen:

- aktuell (12. Mai 2025) 53 Dokumente unter „open consultations“

https://www.ema.europa.eu/en/news-events/open-consultations

EMA Newsletters:

- ✓ the monthly Human Medicines Highlights Newsletter for patients and healthcare professionals is a key tool to receive the latest news about medicines in the EU (subscribe).
- ✓ EMA also publishes other newsletters providing updates on various topics. An overview of all newsletters available for subscription can be found here: Newsletters | European Medicines Agency (EMA).
- ✓ **EMA encourages everybody** to consider **subscribing to the newsletters relevant** to your areas of interest.

Allfälliges

EU Urban Wastewater Treatment Directive

- ✓ Directive (EU) 2024/3019
- ✓ Published in the Official Journal on 12 DEC 2024
- ✓ In effect on 01 JAN 2025
- ✓ Member states to implement until 31 July 2027
- ✓ Additional responsibility of the manufacturer marketing pharmaceutical and cosmetic products listed in Annex III by 31 DEC 2028
- ✓ Member states will have to establish producer responsibility organisations
- ✓ Manufacturers of pharmaceutical (falling within scope of 2001/83) and cosmetic products (in scope of Regulation 1223/2009) will have to take over at least 80% of total costs of 4th step of urban waste water treatment
- ✓ Exemptions possible (quantities below 1 tonne per year, or substances rapidly biodegradable in wastewater or do not generate micropollutants in wastewater at the end of their life)
- ✓ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L_202403019

- ✓ Am 7. März 2025 endete die Frist zur Einreichung einer Nichtigkeitsklage gegen die kommunale Abwasserrichtlinie

  Cosmetics Europe, die EFPIA sowie zehn Unternehmen, die Mitglieder von Medicines for Europe sind, haben Klage beim Gericht der EU (EuG) eingereicht. Ziel ist die Nichtigerklärung der Artikel 9 und 10, die die EPR-Verpflichtungen (Extended Producer Responsibility) betreffen.
- ✓ Änderungsantrag für ein neues Impact assessment im EU-Parlament (7.5.2025) angenommen
- ✓ -> ein wichtiger Schritt, aber noch nicht das Ziel!

Allfälliges

EU Packaging and Packaging Waste Regulation (PPWR)

- Am 16. Dezember 2024 hat der Rat der Europäischen Union der „Packaging and Packaging Waste Regulation“ (PPWR), auch als EU-Verpackungsverordnung bekannt, förmlich zugestimmt.
- In Kraft seit 22.1.2025
- PPWR gilt ab 12. August 2026
- Ziel: Verpackungen zu minimieren als auch Verpackungsmüll zu vermeiden.
- Als EU-Verordnung unmittelbar in den Mitgliedsstaaten anwendbar
- Die PPWR verfolgt folgende Ziele, die bis zum 1. Jänner 2030 sicherzustellen sind:
  - •Recyclingfähigkeit von Verpackungen (Art. 6) (Ausnahme für Primärverpackung von AM zunächst bis 31.12.2034)
  - •Verwendung von mehr recyceltem Material in Kunststoffverpackungen (Art. 7) Ausnahme zunächst bis 31.12.2027 (gelten nicht für Umverpackungen und Transportverpackung)
  - •Vermeidung von zu viel Leerraum in den Verpackungen, Leerraumverhältnis darf zukünftig höchstens 50% betragen (Art. 24 (1)), Füllmaterial gilt als Leerraum (Art. 24 (3)),
  - •Minimierung von Verpackungen (Art. 10), wobei die Funktionsfähigkeit der Verpackung noch gewährleistet sein muss (Art. 10 (1)).
  - •Kennzeichnung (Piktogramm oder QR-Code) um Sortieren zu erleichtern

•Task Force der Pharmig mit Vertretern aus Unternehmen, die in Österreich Arzneimittel verpacken

Allfälliges

EU parliament requested new requirement during new Pharma legislation development:

- ✓ “each single dose of the blister pack shall include the following labelling particulars:
  - (a) the name of the medicinal product followed by its strength and pharmaceutical form;
  - (b) a data matrix code in which the following information is encoded:
    - (i) the Global Trading Index Number (GTIN)
    - (ii) the expiry date
    - (iii) the batch number”
- ✓ Industry and associations need to observe further development of new Pharma legislation

Allfälliges

Pilot project for English only packaging and leaflets in Nordic countries:

- ✓ Drug regulators in Denmark, Finland, Iceland, Norway, and Sweden have announced a pilot project to test English-only packaging and leaflets for certain medicines in the Nordic countries.
- ✓ Applies to 20 critical medicinal products produced in low volumes, used in hospitals, and administered by healthcare professionals.
- ✓ The aim of the project is to enhance the supply security of critical hospital medicines across Denmark, Finland, Iceland, Norway, and Sweden.
- ✓ The project will begin from 01 January 2025 and run for five years. Nordic health authorities have also published guidance and a form for companies wishing to participate in the initiative.

Allfälliges

PIC/S guidance on Remote Assessments:

- ✓ Remote assessments Guidance and Aide Memoire
- ✓ Effective 01 JAN 2025
- ✓ Interesting note: "… *in a non-English speaking country …,* ***machine translation*** *can be utilised, but* ***should be indicated as such****."*
- ✓ https://picscheme.org/docview/9256
- ✓ https://picscheme.org/docview/9257

PIC/S granted the status of Associated Partner Organization to the African Union Development Agency - New Partnership for Africa's Development (AUDA-NEPAD).

- ✓ The partnership aims to improve GMP standards, train inspectors, and help African regulatory authorities join PIC/S.

Allfälliges

Brexit: Windsor Framework explainer

- ✓ Published by MHRA
- ✓ 20 NOV 2024
- ✓ https://www.gov.uk/government/publications/windsor-framework-explainer

UK MHRA: Plasma Master Files (PMF) and Vaccine Antigen Master Files (VAMF)

- ✓ MHRA published guidance on how to apply for MA for PMF and VAMF
- ✓ Agency accepts national PMF applications while continuing to recognize existing EU PMFs (and related inspections)
- ✓ PMF holders to inform agency of any annual updates and EMA application decisions within 4 weeks
- ✓ MHRA may request additional information
- ✓ However, no VAMF procedure currently exists in the UK
- ✓ https://www.gov.uk/guidance/licensing-plasma-master-files-and-vaccine-antigen-master-files

Allfälliges

UK MHRA: new regulations for clinical trials:

- ✓ The new regulations for running clinical trials in the UK have now been signed into law after they were laid in Parliament in December 2024
- ✓ The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024
- ✓ The new regulations will take full effect from **10 April 2026**, following a 12-month implementation period starting 11 April 2025.

UK MHRA: reminder on "UK only":

- ✓ The 'UK Only' statement can only be applied to medicines via a sticker **until 30 June 2025**.
- ✓ After this date, 'UK Only' must be printed directly onto packaging.
- ✓ If you are using stickering now, it is important to ensure you are ready for 'UK Only' to be printed on packs from 1 July 2025. Stickers will not be accepted for products released to market from that date, however, products with 'UK Only' stickering that have been QP certified before 1 July 2025, can continue to be supplied to patients until the date of their expiry.
- ✓ Parallel Import (PLPI) products are not affected and can continue using stickers over labelling.
- ✓ https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework#:~:text=The%20'UK%20Only'%20statement%20can,be%20allowed%20for%20these%20products.

Allfälliges

Swissmedic Position Paper on Clinical Trials:

- ✓ Joint publication by Swissmedic and Swissethics
- ✓ Medicinal products examines for the first time in humans

• https://www.gmp-compliance.org/gmp-news/swissmedic-position-paper-on-clinical-trials?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW51-2024

Swissmedic Update of Technical Interpretation on the PQR:

- ✓ Technical Interpretation I-SMI.TI.14e
- ✓ Version 7.0
- ✓ Minimum expectations that inspectors may have
- ✓ Clarifying responsibilities of manufacturer and Marketing Authorization Holder, intervals and responsibilities for parallel import

• https://www.gmp-compliance.org/gmp-news/switzerland-update-of-the-technical-interpretation-on-the-pqr?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW14-2025

Switzerland/Canada:

- ✓ Health Canada updated the Mutual Recognition Agreement with Switzerland, effective 31 January 2025. The updates include mutual recognition of GMP certificates for extra-jurisdictional inspections, API, and stable medicinal products derived from human blood or plasma. These changes aim to streamline compliance and enforcement while maintaining GMP standards
- ✓ https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/establishment-licences/drug-establishment-licensing-bulletin/updates-mutual-recognition-agreement-canada-switzerland.html

Allfälliges

Glossary of ICH Terms and Definitions published

- ✓ This version 7 of the glossary is available after free registration on the CIOMS website, providing a useful resource of terms and definitions.

https://www.gmp-compliance.org/gmp-news/glossary-of-ich-terms-and-definitions-published?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW46-2024

ICH Q9(R1) Annex 1 updated

- ✓ Questions and Answers by removing outdated text and rephrasing Q&As in view of implementation of Q8, Q9, and Q10
- ✓ Minor additions to address minor content gaps and improve readability
- ✓ https://ich.org/news/ich-q9r1-iwg-updated-q9r1-annex-1-q8q9q10-questions-answers?source=email

ICH published revised training materials for ICH Q8, Q9, and Q10

- ✓ 57 slides
- ✓ https://www.ich.org/news/ich-q9r1-iwg-updated-training-materials

Allfälliges

ICH revised guideline Q1 Stability Testing:

- ✓ Available for comments
- ✓ Deadline for comments: 27 MAY 2025
- ✓ Completely rewritten previous 2003 guideline
- ✓ Consolidating existing 5 stability guidelines into one and addressing new topics (e.g., advanced therapies, bracketing and matrixing, novel excipients, etc.)
- ✓ 108 pages, 18 sections, and 3 annexes
- ✓ https://database.ich.org/sites/default/files/ICH_Q1EWG_Step2_Draft_Guideline_2025_0411.pdf

Final ICH E6(R3) Guideline on GCP released

- ✓ Unified standard to facilitate mutual acceptance of clinical trial data for ICH member countries
- ✓ https://www.gmp-compliance.org/gmp-news/final-ich-e6r3-guideline-on-gcp-released?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW04-2025

Saudia Arabia SFDA has been elected as a member of the administrative committee of the ICH,

- ✓ becoming the first Middle Eastern entity to join, alongside 7 international counterparts and 8 representatives from global organizations.

Allfälliges

EDQM: A new era for the European Pharmacopoeia – Online-only format from June 2025

- ✓ The discontinuation of the printed version is a step towards becoming more environmentally friendly.
- ✓ A great set of new features in the new online platform will improve the user experience at all levels and enable the Ph. Eur. to better meet subscribers' needs for years to come
- ✓ Starting with issue 12.1, the Ph. Eur. will be available exclusively online
- ✓ Users will be guided seamlessly to the content they need through powerful search tools, a dashboard and new filters and attributes.
- ✓ All subscriptions to the 11th Edition will remain valid during the transitional period until the end of 2025.
- ✓ As of 1 January 2026, users will only be able to subscribe to the online version.
- ✓ Stay tuned for more details about this important step in the evolution of the Ph. Eur.

https://www.edqm.eu/en/-/a-new-era-for-the-european-pharmacopoeia-online-only-format-from-june-2025

Allfälliges

Supplement 11.7 of Ph. Eur. available

- ✓ All holders of CEPs are advised to update specifications and CEPs to comply with new monographs by 01 APR 2025
- ✓ https://www.gmp-compliance.org/gmp-news/supplement-11-7-of-the-european-pharmacopoeia-ph-eur-available?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW48-2024

The European Pharmacopoeia Ph. Eur. 11.8 was published and will get effective on 01-July-2025

- ✓ All CEP holders are required to adapt their specifications and thus the respective CEPs to comply by 01 JUL 2025
- ✓ https://www.gmp-compliance.org/gmp-news/edqm-supplement-11-8-to-the-european-pharmacopoeia-available?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-MEU-KW05-2025

EDQM published new chapter "Quality of Data"

- ✓ Comments until 31 DEC 2024
- ✓ Chapter 5.38. QUALITY OF DATA
- ✓ https://www.gmp-compliance.org/gmp-news/edqm-publishes-new-chapter-quality-of-data-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW42-2024

Allfälliges

EDQM publishes new FAQ on SST (System Suitability Test)

- ✓ SST in chromatographic assay procedures
- ✓ Press release by EDQM on 17 DEC 2024

https://www.gmp-compliance.org/gmp-news/edqm-publishes-new-faq-on-system-suitability-test-sst?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW02-2025

EDQM: New guideline for sterile substances published:

- ✓ New guideline "Content of the dossier for sterile substances (PA/PH/CEP "23) 54)"
- ✓ Published in November
- ✓ https://www.gmp-compliance.org/gmp-news/edqm-new-guideline-for-sterile-substances-published?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-MEU-KW49-2024

EDQM: Publication on establishment study for PKA in Albumin BRP replacement batches now online

- ✓ 24 laboratories (including OMCL and manufacturer) participated
- ✓ https://www.edqm.eu/en/-/publication-on-the-establishment-study-for-pka-in-albumin-brp-replacement-batches-now-online

Allfälliges

New Ph. Eur. Chapters on COC, COP, and SBC approved

- ✓ Following the new Ph. Eur. Chapter 2.4.35 on Elemental Impurities in Plastic Materials (published in Ph. Eur. Supplement 11.7), the European Pharmacopoeia Commission (EPC) approved the following 3 new Ph. Eur. plastic chapters for containers:
  - 3.1.17. Cyclo-Olefin Copolymers (COC),
  - 3.1.16. Cyclo-Olefin Polymers (COP), and
  - 3.1.18. Styrene Block Copolymers (SBC).
- ✓ The new general chapters provide specifications for COC, COP and SBC materials, used in the manufacture of containers for pharmaceutical use.
- ✓ The texts will be published in the 12th Edition of the Ph. Eur. They will become effective as of 1 January 2026.

- https://www.gmp-compliance.org/gmp-news/new-ph-eur-chapters-on-coc-cop-and-sbc-approved?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW50-2024

Ph. Eur. Chapter 2.1.7. Balances for Analytical Purposes

- ✓ Pharmaeuropa issue 37.1
- ✓ Proposal for revised chapter
- ✓ Published for comments until 31 MAR 2025

- https://www.gmp-compliance.org/gmp-news/pharmeuropa-chapter-2-1-7-balances-for-analytical-purposes-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW02-2025

Allfälliges

Pharmeuropa: 4 draft chapters on elemental Analysis

- ✓ Published for comments
- ✓ Pharmeuropa issue 37.2:
  - 2.2.22. Atomic emission spectrometry
  - 2.2.23. Atomic absorption spectrometry
  - 2.2.57. Inductively coupled plasma-atomic emission spectrometry
  - 2.2.58. Inductively coupled plasma-mass spectrometry
- ✓ Comments until 30 JUN 2025
- ✓ https://www.gmp-compliance.org/gmp-news/pharmeuropa-four-draft-chapters-on-elemental-analysis-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW15-2025

New Ph. Eur. Chapter 2.5.45 on Photoionisation Detectors:

- ✓ Published for comments
- ✓ PIDs in measuring hydrocarbons and oils (e.g. for EM or compressed air systems)
- ✓ Deadline for comments: 31 MAR 2025
- https://www.gmp-compliance.org/gmp-news/pharmeuropa-new-chapter-2-5-45-on-photoionisation-detectors-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW04-2025

Allfälliges

OMCL Network welcomes Türkiye as a full member

- ✓ The Analysis and Control Laboratories Department of the Turkish Medicines and Medical Devices Agency has become a full member of the General European OMCL Network (GEON)
- ✓ The GEON is now proud to count 68 laboratories from 42 countries among its members
- ✓ https://www.edqm.eu/en/-/omcl-network-welcomes-t%C3%BCrkiye-as-a-full-member

Allfälliges

Chaos at FDA caused by Trump administration:

- Hundreds of US FDA employees were fired by the New Administration. Among those affected were about 200 device reviewers and 40 statisticians at the FDA's device center. Among them were those working on artificial intelligence and digital health.
- Only one week later FDA has reversed course and is rehiring staff and calling back some laid-off FDA-employees back to work.
- https://insights.citeline.com/pink-sheet/agency-leadership/us-fda/breaking-some-laid-off-fda-employees-called-back-to-work-4GBFWSJP35DPDKHGQKH5JYTWZI/
- The deadline for US FDA staff to return to in-office work passed on 24 February 2025, with a mandate that employees either return to office or face termination. Wilson Bryan, former FDA Director, has expressed concerns about the impact of the return-to-office mandate on attracting skilled staff.
- https://www.politico.com/news/2025/02/24/musk-federal-employees-administrative-leave-022452?source=email
- The Alliance for Stronger FDA has sent a letter to Congress urging support for the US FDA, emphasizing the need for adequate resources and flexibility to maintain its expertise and capacity. The letter also expresses concern over recent staff terminations and their potential impact on medical innovation and patient safety.
- https://static1.squarespace.com/static/60b686c7e1b13a0b207ccb28/t/67b6011d03d52e1f29a881a3/1739981085101/House+Alliance+FDA+RIF+Letter+17+Feb+2025.pdf

Allfälliges

New US-Administration Launches Massive 10-to-1 Deregulation Initiative:

- The New Administration has issued an executive order introducing a “10 to 1” deregulation policy, requiring the **elimination of ten existing regulations for every new one**. This expands on the previous “2 to 1” approach. The order aims to reduce regulatory burdens, especially in healthcare. The federal government is currently under a regulatory freeze; however, once the new Health and Human Services (HHS) secretary is confirmed, the department could initiate regulatory cuts. This requirement will likely dramatically impair FDA’s ability to issue new guidance and regulations.
- https://www.whitehouse.gov/fact-sheets/2025/01/fact-sheet-president-donald-j-trump-launches-massive-10-to-1-deregulation-initiative/

Allfälliges

FDA announces expanded use of unannounced inspections at foreign Manufacturing Facilities:

- ✓ 06 MAY 2025
- ✓ “to ensure that foreign companies will receive the same level of regulatory oversight and scrutiny as domestic companies.”
- ✓ “In addition, the FDA will evaluate the agency’s policies and practices for improvements to the foreign inspection program to ensure that the FDA is the gold standard for regulatory oversight.”
- ✓ For more information about FDA inspections, visit the Inspections Database Frequently Asked Questions and Inspections Yield Valuable Results, Regardless of Classification.
- ✓ https://www.fda.gov/news-events/press-announcements/fda-announces-expanded-use-unannounced-inspections-foreign-manufacturing-facilities

Allfälliges

FDA announces Experiential Learning Site Visit Program

- ✓ Providing FDA staff opportunity to engage directly with industry site, gaining hands-on experience, and insights into contemporary practices
- ✓ To improve FDA staff knowledge
- ✓ FDA reviewers, inspectors, and scientists to observe real-world manufacturing and quality technologies and systems
- ✓ Voluntary participation from industry
- ✓ https://www.federalregister.gov/documents/2024/08/08/2024-17640/office-of-pharmaceutical-quality-experiential-learning-site-visit-program-program-announcement?utm_medium=email&utm_source=govdelivery

FDA guidance for industry: "Advanced Manufacturing Technologies Designation Program"

- ✓ Finalizing the 2023 draft
- ✓ Recommendations to those interested in participating in FDA's AMT program
- ✓ Key benefits:
  - Early engagement with FDA
  - Expedited assessment
  - Improved drug supply and quality
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/advanced-manufacturing-technologies-designation-program?utm_medium=email&utm_source=govdelivery

Allfälliges

FDA Draft Guidance “Chemical Analysis for Biocompatibility Assessment of Medical Devices”

- ✓ Draft Guidance for Industry and Food and Drug Administration Staff
- ✓ https://www.federalregister.gov/documents/2024/09/20/2024-21575/chemical-analysis-for-biocompatibility-assessment-of-medical-devices-draft-guidance-for-industry-and

FDA Draft Guidance “Considerations for Complying with 21 CFR 211.110”

- ✓ 211.110 “Sampling and testing of in-process materials and drug products”
- ✓ Published for comments until end of March 2025
- ✓ General Considerations for in-process sampling and testing
- ✓ Additional Considerations for Advanced Manufacturing and Process Models
- ✓ https://www.fda.gov/media/184825/download

Allfälliges

FDA final guidance “Bioanalytical Method Validation for Biomarkers”

- ✓ Validation of bioanalytical methods for evaluating biomarker concentrations
- ✓ Additionally, covering development of bioanalytical methods for biomarker concentration in non-clinical study samples
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bioanalytical-method-validation-biomarkers?source=email

FDA published draft guidances for industry on donor eligibility for HCT/Ps:

- ✓ HCT/Ps (human cells, tissues, and cell-based products)
- ✓ To further reduce risk of transmission of HIV, HCV, and HBV
- ✓ Applies to donations collected from 25 May 2025 onwards
- https://www.gmp-compliance.org/gmp-news/publication-of-three-fda-draft-guidelines-on-donor-eligibility-for-hct-ps?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW04-2025
- ✓ Under the link below please find a recorded Webinar by CBER:
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommendations-determining-eligibility-donors-human-cells-tissues-and-cellular-and-tissue-based?utm_medium=email&utm_source=govdelivery

Allfälliges

USP Chapter <621> Chromatography

- ✓ Published for comments
- ✓ Comments can be submitted until 31 MAY 2025
- ✓ System Sensitivity and Peak Symmetry subsections were further modified to clarify the applications of these new requirements

• https://www.gmp-compliance.org/gmp-news/further-modifications-to-usp-chapter-621-chromatography-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW12-2025

USP chapters <31> and <1331> on Volumetric Apparatus

- ✓ Published again for comments
- ✓ Pharmacopoeial Forum, PF 51(1)
- ✓ Based on comments received, previous drafts canceled and replaced with new suggestions
- ✓ Comments until 31 MAR 2025

• https://www.gmp-compliance.org/gmp-news/usp-chapters-31-and-1331-on-volumetric-apparatus-again-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW04-2025

USP published Draft Chapter <1110> on Contamination Control Strategy

- ✓ A more detailed presentation of the individual points and the associated content can be found after prior registration on the website of the USP

• https://www.gmp-compliance.org/gmp-news/usp-publishes-draft-chapter-on-contamination-control-strategy

Allfälliges

Revised USP Chapter <383> Cured Silicone Elastomers

- ✓ Draft chapter open for comments until 31 JAN 2025
- ✓ New chapter will become official on 01 DEC 2027
- ✓ https://www.gmp-compliance.org/gmp-news/revised-usp-chapter-383-cured-silicone-elastomers?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW46-2024

USP seeks early input

- ✓ Proposed new General Chapter <318> NMR Spectroscopy Monomer Ratio Determination for Lactide-Glycolide Polymers
- ✓ Deadline was 24 NOV 2024
- ✓ Text is planned to be published for comments in September 2025

https://www.gmp-compliance.org/gmp-news/usp-seeks-early-input-on-proposed-new-general-chapter-318?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW45-2023

USP proposed update to <1058> on Analytical Instruments and System Qualification

- ✓ Published in the Pharmacopoeial Forum, PF 51(2)
- ✓ Comments can be submitted until 31 MAY 2025
- https://www.gmp-compliance.org/gmp-news/proposed-update-to-usp-1058-on-analytical-instrument-and-system-qualification?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW11-2025-MEU

Allfälliges

USP

- The **USP-NF 2025 Issue 2** was published and will get effective on **01-Aug-2025**.
- Some chapters/monographs highlighted here:
- **NEW General Chapters** of this supplement:
  - ✓ <72> Respiration-Based Microbiological Methods for the Detection of Contamination in Short-Life Products
  - ✓ <73> ATP Bioluminescence-Based Microbiological Methods for the Detection of Contamination in Short-Life Products
  - ✓ <382> Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems
  - ✓ <1060> Mass Spectrometry-Based Multi-Attribute Method for Therapeutic Proteins
- **Revised General Chapters** of this supplement:
  - ✓ **General Notices and Requirements**
  - ✓ <467> Residual Solvents
  - ✓ <621> Chromatography
  - ✓ <1071> Rapid Microbiological Methods for the Detection of Contamination in Short-Life Products-A Risk-Based Approach
  - ✓ <1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products
  - ✓ <1132.1> Residual Host Cell Protein Measurement in Biopharmaceuticals by Liquid Chromatography-Mass Spectrometry
  - ✓ <1467> Residual Solvents-Verification of Compendial Procedures and Validation of Alternative Procedures
- **Revised Monographs** of this supplement:
  - ✓ Trehalose

Allfälliges

USP Announces corrections to general Chapter <1132.1> on Residual Host Cell Protein Measurement

- ✓ The United States Pharmacopeia (USP) has identified necessary minor corrections to General Chapter <1132.1> Residual Host Cell Protein Measurement in Biopharmaceuticals by Mass Spectrometry. All changes become effective on 01 May 2025

USP Revision of Chapter <1071> on Rapid Methods and its effect on other USP chapters:

- ✓ Implementation planned for August 2025
- ✓ Other chapters or documents will be affected by the revision of <1071>:
  - Chapter Guide; Vaccines
  - Chapter Guide: Gene and Cell Therapy Products
  - Chapter Guide: Microbiology Products
  - <1117> Microbiological Best Laboratory Practices
  - <1046> Cell-based advanced therapies and tissue-based product
- https://www.gmp-compliance.org/gmp-news/revision-of-usp-chapter-1071-on-rapmethods-and-its-effect-on-other-usp-chapters?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW09-2025-MEU

Allfälliges

“Code of Practice for QPs – Duties and Responsibilities for Qualified Persons in the EU”

- EQPA updated the guide to version 11.0
- Chapter 4.3.4 on Brexit and consequences was revised once more
- Annex updated with information on national requirements in Poland
- New Version 11.0 available in the member area of EQPA: https://www.qp-association.eu/qpag_good_practice_guide.html

Allfälliges

The Japanese Pharmacopoeia 18th Edition Supplement II ****was published in English and has a transition period until 31-December-2025.

New ISO/TR 33402:2025 on Reference Material Preparation:

- ✓ January 2025
- ✓ New Technical Report providing guidance on best practices
- ✓ 41 pages
- ✓ https://www.gmp-compliance.org/gmp-news/new-iso-tr-334022025-on-reference-material-preparation?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-KW09-2025-MEU

EAEU Draft Guidelines on Planning Risk-Based Inspections of Pharmaceutical Manufacturers

- ✓ Eurasian Economic Commission
- ✓ Comments until 03 MAR 2025
- ✓ https://eec.eaeunion.org/upload/files/deptexreg/LSMI/Guidelines%20on%20Planning%20Risk-Based%20Inspections%20of%20Pharmaceutical%20Manufacturers.pdf

Allfälliges

Argentina ANMAT published draft regulation on Two-Dimensional Codes on packaging:

- ✓ draft regulations requiring the inclusion of a bidimensional code (QR or future technologies) on the packaging of medicinal products.
- ✓ This code will provide easy access to updated prospectus information through mobile devices.
- ✓ The implementation of this requirement will be **optional until 31 December 2025**, after which it becomes mandatory.
- ✓ Manufacturers must submit the updated packaging for approval, and ANMAT will maintain the accuracy of the information accessible through the code.
- ✓ https://opinionpublica.anmat.gob.ar/proyectos/7326.pdf (Spanish)

Mexico COFEPRIS defines criteria for recognizing foreign regulatory approval of clinical trial protocols:

- ✓ Foreign Regulatory Authorities: US FDA, UK MHRA, Health Canada, EMA
- ✓ Part of reliance based regulatory procedure, leveraging trusted regulatory practices to streamline approval processes
- ✓ Stakeholder invited to submit comments

Allfälliges

Brazil ANVISA introduces mandatory electronic document submission from March 2025

- ✓ Starting 13 MAR 2025
- ✓ All document submission to be made electronically
- ✓ Resolution (RDC) No. 947 defines electronic and digital signatures
- ✓ https://anvisalegis.datalegis.net/action/ActionDatalegis.php?acao=abrirTextoAto&link=S&tipo=RDC&numeroAto=00000947&seqAto=000&valorAno=2024&orgao=RDC/DC/ANVISA/MS&cod_modulo=310&cod_menu=8542

Brazil ANVISA approved list of equivalent foreign regulatory authorities

- ✓ To enhance regulatory reliance in registration and inspection
- ✓ Selected authorities include those from Colombia, Mexico, Peru, Chile, Australia, Egypt, Thailand, and UK
- ✓ https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2024/anvisa-seleciona-autoridades-estrangeiras-prioritarias-para-fortalecer-confianca-regulatoria

Brazil ANIVSA recognizes CEPs

- ✓ CEPs of EDQM can now be used when applying for medicinal products in Brazil

- https://www.gmp-compliance.org/gmp-news/anvisa-recognises-ceps?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-MEU-KW03-2025

Allfälliges

The Brazilian Pharmacopoeia 7th edition ****was published in December 2024 with a transitional period of 180 days.

- **New Chapters:**
- 5.5.2.7. Tests for Pyrogen Evaluation
- 5.5.2.7.1 Moncyte Activation test
- 8.11 Common Brazilian Denomination
- 8.12 In Vitro - in Vivo Correlation Studies
- **Revised Chapters:**
- 5.1.3.2 FRIABILITY TEST
- 5.2.14 ULTRAVIOLET, VISIBLE AND INFRARED SPECTROPHOTOMETRY
- 5.2.17 CHROMATOGRAPHY
- 5.2.17.1. THIN LAYER CHROMATOGRAPHY
- 5.2.17.2. PAPER CHROMATOGRAPHY
- 5.2.17.3. OPEN-COLUMN CHROMATOGRAPHY
- 5.2.17.4 HIGH PERFORMANCE LIQUID CHROMATOGRAPHY
- 5.2.17.4.1 ION CHROMATOGRAPHY
- 5.2.17.5. GAS CHROMATOGRAPHY
- 5.2.17.5.1 GAS CHROMATOGRAPHY IN CONFINED SPACE (headspace)
- 5.2.28. DETERMINATION OF OSMOLALITY
- 5.5.2.7.2. PYROGEN TEST IN RABBITS
- 5.5.2.7.3 TESTING FOR BACTERIAL ENDOTOXINS
- 6.2.4 BIOCOMPATIBILITY
- **Deleted Chapter:**
- 5.5.2.3 TOXICITY

- If you need access to the Brazilian Pharmacopoeia, please use the following link.

Allfälliges

WHO Guidance on wastewater and Solid Waste Treatment in Antibiotics Production

- ✓ Aim is to minimize antibiotic resistance
- ✓ 80 pages document
- ✓ https://www.gmp-compliance.org/gmp-news/who-guidance-on-wastewater-and-solwaste-treatment-in-the-antibiotics-production?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-MEU-KW44-2024

WHO draft guideline on Continuous Manufacturing

- ✓ Intended to provide global framework
- ✓ Aimed at manufacturers as well as regulatory authorities
- ✓ Deadline for comments: 07 MAR 2025
- ✓ https://www.gmp-compliance.org/gmp-news/who-publishes-guideline-on-continuous-manufacturing?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW06-2025

12th Edition of The International Pharmacopoeia:

- ✓ Legal status, wherever a national or regional authority refers to it
- ✓ Includes amongst others also tests for EG and DEG in some preparations
- https://www.gmp-compliance.org/gmp-news/12th-edition-of-the-international-pharmacopoeia?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW14-2025

Allfälliges

China GMP guide for sterile medicinal products:

- ✓ China NMPA published comprehensive draft of new GMP guideline for manufacture of sterile medicinal products
- ✓ Very similar to the well-known Annex 1 of EU-GMP-Guide
- ✓ Aims to promote modern production techniques and increase product safety
- ✓ Companies are invited to comment by 30 MAY 2025
- ✓ No official translation yet
- ✓ https://www.gmp-compliance.org/gmp-news/update-of-the-gmp-guideline-for-sterile-medicinal-products-in-china

Chinese Pharmacopoeia 2025 was released on 25-Mar-2025, see official announcement.

- ✓ The ChP 2025 will be **effective as of 01-Oct-2025**.

Allfälliges

African Regulators reach big WHO milestone

- ✓ Egypt, Rwanda, and Senegal achieved Maturity Level 3 accreditation from WHO
- ✓ Indicating stable and well-functioning regulatory systems
- ✓ Other ML3 countries in Africa include Ghana, Nigeria, South Africa, Tanzania, Zimbabwe
- ✓ https://insights.citeline.com/pink-sheet/geography/middle-east-and-africa/african-regulators-reach-big-who-milestones-IHIMW25GTFGADNGU266LX33IWY/

- Präsentationen werden wieder im Internet abrufbar sein:
  www.austria-qp.at
- Teilnehmerliste/Schulungsdokumentation: *Regine Tomasits*
- Vorschläge zur Verbesserung/Aufwertung der AQPA-Homepage?
- Themen für zukünftige Treffen / Forum?
- Bei Fragen oder Anregungen, E-mail an: info@austria-qp.at
- Tipp: Nutzen Sie auch mal das EQPA Discussion Forum!
  https://www.gmp-journal.com/current-articles/details/frequently-asked-questions-by-qps-the-eqpa-discussion-forum.html
- Tipp: Neuigkeiten von Behörden zeitnah über den ECA GMP Newsletter:
  - Schreiben Sie an support@gmp-compliance.org
  - Frühere Newsletters unter "GMP News" auf der ECA Academy Website

Termine

- **Qualified Person Forum 2025 der EQPA:**

  26.-28. November 2025 in Barcelona, Barceló Sants Hotel

  Programm: https://www.qp-forum.org/

- **Austrian QP Forum 2026:**

  09.-10. Juni 2026, Doubletree by Hilton Schönbrunn

- **Nächstes Vereinstreffen der AQPA mit Generalversammlung:**

  Wahlvorschläge für den Vorstand

  16. Oktober 2025, Austria Trend Parkhotel Schönbrunn

Wir wünschen einen schönen Abend,
viel Spaß beim Netzwerken und
hoffen auf zahlreiches reales Wiedersehen bei der
Generalversammlung am
16. Oktober 2025

Bleiben Sie gesund!

Der erweiterte AQPA-Vorstand:

Georg Göstl, Obmann
Gabriela Schallmeiner, Obmann-Stellvertreterin
Regine Tomasits, Schriftführerin
Markus Thiel, Kassier

Winfried Chang
Klaus Hofstädter
Carina Rappel
Stefan Schneider
Richard Vasicek