Vereinstreffen der AQPA

24. Mai 2023

Der AQPA-Vorstand:

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

Agenda

- 18:00 Begrüßung
- Präsentationen:
  - ICH Q9 Revision *(Regine Tomasits/ViruSure)*
  - EQPA: QP Code of Conduct *(Georg Göstl/Takeda)*
  - Allfälliges:
    - Erweiterung des AQPA-Vorstandes *(Georg Göstl/Takeda)*
    - Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
- Teilnehmerliste *(Regine Tomasits/ViruSure)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

Erweiterung des Vorstandes der AQPA

- Zusätzlich im Vorstand (Mitarbeit, aktuell noch ohne direkte Rolle gemäß Statuten):
  - Winfried Chang
  - Klaus Hofstädter
  - Carina Rappel
  - Stefan Schneider
  - Richard Vasicek

Allfälliges

- Europäische Kommission arbeitet seit der Vorlage der Pharma Strategie im November 2020 an einer Revision folgender vier Rechtsakte:
  - RL 2001/83 (allgemeines Arzneimittelrecht, nationale Zulassungen)
  - VO 726/2004 (allgemeines Arzneimittelrecht, zentrale Zulassungen)
  - VO 141/2000 (über Arzneimittel für seltene Leiden)
  - VO 1901/2006 (über Kinderarzneimittel)

- **26 April – The European Commission published proposal for the EU Pharmaceutical Legislation**
  - The proposal consists of a Regulation and a Directive, as well as a draft EU-level action on antimicrobial resistance. It is the most extensive overhaul of the legislative provisions for the EU pharmaceutical industry in 20 years.
  - The two proposals will eventually replace existing EU general pharma legislation, currently set out across multiple legislative texts. It remains separate from EU SoHO Regulation.
  - See the EU Commission press release
  - Will also include updated requirements for practical experience for Qualified Persons (based on EQPA-submission)
  - Consequences for GMP-requirements:
    - https://www.gmp-compliance.org/gmp-news/gmp-update-consequences-from-the-new-eu-commission-proposal?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW18-2023

Allfälliges

EMA and PIC/S published Concept Paper on revision of Annex 11 of GMP-Guide:

- Computerised Systems
- Update to replace relevant parts of Q&As on Annex 11 and Data Integrity
- Include guidance for acceptance of AI/ML algorithms used in critical GMP applications
- End of consultation: 16 JAN 2023
- Proposed timetable:
  - Publication and commenting of a draft of the new Annex 11: March 2025.
  - Publication by EC – June 2026
  - Adoption by PIC/S -September 2026
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/concept-paper-revision-annex-11-guidelines-good-manufacturing-practice-medicinal-products_en.pdf

EMA / HMA: Evaluation Guide for GMP Regulatory Compliance Programme:

- Audit Checklist, Revision 3 (including API and common with Canada and PIC/S)
- EMA/INS/GMP/119415/2023
- Published 13 March 2023
- https://www.ema.europa.eu/en/documents/other/evaluation-guide-good-manufacturing-practice-regulatory-compliance-programme-audit-checklist_en.pdf

Allfälliges

EMA released an updated organizational structure:

- ✓ Human Medicines Division
- ✓ Regulatory responsibilities are now allocated to six therapeutic areas:
  - Oncology and Haematology (including plasma-derived medicinal products)
  - Vaccines and therapies for infectious diseases
  - Therapies for neurologic and psychiatric disorders
  - Endocrine and cardiovascular diseases
  - Therapies for immune and inflammatory diseases
  - Advanced Therapies
- ✓ Blood Products Working Party (BPWP) renamed “Haematology Working Party (HAEWP)
- ✓ New org chart:
- ✓ https://d31hzlhk6di2h5.cloudfront.net/20221215/d6/37/22/2d/e5d7f3280350b7b6a7f2538e/organisation-chart-human-medicines_en.pdf

EMA/CMDh: Update of the Q&A Document on Nitrosamines

- ✓ Version 15 published 30 MAR 2023
- ✓ https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-marketing-authorisation-holders/applicants-chmp-opinion-article-53-regulation-ec-no-726/2004-referral-nitrosamine-impurities-human-medicinal-products_en.pdf

Allfälliges

Amendment to the CTR on IMP labelling:

- Requirements revised regarding expiry dates by means of a Delegated Regulation
- Delegated Regulation 2022/2239
- Published on 15 NOV 2022
- Enter into force 20 days after its publication
- https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R2239

EMA: all initial Clinical Trial Applications must be submitted through CTIS since 31 JAN 2023

- Regulation (EU) No 536/2014
- CTIS went live on 31 JAN 2022
- Following 1 year transition period, from 31 JAN 2023 all initial CTA must be submitted via CTIS
- https://www.ema.europa.eu/en/news/use-clinical-trials-information-system-becomes-mandatory-new-clinical-trial-applications-eu

EMA consultation: Launch of public consultation on ACT (Accelerating Clinical Trials) in the EU:

- Concept paper published together with public consultation
- Public consultation can be accessed until 03 MAR 2023 at this link: EUSurvey - Survey (europa.eu)
- For more information please consult the web page Accelerating Clinical Trials in the EU (ACT EU)

Allfälliges

EMA Reflection Paper on Criteria to be considered for the evaluation of new active substance (NAS) status of biological substances:

- Guidance on elements required to be submitted to substantiate a NAS claim
- Public consultation until 31 May 2023
- https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-criteria-be-considered-evaluation-new-active-substance-nas-status-biological_en.pdf

EMA update of Checklists for Changes & Variations:

- ✓ Validation checklist for Type II (non)clinical variations
  - Updated
- ✓ Validation checklist for Type II quality variations
  - Issued in May 2021

https://www.gmp-compliance.org/gmp-news/update-on-the-ema-checklists-for-changes-variations

Interesting reading:

- EMA: Best practices to fight antimicrobial resistance
- ICMRA (International Coalition of Medicines Regulatory Authorities) published a report
- Highlighting regulatory and non-regulatory interventions used in different countries
- https://www.ema.europa.eu/en/news/best-practices-fight-antimicrobial-resistance

Allfälliges

EMA: final GCP Guideline on Computerized Systems and Data Integrity:

- EMA/INS/GCP/112288/2023
- 52 pages
- Following draft guideline (published June 2021), the final guideline has now been published
- Will become effective 09 SEP 2023 (6 months after publication)
- Regulatory expectations to validation, operation and safe use of IT systems in Clinical Trials
- Replaces “Reflection Paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials”
- New expression: **ALCOA++** (in addition to ALCOA+ it includes Traceability throughout the Data Life Cycle)
- Very explicit statement:
- ***“4.11. Direct access***
- All relevant computerised systems should be readily available with **full, direct and read-only access** (this requires a unique identification method e.g. username and password) upon request by **inspectors from regulatory authorities**. If a computerised system is decommissioned, direct access (with a unique identification method) to the data in a timely manner should still be ensured (see section 6.12.).”

- https://www.gmp-compliance.org/gmp-news/final-gcp-guideline-on-computerized-systems-and-data-integrity?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW12-MEU
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guideline-computerised-systems-electronic-data-clinical-trials_en.pdf

Allfälliges

European Commission: Canada included on the "White List" for API imports

- 26 JAN 2023
- https://health.ec.europa.eu/medicinal-products/falsified-medicines/importation-active-substances-listing-third-countries_en

European Chemical Agency (ECHA) plans ban or restriction of perfluorinated and polyfluorinated alkyl substances (e.g. PTFE):

- Potentially impacting approx. 4.700 fluoropolymer chemicals
- Planned bans would predictably lead to issues in production, supply chains and availability problems
- ECHA started consultation on possible restrictions
- EFPIA already very active, as this potentially could have impact on almost every product

https://www.gmp-compliance.org/gmp-news/restrictions-for-ptfe-used-in-pharmaceutical-plant-engineering?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW05-MEU

Allfälliges

ICH Q9 revision (Quality Risk Management):

- Revision has reached step 4 and is now moving into implementation
- Effective Date 23 JUL 2023
- Detailed analysis in GMP News Article:
- https://www.gmp-compliance.org/gmp-news/the-new-ich-q9-revision-on-quality-risk-management-becomes-effective-as-of-23-july-2023-a-detailed-analysis
- Slide deck for training made available by ICH:
- https://admin.ich.org/sites/default/files/inline-files/ICH%20Q9R1_Step_4_Presentation_2023_0314.pdf

EMA published ICH Guideline Q5A(R2) "Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin":

- Public consultation
- Deadline for comments: 10 FEB 2023
- https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q-5-r2-viral-safety-evaluation-biotechnology-products-derived-cell-lines-human-animal-origin_en.pdf

Allfälliges

MDCG (Medical Device Coordination Group) 2022-16 - Guidance on Authorised Representatives Regulation (EU) 2017/745 and Regulation (EU) 2017/746 - October 2022

- Draft Guidance on Authorised Representatives Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)
- https://health.ec.europa.eu/latest-updates/mdcg-2022-16-guidance-authorised-representatives-regulation-eu-2017745-and-regulation-eu-2017746-2022-10-31_en

MDCG 2019-6 Rev.4 - Q&A: Requirements relating to notified bodies (October 2022)

- https://health.ec.europa.eu/latest-updates/mdcg-2019-6-rev4-questions-and-answers-requirements-relating-notified-bodies-october-2022-2022-10-27_en

Allfälliges

EU Commission published Staff Working Document "Structured Dialogue on the security of medicines supply"

- Vulnerabilities in global supply chains: reasons and possible solutions
- https://health.ec.europa.eu/latest-updates/staff-working-document-vulnerabilities-global-supply-chains-medicines-structured-dialogue-security-2022-10-17_en

Interesting reading: Is it possible to monitor Biofilm Infestation using online TOC-measurement?

- **Unfortunately, this is <u>not</u> possible**
- https://www.gmp-compliance.org/gmp-news/is-it-possible-to-monitor-for-biofilm-infestation-using-online-toc-measurement?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW15-MEU

Allfälliges

Danish authority (DMA) updated document on Requirements for a QP:

- ✓ Unlike many other EU Member States, practical experience is not limited to quality control. In Denmark, a minimum of two years' experience in manufacturing, quality assurance or quality control in a pharmaceutical company is required.
- ✓ The QP must have sufficient knowledge of the quality system, including validation documentation, and be familiar with all production and quality control facilities.
- ✓ The authority expects the QP to spend at least ten hours per week in the company.
- ✓ DMA expects an acting QP to attend a course, seminar, conference or similar focusing on GMP at least once a year. If this is not possible, the QP is expected to meet with other persons to exchange experiences.
- ✓ Special feature in Denmark is the “Delegated QP”, appointed by the company (does not have to be approved by DMA); however, the appointed QP remains responsible, must perform spot checks and countersign all releases.
- ✓ EQPA has already submitted a request for change of Directive 2001/83/EC to not limit practical experience to QC, but to accept also other experience. With certain countries officially having similar expectations we have to see further developments during revision of Directive 2001/83/EC
- ✓ https://laegemiddelstyrelsen.dk/en/search/~/media/5E7508C555364B16B7FA4AB20ACFF66C.ashx

Allfälliges

Mutual Recognition Agreements:

- **MRA Switzerland/USA:**
  - ✓ signed on 12 JAN 2023
  - ✓ But: before the MRA enters into force, the FDA must determine whether Swissmedic is able to carry out inspections that meet US requirements (and vice versa)
  - ✓ No timeline provided so far
  - ✓ https://www.fda.gov/media/164511/download

- **MRA USA/EU: expansion to plasma-fractionation**
  - ✓ Joint statement during meeting of US/EU Trade and Technology Council (December 2022)
  - ✓ But not yet finally implemented (FDA-website: July 2025 to consider for further assessment)
  - ✓ https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra
  - ✓ https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreement-mra

Allfälliges

Brexit: Agreement on Northern Ireland Protocol also with Consequences for Medicines:

- "*Windsor Framework*"
- In the future, "*novel medicines*" authorised by the UK Medicines Agency MHRA will also be available in Northern Ireland under the same conditions. These novel medicinal products must then be authorised and placed on the market according to UK regulations. Corresponding EU regulations and authorisations no longer apply in this case. This in turn means that companies need to be authorised to supply medicines to Northern Ireland. If they are, the European Medicines Agency (EMA) requirements can be neglected.
- Medicines that are then on the market in Northern Ireland may not enter the EU internal market. Prescription medicines will then not be allowed to carry EU safety features! The requirements of the relevant EU Directive (Falsified Medicines Directive) and the associated Delegated Regulation (EU) 2016/161 relating to safety features for medicinal products will be repealed for Northern Ireland. The packaging design can then be aligned for the entire United Kingdom (i.e. including Northern Ireland). In order to include non-prescription medicines, all medicines marketed in Northern Ireland will bear the words "*UK only*".
- So far, the Windsor Framework is just a draft that still needs to be translated into legally binding instruments.
- https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1268

Allfälliges

UK maintains Acceptance of Batch Testing and QP Certification in the EU

- Published on 15 DEC 2022 by UK-government

https://www.gov.uk/government/consultations/the-future-strategy-for-batch-testing-of-medicinal-products-in-great-britain/outcome/the-future-strategy-for-batch-testing-of-medicinal-products-in-great-britain-government-response

MHRA resumes international inspections:

- MHRA inspectorate blog
- Similar to EU also MHRA extended again until end of 2023

https://mhrainspectorate.blog.gov.uk/2022/11/08/return-to-international-gmp-inspections/

Swissmedic specifies requirements for EU-GMP-Certificates:

- EMA extension of GMP-certificates until end of 2023 accepted by Swissmedic
- No longer any need to generally extend the validity dates on Swissmedic GMP-Certificates

https://www.gmp-compliance.org/gmp-news/usp-proposes-to-add-flexibility-in-the-selection-of-parenteral-packaging?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW06-MEU

Allfälliges

Aktuelle Inspektionserfahrung mit SwissMedic

- Internationally harmonized requirements for MRA-Batch Certificates published by EMA (01 June 2011):
  - https://health.ec.europa.eu/system/files/2016-11/mra_batch-certificate_05-2011_0.pdf
- Information missing on some of the CoAs:
  - **10. Name, address and authorisation number of all manufacturing sites and quality control sites**
  - **11. Certificates of GMP Compliance of all sites listed under 10 or, if available, EudraGMP reference numbers**
- For information: currently EU-MRA/ACAA countries include:
  - Australia, Canada, Israel, Japan, New Zealand, Switzerland, USA
  - Details published/updated by EMA at:
  - https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra

Allfälliges

Broader Acceptance of GMP Inspection Reports from PIC/S Countries:

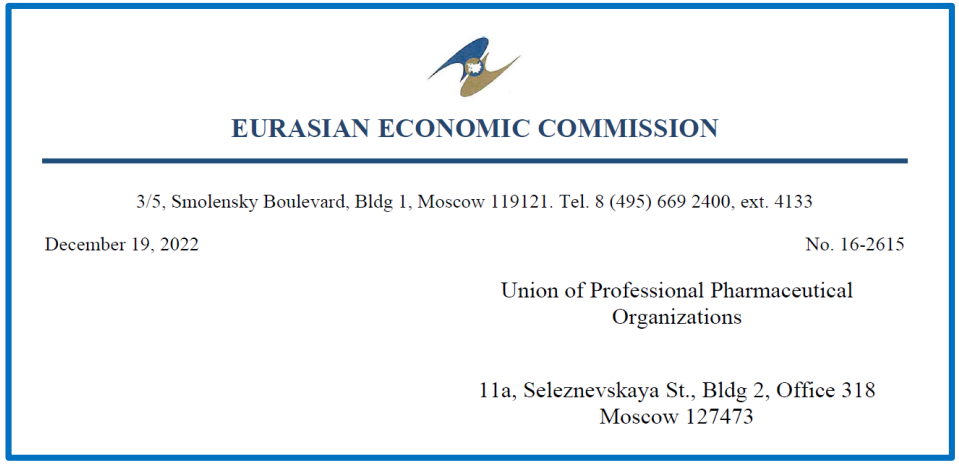
- "Access Consortium" consisting of representatives of regulatory authorities from Australia (Therapeutic Goods Administration), Canada (Health Canada), Singapore (Health Sciences Authority), Switzerland (Swissmedic) and recently also from the UK (Medicines and Healthcare Products Regulatory Agency, MHRA).
- The aim of this consortium is to promote international cooperation, reduce duplication of work and increase the capacities of the individual authorities.
- https://www.gmp-compliance.org/gmp-news/broader-acceptance-of-gmp-inspection-reports-from-pic-s-countries?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW47+-+MEU

Allfälliges

- **Eurasian Economic Commission** (19 DEC 2022) confirmed alignment of EEC/EAEU GMP rules with EU/PIC/S GMP rules:

Mitglieder:
- Russland
- Weissrussland
- Kasachstan
- Kirgisistan
- Armenien

Beobachter:
- Kuba
- Moldawien
- Usbekistan



EURASIAN ECONOMIC COMMISSION

3/5, Smolensky Boulevard, Bldg 1, Moscow 119121. Tel. 8 (495) 669 2400, ext. 4133

December 19, 2022 No. 16-2615

Union of Professional Pharmaceutical Organizations

11a, Seleznevskaya St., Bldg 2, Office 318
Moscow 127473

...

By this letter, the Eurasian Economic Commission (hereinafter, the Commission) advises that the requirements of Eurasian Economic Union's Good Manufacturing Practice approved by the Commission Council's Resolution No. 77 dated November 03, 2016 (in the version of the Commission Council's Resolution No. 65 dated July 14, 2021) are aligned with the requirements of European Union's Good Manufacturing Practice for Human and Veterinary Medicinal Products and with the Pharmaceutical Inspections Cooperation System (PIC/S) principles.

...

Allfälliges

EDQM: Supplement 11.2 of Ph. Eur. available:

- This supplemental edition lists several updated monographs that will be implemented on 01 July 2023. All CEP holders (Certificate of Suitability of Monographs of the European Pharmacopoeia holders) are encouraged to align their specifications and thus the respective CEPs to the new monographs.
- The list of categorized monographs and further information on the European Pharmacopoeia (Ph.Eur.) Supplement 11.2 can be found on the EDQM website.

EDQM new document on revised chapter 2.2.46 Chromatographic Separation Techniques:

- 22 pages
- "useful and easy reference guide to main changes made in 11th Edition versus the 10th Edition version"

https://www.edqm.eu/en/-/general-chapter-2.2.46.-chromatographic-separation-techniques-comparison-of-requirements-in-the-ph.-eur.-10th-and-11th-editions

- https://extranet.edqm.eu/4DLink1/pdfs/addon/20246.pdf
- Implementation date 01 JAN 2023
- EDQM **published press release** (14 DEC 2023): another revision will be included in Supplement 11.3 (to be published in July 2023 and implemented on 01 JAN 2024)
- In the meantime EDQM advises to continue S/N ratio as described through Supplement 10.8

https://www.edqm.eu/en/-/signal-to-noise-ratio-revision-of-ph.-eur.-general-chapter-chromatographic-separation-techniques-2.2.46-

Allfälliges

EDQM – newsroom: “CEP holders – How to submit a nitrosamine risk assessment”

- ✓ Minor revisions in section 3.2.S.3.2
- ✓ CEP holders also reminded that if changes to synthesis or control strategy are introduced, they should be suitably classified according to EDQM guideline
- ✓ https://www.edqm.eu/en/-/how-can-cep-holders-submit-nitrosamine-risk-assessment

EDQM updated list of Reference Substances:

- ✓ More than 3000 substances
- ✓ https://www.edqm.eu/en/-/24-replacement-batches-released-in-january-2023

Public Consultation on 2 Ph.Eur. Chapters on Pharmaceutical Technology Procedures

- ✓ Press release on 01 FEB 2023
- ✓ Revised General Chapter 2.9.3. Dissolution of Tablets and Capsules
  - https://www.gmp-compliance.org/gmp-news/pharmeuropa-revised-chapter-2-9-3-dissolution-test-for-soldosage-forms-published-for-comment
  - Deadline for comments: 31 MAR 2023
- ✓ New General Chapter 2.9.55 Characterisation of Powder Behaviour during Compression
  - https://www.gmp-compliance.org/gmp-news/public-consultation-on-two-ph-eur-chapters-on-pharmaceutical-technology-procedures?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW07-MEU
  - Deadline for comments: 31 MAR 2023

Allfälliges

EDQM: New CEP 2.0

- "CEP of the future" now named "CEP 2.0"
- New design to support stakeholders in handling CEPs and increase transparency of provided information
- https://www.edqm.eu/en/what-is-the-cep-2.0

EDQM: New Procedure for CEPs:

- Three types of documents:
  - *governance documents for the CEP procedure*
  - *technical guidelines*
  - *administrative or operational documents*
- a **review procedure**, which can be public or only for a specific target group, has now been introduced
- https://www.edqm.eu/en/-/management-of-edqm-cep-documents-edqm-introduces-a-consultation-phase

EDQM monthly CEP Report:

- Overview of numbers of new and revised CEPs, reports on withdrawn or expired CEPs
- Number of inspection carried out by EDQM (on-site and remote)
- https://www.edqm.eu/documents/52006/335525/Certification+Monthly+Report+-+End+of+September+2022.pdf/0ed778cf-e738-4e38-5cba-6acd46c8782d?t=1665148951023
- https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-september-2022

Allfälliges

Ph. Eur: Nitrosamine Impurities: General monographs revised:

- ✓ Substances for pharmaceutical use (2034)
- ✓ Pharmaceutical preparations (2619)
- ✓ Extended by a section containing requirements with regard to possible contamination by nitrosamines
- ✓ For each API a risk assessment on possible nitrosamine impurities has to be carried out
- ✓ If such risk is identified, measure to minimize the risk must be taken
- ✓ Control strategy must be implemented to reliably detect and monitor
- ✓ Revised monographs will appear in Supplement 11.3 in July 2023 and will apply as of 01 JAN 2024
- ✓ https://www.gmp-compliance.org/gmp-news/nitrosamine-impurities-edqm-completes-general-monographs-2034-and-2619?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW05-MEU

Ph. Eur. Revised Chapter 2.9.1

- Disintegration of tablets and capsules
- Published for comments (deadline 30 June 2023)

- https://www.gmp-compliance.org/gmp-news/pharmeuropa-revised-chapter-2-9-1-disintegration-of-tablets-and-capsules-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW16-2023

Allfälliges

Ph. Eur. Chapter 5.1.13 Pyrogentest

- ✓ Published for comments until 31 MAR 2023
- ✓ Details see the EDQM Website (registration required)
- ✓ https://www.gmp-navigator.com/gmp-news/pyrogenitaetspruefung-europaeisches-arzneibuch-wird-weiter-aktualisiert?utm_source=Newsletter&utm_medium=email&utm_campaign=Sondernewsletter+DE+-+Blut+-+KW08+2023

Ph. Eur. Commission welcomes Ethiopian FDA as observer

- ✓ https://www.edqm.eu/en/-/ph.-eur.-commission-welcomes-ethiopian-fda-as-observer

Allfälliges

EMA-Link zu aktuellen Q&A zu GMP und GDP:

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:

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

Data Integrity – new guidance document by APIC

- Version 1, issued April 2023
- nice, practical FAQ document that deals with very specific issues

https://apic.cefic.org/wp-content/uploads/2023/04/FAQ-DI-APIC-TF-April-2023.pdf

Allfälliges

ICH Q3C: Corrected Version of the Guideline for Residual Solvents Published

- ✓ Methyltetrahydrofuran removed from table 4 in Chapter 4.4
- ✓ Revision (R8) of April 2022 now corrected and published
- ✓ https://database.ich.org/sites/default/files/ICH_Q3C-R8_Guideline_Step4_2021_0422.pdf

ICH Q13: Final Version of Guideline for Continuous Manufacturing published

- ✓ Final version: adopted on 16 NOV 2022
- ✓ https://database.ich.org/sites/default/files/ICH_Q13_Step4_Guideline_2022_1116.pdf

ICH M10 Guideline on Bioanalytical Method Validation and Study Sample Analysis

- ✓ EMA published updated Q&A
- ✓ Date of coming into effect was 21 JAN 2023
- ✓ FDA implementation date was 07 NOV 2022
- ✓ https://www.ema.europa.eu/en/ich-m10-bioanalytical-method-validation-scientific-guideline

Improved ISO-Standard ISO 22519:2023 “Membrane-based generation of water for injection (WFI)”

- finally issued

Allfälliges

FDA explains what will happen to CDER guidances and emergency use authorizations as the public health emergency ends

- US Public Health Emergency expired on **May 11, 2023**.
- Please use the following link you would like to the review any of the listed guidances https://www.fda.gov/regulatory-information/search-fda-guidance-documents#guidancesearch

FDA published GfI "Comparability Protocols for Postapproval Changes to the Chemistry, Manufacturing, and Controls Information in an NDA, ANDA, or BLA":

- ICH Q12 guideline on pharmaceutical product life cycle management is implemented in the US
- Combination products also addressed
- Final guidance published October 2022
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/comparability-protocols-postapproval-changes-chemistry-manufacturing-and-controls-information-nda

FDA released two updated CPGs (Compliance Program Guides):

- CPG for PAI (pre-approval inspections):
- https://www.fda.gov/media/121512/download?utm_medium=email&utm_source=govdelivery
- CPG for routine surveillance inspections:
- https://www.fda.gov/media/75167/download?utm_medium=email&utm_source=govdelivery

Allfälliges

FDA Draft Guidance for Industry on Statistical Approaches for Assessing Bioequivalence:

- ✓ 29 pages, will replace previous version of February 2001
- ✓ Distributed for comment purposes only
- ✓ Deadline for comments: 04 FEB 2023
- ✓ https://www.fda.gov/media/163638/download

FDA Draft Guidance for Industry "Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug of Device Inspection"

- ✓ Revision 1
- ✓ Published 16 DEC 2022 for comments
- ✓ FDA particularly interested in comments of inclusion of devices
- ✓ Until finalization of this draft the October 2014 FDA guidance remains in effect
- ✓ https://www.fda.gov/media/163927/download

FDA discussion paper: Artificial Intelligence in Drug Manufacturing

- Interesting reading
- Presenting areas for consideration and potential policy development identified by CDER
- CDER will use feedback submitted to the docket to inform future policy development.
- *"FDA's Pharmaceutical Quality for the 21st Century Initiative promotes … pharmaceutical manufacturing sector that reliably produces quality drugs without excessive regulatory oversight."*
- Please submit your comments regarding this discussion paper to https:// www.regulations.gov, Docket No. FDA-2023-N-0487
- https://www.fda.gov/media/165743/download?utm_medium=email&utm_source=govdelivery

Allfälliges

NEW: USP-NF 2023 Issue 1:

- Published in Nov. 2022 (effective 01-May-2023)
  - Some chapters/monographs we want to highlight are added here:
    - ⟨795⟩ Pharmaceutical Compounding—Nonsterile Preparations (will get effective 01-Nov-23)
    - ⟨797⟩ Pharmaceutical Compounding—Sterile Preparations (will get effective 01-Nov-23)
    - ⟨905⟩ Uniformity of Dosage Units (harmonization between USP, EP and JP; will get effective 01-Nov-23)

USP <711> Dissolution:

- New proposal published for comments
- Published in Pharmacopoeial Forum PF 48(6)
- Comments until 31 JAN 2023
- https://www.gmp-compliance.org/gmp-news/new-proposal-for-usp-chapter-711-dissolution-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW48+-+MEU

USP chapter "Elemental Impurities-Limits" issued for comments:

- ✓ Second revision of ICH Q3D(R2) finalized and available on ICH website
- ✓ As a result <232> chapter of USP now revised
- ✓ Published for comments until 31 January 2023
- ✓ Draft chapter is available for comments after one-time registration on the Pharmacopoeial Forum website
- ✓ https://www.uspnf.com/pharmacopeial-forum

Allfälliges

USP proposes to add flexibility in selection of parenteral packaging

- ✓ To help address concerns about supply of glass vials
- ✓ https://www.gmp-compliance.org/gmp-news/usp-proposes-to-add-flexibility-in-the-selection-of-parenteral-packaging?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW06-MEU

USP clarifies requirements for Plastic Packaging Systems:

- ✓ Revision of scope of <661> "Plastic Packaging Systems and Their Materials of Construction"
- ✓ Published to clarify testing expectations as outlined in <661.1> and <661.2>
- ✓ Will become official on 01 DEC 2025
- ✓ The draft for chapter <661> is published in Pharmacopeial Forum (PF) 49(1).
- ✓ The comment period runs until 31 March 2023
- ✓ https://www.gmp-compliance.org/gmp-news/usp-clarifies-requirements-for-plastic-packaging-systems

USP: New Chapter <1083> Supplier Qualification

- ✓ Published on 01 FEB 2023 as part of USP-NF 2023 Issue 2
- ✓ Official date 01 AUG 2023
- ✓ https://online.uspnf.com/uspnf/document/1_GUID-011C4CA7-B8DF-4A7A-953B-D1EC7C851657_2_en-US?source=Search%20Results&highlight=supplier%20qualification

Allfälliges

USP: Revision of Chapter <621> Chromatography

- USP published Notice of Intent to Revise
- Topic: Calculation of the signal to Noise ratio
- Revision will be published as a Revision Bulletin on 24 March 2023
- https://www.gmp-compliance.org/gmp-news/revision-of-usp-chapter-621-chromatography-concerning-signal-to-noise-ratio?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW05-MEU

USP: Revision of General Chapter <661.1> Plastic Materials of Construction

- Sections on Polycarbonate and PVC updated
- Posted 27 JAN 2023
- Official 01 DEC 2025
- https://www.uspnf.com/official-text/revision-bulletins

USP: Updates on “Residual Solvents”

- <1467> Published for comments
- Deadline for comments: 31 MAR 2023
- The draft chapter "<1467> RESIDUAL SOLVENTS-VERIFICATION OF COMPENDIAL PROCEDURES AND VALIDATION OF ALTERNATIVE PROCEDURES" can be consulted and commented on after completing a one-time registration on the Pharmacopeial Forum website.

Allfälliges

USP Chapter <1236> Solubility Measurements

- Published for comments
- Comments until 31 March 2023. The draft of the revised chapter is available on PF Online

USP proposal to modify the Glass General Chapter <660>

- ✓ Due to current shortages of glass vials, USP is announcing a proposal to modify USP <660>
- ✓ Change from composition based to performance based Type 1 glass definition
- ✓ It is expected that the revision to General Chapter <660> will be published in Pharmacopeial Forum PF 49(2) [March-April 2023], with a comment deadline of 31 May 2023.
- ✓ Please see the Notice of Intent to Revise: <660> Container-Glass for additional details.

USP Chapter under revision:

- <87> Biological Reactivity, in vitro
- Additional information can be found at Pharmacopoeial Forum

USP: New Definition of Pharmaceutical Grade Plastic Packaging Materials

- Proposed USP General Chapter <1031> The Biocompatibility of Pharmaceutical Packaging Systems and their Materials of Construction
- Published for comment in the current issue of Pharmacopeial Forum.
- It outlines a risk-based approach to biocompatibility evaluation

Allfälliges

USP-NF Stimuli Article on Linearity of Measurement Methods

- Published in PF 48(5)
- Providing a very generic definition of linearity, useful to support both method calibration and accuracy studies
- The article is available on PF Online via the USP Website Access Point.. The deadline for submitting comments was November 30, 2022.
- https://www.gmp-compliance.org/gmp-news/usp-nf-stimuli-article-on-linearity-of-measurement-methods?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW43+-+MEU

USP-NF Stimuli Article on QbD Principles in Method Development

- Published in the Pharmacopoeial Forum, PF 49(1)
- Focusing on “flexible methods in OTC drugs”
- The full article is available on PF Online via the USP Website Access Point.
- The deadline for submitting comments is 31 March 2023.

Allfälliges

4 JP drafts and a Briefing Note related to balances published for comments:

- Published at PMDA-website
- Planned to be included in Supplement II of JP 18th edition
  - Draft of revised General Test "<9.62> Measuring Instruments, Appliances"
  - Draft of new General Information "<G1-6-182> Concept of Weighing in the Japanese Pharmacopoeia"
  - Draft of new General Information "<G1-7-182> Calibration, Inspection, and Weight of a weighing instrument (balance)"
  - Draft of new General Information "<G1-8-182> Installation Environment, Basic Handling Method, and Precautions for Weighing of a Balance"
- Comments until 31 MAR 2023
- https://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/pub-comments/jp/0033.html

New JP UV-Visible and IR reference spectra published:

- 5 new spectra made available as pdf-files
- New monographs for APIs and tablets also published
- Comments until 31 MAR 2023
- https://www.pmda.go.jp/english/rs-sb-std/standards-development/jp/pub-comments/jp/0034.html

Allfälliges

WHO published harmonized text for EU and PIC/S GMP-Guide Annex 1

- Technical Report Series 1044
- 22 DEC 2022
- “practically identical” with EU-GMP-Guide Annex 1
- https://www.who.int/publications/i/item/9789240063822

WHO – GMP for Excipients:

- New guideline published for comments
- Deadline: 26 MAY 2023
- https://www.gmp-compliance.org/gmp-news/who-excipients-gmp-guideline-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW18-2023

11th Edition of The International Pharmacopoeia:

- WHO
- New, revised, and omitted texts: list in annex to the preface
- https://digicollections.net/phint/2022/index.html#p/home

Algeria: New GMP-Guidelines

- Published by ministry of Pharmaceutical Industry on 22 SEP 2022

- 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

- Nächstes **Vereinstreffen** der AQPA als **<u>Generalversammlung</u>** mit Wahl des Vorstandes:

  <u>10. Oktober 2023</u>

  Doubletree by Hilton Vienna Schönbrunn

- **Qualified Person Forum 2023 der EQPA:**

  11.-13. Oktober 2023 in Wien

  Doubletree by Hilton Vienna Schönbrunn

- **Austrian QP Forum 2024:**

  13.-14. Juni 2024

  Doubletree by Hilton Vienna Schonbrunn

- **Vereinstreffen im Rahmen des AQPA Forum 2024:**

  13. Juni 2024

Wir wünschen einen schönen Abend,
viel Spaß beim Netzwerken und
hoffen auf zahlreiches reales Wiedersehen am
10. Oktober 2023

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