Generalversammlung und Vereinstreffen der AQPA

10. Oktober 2023

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
- 18:00 Begrüßung
- Rechnungsprüfung -> bitte 2 Freiwillige melden
- Eingereichte Vorschläge zur Änderung des Vorstandes
- Wahl des Vorstandes
- Präsentationen:
  - Cell Banking – Characterization & Safety Requirements *(Walter Tabotta/ViruSure)*
  - QP-Declaration für IMP *(Gabriela Schallmeiner/Inspection Ready)*
  - Allfälliges: Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
- Teilnehmerliste *(Regine Tomasits/ViruSure)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

Wahl des Vorstandes

- Wahlvorschlag:
  - Obmann – Georg Göstl
  - Obmann Stellvertreterin – Gabriela Schallmeiner
  - Kassier – Markus Thiel
  - Schriftführerin – Regine Tomasits
  - Erweiterter Vorstand:
    - Winfried Chang
    - Klaus Hofstädter
    - Carina Rappel
    - Stefan Schneider
    - Richard Vasicek
- Alternative Vorschläge?
- Abstimmung durch Handzeichen

Allfälliges

Austrian authority published Q&A concerning implementation period for variations

- ✓ in principle, AGES/BASG follows a “zero days” implementation timeframe *(“The QP must always certify / release a batch according to the dossier valid at the time. In principle, for Type IB and Type II variations […], the date of BASG approval is the date of the dossier variation.”).* However, AGES/BASG offers a solution for variations which cannot be implemented right away (most cases) – it is possible to specify a future implementation date or implementation timeframe after approval in the eAF or alternatively, in the cover letter of the variation application. In this respect, no limit or maximum period is mentioned in the FAQ text.
- ✓ The FAQ specifically mentions that a change can only be implemented once within the period mentioned in the application *(“Switching back and forth between the old and the new dossier is not possible”)*.
- ✓ https://www.basg.gv.at/en/companies/marketing-authorisation-life-cycle/faq-marketing-authorisation-life-cycle/application-for-variation/implementierungsfrist

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)
- 8-wöchige Frist zur Abgabe von Rückmeldungen: 08 NOV 2023
- Pharmig-Aktivitäten:
  - Im Juli 2023 wurde auf Einladung des BMSGPK/BMAW ein Kick-Off Meeting zum "EU-Pharmapaket" abgehalten. Die PHARMIG hat im Zuge dessen - basierend auf den vorliegenden Unterlagen der EFPIA und unter Einbindung von Unternehmensvertreter:innen - eine vorläufige Stellungnahme erarbeitet. Diese fokussiert insbesondere auf jene Passagen im Richtlinien- und Verordnungsentwurf, welche aus Sicht der pharmazeutischen Industrie besonders kritisch zu betrachten sind. Angesichts des Umfangs des Pakets sind jedoch noch nicht alle relevanten Aspekte inkludiert. Die vorliegende Fassung wird von der eingerichteten Taskforce laufend erweitert, adaptiert und aktualisiert.
- EQPA Stellungnahme zum zukünftigen Anforderungsprofil (Berufserfahrung) einer QP wurde abgeschickt

Allfälliges

New EMA Q&A on remote batch certification by the QP:

- ✓ New July 2023
- ✓ https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers#questions-and-answers-on-remote-batch-certification-/-confirmation-by-the-qualified-person-(qp)---new-july-2023-section

New EMA Q&A on residency of the QP:

- ✓ New July 2023
- ✓ https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers#questions-and-answers-on-remote-batch-certification-/-confirmation-by-the-qualified-person-(qp)---new-july-2023-section

EMA updated Q&A “Is a “Chain of Contracts” allowed?”:

- ✓ https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers#eu-gmp-guide-part-i:-basic-requirements-for-medicinal-products:-chapter-7:-outsourced-activities-section

Allfälliges

New EMA guidelines and Revisions in GMP-area:

- ✓ New version of 3-year work plan for Quality Domain published
- ✓ Several planned documents focusing on veterinary medicinal products
- ✓ Revision of “GMP and MAH” (Q4/2023)
- ✓ Revision of Annex 16 (Q4/2024)
- ✓ Revision of Annex 15 (Validation) (Q2/2024)
- ✓ Revision of GMP for ATMPs (Q4/2024)
- ✓ Revision of Annex 11 (Computerised Systems) (Q1/2026)
- ✓ Revision of Chapter 4 (Documentation) (Q1/2026)
- ✓ https://www.gmp-compliance.org/gmp-news/new-ema-guidelines-and-revisions-in-gmp-area?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW20-2023

New EMA Guidance to prevent and mitigate Medicines Shortages:

- ✓ EMA Guidance for Industry
- ✓ “Good practices to ensure continuity in the supply of human medicines, prevent shortages and reduce their impact”
- ✓ Emphasizing importance of proactive measures
- ✓ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/good-practices-industry-prevention-human-medicinal-product-shortages_en.pdf

Allfälliges

EMA and European medicines regulatory network lift COVID-19 business continuity status:

- ✓ Published 10 MAY 2023

https://www.ema.europa.eu/en/news/ema-european-medicines-regulatory-network-lift-covid-19-business-continuity-status

EMA Phasing out of extraordinary COVID-19 regulatory flexibilities

- ✓ Published 06 July 2023
- ✓ On-site GMP and GDP inspection restarted
- ✓ GMDP Inspectors Working Group will issue an update on approach for 2024 for GMP-certificates extended until 31 DEC 2023
- ✓ IWG will also issue guidance on how remote arrangements for QPs can be applied in future

https://www.ema.europa.eu/en/news/phasing-out-extraordinary-covid-19-regulatory-flexibilities

EMA: good safety profile of COVID-19 vaccines confirmed by global regulators:

- ✓ Joint statement by ICMRA (38 regulatory agencies from every region in the world)
- ✓ More than 13 billion doses of COVID-19 vaccines administered worldwide shows that these have a very good safety profile in all age groups
- ✓ Vaccines have saved millions of lives worldwide by significantly reducing risk of severe disease, hospitalization and death from infection with SARS-CoV-2
- ✓ Statement also draws attention to devastating impact of false and misleading information and encourages people to get information from trusted sources.

https://www.ema.europa.eu/en/news/global-regulators-confirm-good-safety-profile-covid-19-vaccines

Allfälliges

EMA updates of Q&As for pre- and post- authorisation procedural advice for users of the centralized procedure:

- ✓ New answers for “Submission of responses to list of questions/list of outstanding issues” and “Extension of marketing authorisation”
- ✓ Pre-authorisation: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure-document_en.pdf
- ✓ Post-authorisation: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure-document_en-0.pdf

EMA Procedural advice on recommendations on unforeseen variations according to Article 5 of Regulation (EC) 1234/2008

- ✓ EMA/588416/2008 Rev. 2
- ✓ 16 MAY 2023
- ✓ Variations whose classification is not provided for in the guideline or Annex
- ✓ Submitted to EMA as a ticket via the EMA Service Desk, using the “Question” option
- ✓ https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-procedural-advice-recommendations-unforeseen-variations-according-article/2008_en.pdf

CMDh/HMA: Best Practice Guide on Variations:

- ✓ In July 2023 individual chapters of Best Practice Guides (BPGs) were updated and published on HMA (Heads of Medicines Agencies) website
- ✓ https://www.hma.eu/human-medicines/cmdh/procedural-guidance/variation.html

Allfälliges

EMA Revised Transparency Rules for the CTIS:

- ✓ Public consultation, comments until 28 JUN 2023
- ✓ Adopted by EMA Management Board: 05 OCT 2023
- ✓ Removal of deferral mechanism
- ✓ Benefit patients, because key clinical trial information is published early
- ✓ System is more user-friendly
- ✓ Revised rules will apply in second quarter of 2024 (effective date will be communicated)
- ✓ https://www.ema.europa.eu/en/documents/other/revised-ctis-transparency-rules_en.pdf

EMA published new and revised product-specific bioequivalence guidances

- ✓ Revised guidances will become effective by 01 JAN 2024
- ✓ New drafts published for comments (deadline: 30 SEP 2023)
- ✓ https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-pharmacology-pharmacokinetics/product-specific-bioequivalence-guidance

New Annex to and Renewed Revision of EMA's Q&A on Nitrosamines:

- ✓ Q&A 10 ("Which limits apply for nitrosamines in medicinal products?") explains in detail how to set acceptable intakes (AI) for N-nitrosamines.
- ✓ Further explanations and examples are provided in the new Annex 2
- ✓ Revision 17 Corr.
- ✓ Temporary acceptable intakes no longer need to be set

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

EMA: Q&A on "Parallel Distribution" updated:

https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/frequently-asked-questions-about-parallel-distribution#safety-updates/bulk-changes/annual-update-section

EMA website has been launched for Accelerating Clinical Trials in the EU Initiative:

- ✓ Website available at https://accelerating-clinical-trials.europa.eu/
- ✓ Multi-stakeholder platform
- ✓ Implementation of the CTR
- ✓ Voluntary procedures in scientific advice
- ✓ Simultaneous national scientific advice pilot
- ✓ News and events and ongoing activities
- ✓ https://accelerating-clinical-trials.europa.eu/select-language?destination=/node/1

Allfälliges

EMA Reflection Paper on use of Artificial Intelligence

- ✓ 19 JUL 2023
- ✓ Draft published for comments until 31 DEC 2023
- ✓ A key principle is that it is the responsibility of the MAH to ensure that any algorithms, models, datasets, etc. used are fit for purpose and meet ethical, technical, scientific and regulatory standards.
- ✓ https://www.ema.europa.eu/en/news/reflection-paper-use-artificial-intelligence-lifecycle-medicines
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/draft-reflection-paper-use-artificial-intelligence-ai-medicinal-product-lifecycle_en.pdf

EMA/HMA updated guideline for notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol:

- ✓ EMA/698382/2021
- ✓ Published 30 JUN 2023
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-notification-serious-breaches-regulation-eu-no-536/2014-clinical-trial-protocol_en.pdf

EMA published concept paper for guideline on quality aspects of mRNA vaccines:

- ✓ Increasing number of CTAs and MAAs for mRNA vaccines
- ✓ Comments to concept paper by 30 SEP 2023
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-development-guideline-quality-aspects-mrna-vaccines_en.pdf

Allfälliges

EMA Guideline on responsibility of the sponsor with regard to handling and shipping of IMP:

- ✓ EMA/INS/GMP/258937/2022
- ✓ In effect: 01 JAN 2023
- ✓ IMP release procedure
- ✓ Shipping
- ✓ Contractual arrangements or Technical agreements

https://health.ec.europa.eu/system/files/2022-12/guideline_handling-shipping_investigational-mp_en.pdf

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

Allfälliges

News on the Windsor Framework for Medicines Supply in Northern Ireland:

- ✓ MHRA long term solution, effective from 01 January 2025
- ✓ Published 09 JUN 2023
- ✓ https://www.gov.uk/government/news/windsor-framework-medicines-announcement

Regulation (EU) 2023/1182: specific rules relating to medicinal products for market in Northern Ireland

- ✓ Published 14 JUN 2023
- ✓ MHRA-license required
- ✓ Packaging clearly state “UK only”
- ✓ No safety features (per FMD) allowed on packages for N-IRL
- ✓ https://eur-lex.europa.eu/eli/reg/2023/1182/oj

Allfälliges

MRA EU/US FDA:

- ✓ 30 MAY 2023
- ✓ EU recognizes FDA as equivalent for GMP inspections of manufacturers of **veterinary products**
- ✓ US FDA recognizes 16 national CA responsible for veterinary products in the EU
- ✓ List of EU authorities recognized by US FDA: https://health.ec.europa.eu/system/files/2023-05/list_of_recognised_authorities-2023.pdf
- ✓ Assessment of remaining veterinary authorities ongoing; expected to conclude my mid 2024
- ✓ Waiver from import testing will be implemented once FDA has recognized all veterinary authorities of EU member states
- ✓ https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/mutual-recognition-agreements-mra#united-states-(updated)-section

MRA between FDA and Switzerland entered into force

- ✓ 27 JUL 2023
- ✓ Not yet for vaccines for human use
- ✓ https://www.fda.gov/international-programs/international-arrangements/mutual-recognition-agreements-mra

Allfälliges

UK-MHRA announces Cooperation with 7 international partners

- ✓ Singapore, Swissmedic, Health Canada, Australian TGA, EMA, PMDA, FDA
- ✓ UK-MHRA to utilize expertise and decision-making of trusted regulatory partners
- ✓ To bring cutting-edge medicines faster to UK patients
- ✓ Will be in place in early 2024
- ✓ https://www.gov.uk/government/news/mhra-announces-new-recognition-routes-to-facilitate-safe-access-to-new-medicines-with-seven-international-partners

Switzerland: New Declaration of Responsible Person for foreign Manufacturers:

- ✓ Swissmedic clarified conditions for submission of audit report as evidence of GMP-compliance
- ✓ For countries whose GMP controls not considered equivalent by Switzerland
- ✓ Swissmedic has published a so-called "*Guidance document GMP compliance by foreign manufacturers*" and a form "*Declaration by the Responsible Person for foreign manufacturers*“
- ✓ https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/praezisierung-der-vorgaben-fuer-die-einreichung-von-auditberichten.html

SwissMedic plans launch of own GMDP Database:

- ✓ Similar to EudraGMDP database of EMA
- ✓ Accessible to the general public
- ✓ Free access to all electronic GMP/GDP certificates
- ✓ All certificates will be available free of charge
- ✓ Expected to be launched in Q1 of 2024
- ✓ https://www.gmp-compliance.org/gmp-news/swissmedic-launches-own-gmdp-database?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW38-2023

Allfälliges

PIC/S publishes Annual Report for 2022:

- ✓ Armenia and Jordan currently applying for membership
- ✓ Russian Federation's application currently on hold
- ✓ Details on working groups and main tasks see:
- ✓ https://www.gmp-compliance.org/gmp-news/pic-s-publishes-annual-report-for-2022?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW35-2023-MEU

Bulgaria/BDA and Saudi Arabia/SFDA join PIC/S, India is to join PIC/S:

- ✓ As of 01 July 2023 Bulgaria and Saudi Arabia will be 55th and 56th Participating Authorities
- ✓ https://picscheme.org/en/news
- ✓ India is about to join PIC/S as well (confirmed by a government official)
- ✓ https://www.thepharmaletter.com/article/strengthening-regulatory-framework-india-to-join-global-quality-scheme

Philippines applied for PIC/S membership

- ✓ 20 JUN 2023
- ✓ Philippines FDA submitted complete membership application
- ✓ News (picscheme.org)

Allfälliges

The European Pharmacopoeia Ph. Eur. 11.3 was published and will get effective on 01-Jan-2024.

- ✓ **Some** chapters/monographs we want to highlight are added here.
- ✓ **NEW chapters/monographs** of this supplement:
  - 2.9.48. Particle size and shape determination by image analysis
- ✓ **Revised chapters/monographs** of this supplement:
  - 2.2.35. Osmolality
  - 2.2.46. Chromatographic separation techniques
  - 2.6.16. Tests for extraneous agents in viral vaccines for human use
  - 2.7.28. Colony-forming cell assay for human haematopoietic progenitor cells
  - 2.7.29. Nucleated cell count and viability
  - 2.9.7. Friability of uncoated tablets

N-Nitrosamine impurities in Ph.Eur. monographs: update on approach

- ✓ Impact of proposed strategy on already published individual Ph. Eur. Monographs is detailed in a table under the following link:
- ✓ https://www.edqm.eu/en/-/n-nitrosamine-impurities-in-ph.-eur.-monographs-update-on-approach

EDQM releases 21st Edition of the “Blood Guide”:

- ✓ The European Directorate for the Quality of Medicines and HealthCare released the finalized version of the 21st edition of the *"Guide to the preparation, use and quality assurance of blood components,"* commonly known as the EDQM "Blood Guide.“

Allfälliges

Ph. Eur. Commission: elaboration of 3 general texts on mRNA vaccines and components:

- ✓ mRNA Vaccines for human use (5.36), the mRNA packaged in lipid nanoparticles, i.e. mRNA-LNP medicinal product;
- ✓ mRNA Substances for the production of mRNA vaccines for human use (5.39), the mRNA active substances in the manufacture of mRNA vaccines;
- ✓ DNA Template for the preparation of mRNA transcript (5.40), the starting material for the preparation of the mRNA component.
- ✓ Assigned to newly established mRNAVAC Working Party
- ✓ Preparing for incorporation in Ph.Eur. as priority for 2023-2025
- ✓ https://www.edqm.eu/en/-/ph.-eur.-commission-kicks-off-elaboration-of-three-general-texts-on-mrna-vaccines-and-components

Pharmeuropa 35.3: revised Chapter 2.2.47 Capillary Electrophoresis

- ✓ Published for comments
- ✓ https://www.gmp-compliance.org/gmp-news/pharmeuropa-revised-chapter-2-2-47-capillary-electrophoresis-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW28-2023-MEU

CEP holders invited to comment on draft monographs published in Pharmeuropa 35.3

- ✓ Commenting deadline: 30 SEP 2023
- ✓ For companies located in Ph. Eur. Member state, please send comment through the relevant National Pharmacopoeia Authority (details see below link)

- https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-35.3

Allfälliges

Ph. Eur. Update on Pharmaceutical Preparations:

- ✓ Revised version of general monograph published for comments in Pharmeuropa 35.3
- ✓ Comment deadline: 30 SEP 2023
- ✓ Reference to general chapter on Contaminant Pyrrolizidin Alkaloids (2.8.26) added
- ✓ https://www.gmp-compliance.org/gmp-news/ph-eur-update-on-pharmaceutical-preparations?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW28-2023-MEU

EDQM: CEP 2.0: List of authorities and organisations which have access to assessment and/or inspection reports

- ✓ https://www.edqm.eu/en/-/cep-2.0-list-of-authorities-and-organisations-which-have-access-to-assessment-and/or-inspection-reports.

European Pharmacopoeia welcomes Kyrgyz Republic as observer state

- ✓ https://www.edqm.eu/en/-/european-pharmacopoeia-welcomes-kyrgyz-republic-as-observer-state

Allfälliges

Ph. Eur. Changes in testing of Pharmaceutical Water:

- ✓ EDQM announced deletion for test for nitrate in WFI and PW, if the test for conductivity meets requirements for WFI.
- ✓ Additional change for endotoxins pending: use of recombinant factor C
- ✓ Harmonization with USP
- ✓ Amendments adopted in March 2023 and will be published in Supplement 11.4 (October 2023)
- ✓ Will come into force on 01 APR 2024

https://www.gmp-compliance.org/gmp-news/changes-in-testing-for-nitrate-and-endotoxins-in-pharmaceutical-waters-in-the-european-pharmacopoeia?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW39-2023-MEU

EDQM: CEP 2.0 implemented

- ✓ Since beginning September 2023
- ✓ Applicants of a new dossier or renewals will receive a CEP 2.0
- ✓ Available as a PDF file, signed electronically only

https://www.gmp-compliance.org/gmp-news/edqm-cep-2-0-implemented?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW40-2023

Allfälliges

New Pharmeuropa Bio & Scientific Notes article now online: “Assay discrepancies using human coagulation factor VIII chromogenic kits”

- ✓ Study confirmed significant discrepancies using F VIII chromogenic kits
- ✓ Important conclusions include: need for laboratories to perform factor X activation curves for each new chromogenic kit
- ✓ https://www.edqm.eu/en/-/new-pharmeuropa-bio-scientific-notes-article-now-online-assay-discrepancies-using-human-coagulation-factor-viii-chromogenic-kits

Ph. Eur. has now over 100 excipient monographs with an FRC section in Ph. Eur:

- ✓ **FRC** = functionality related characteristics
- ✓ Outlining physical or chemical characteristics of excipient that influence functions when used in specific applications in the final product
- ✓ Not a mandatory part, but provides extremely useful information
- ✓ E.g. FRC for Polysorbate 80 (0428) includes cross-reference to tests for composition of fatty acids and hydroxyl value.
- ✓ Users are encouraged to familiarize themselves with the FRC sections published in Ph.Eur. and check regularly for new texts published for public consultation
- ✓ https://www.edqm.eu/en/-/over-100-excipient-monographs-now-with-an-frc-section-in-the-ph.-eur.

Allfälliges

Interesting reading: “The European Qualified Person – What’s it all about?”

- Essential to understand the role of the QP for non-EU-based company
- https://www.gmp-compliance.org/gmp-news/the-european-qualified-person-whats-it-all-about?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW22-MEU

Interesting reading: “Do Pharmaceutical Water Systems need a sterile Ventilation Filter?”

- Neither PW nor WFI systems are or have to be sterile
- Therefore no “sterile filter” required as vent filter
- Even though they are usually 0.2 µm filters, they should not be called “sterile filter” for this application
- However, testing of integrity for WFI tank filters is necessary
- https://www.gmp-compliance.org/gmp-news/do-pharmaceutical-water-systems-need-a-sterile-ventilating-filter?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW19-MEU

Allfälliges

FDA GfI: “Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol”:

- Guidance is for immediate implementation
- Revision 1, May 2023
- In early 2023: several reports about fatal poisoning with ingested drug liquid drug products (e.g. cough, allergy, analgesic, antiemetic) that were manufacture with DEG or EG-components
- Limit spec for DEG and EG
- ID testing on EACH container of EACH lot
- https://www.fda.gov/drugs/news-events-human-drugs/our-perspective-fda-actions-continue-ensure-safety-nations-drug-supply
- https://www.fda.gov/media/167974/download

FDA published a paper “Facts about the Current Good Manufacturing Practices (cGMP)”

- “C” stands for current, meaning that companies must use technologies and systems that are up-to-date
- Systems and equipment that were “top-of-the-line” 10 or 20 years ago may be inadequate by today’s standards.
- cGMP describe minimum requirements
- Modern, comprehensive quality systems and risk management concepts can also go beyond these requirements
- https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps

Allfälliges

FDA draft guidance related to Postmarketing Noncompliance:

- ✓ If an MAH fails to comply with timetable or other PMR requirements, the MAH is violating the PMR
- ✓ Certain circumstances described which are considered reasonable as good cause for non-compliance
- ✓ If any of those conditions is not met, MAH could be subject to a Warning Letter followed by enforcement action for PMR noncompliance

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/postmarketing-studies-and-clinical-trials-determining-good-cause-noncompliance-section-505o3eii

FDA final guidance on annual status reports and other submissions for postmarketing requirements (PMRs):

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/annual-status-report-information-and-other-submissions-postmarketing-requirements-and-commitments

FDA new guidance on waivers, exceptions, and exemptions from requirements of Section 582 of the FD&C Act:

- ✓ In the context of Drug Supply Chain Security Act (DSCSA)
- ✓ An authorized trading partner or other stakeholder may request a waiver, exception, or exemption from certain requirements related to product tracing, product identifier, authorized trading partners and verification in section 582 of the FD&C Act

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/waivers-exceptions-and-exemptions-requirements-section-582-federal-food-drug-and-cosmetic-act

Allfälliges

FDA draft guidance for Manufacturing Change and Comparability for Human cellular and gene therapy products

- ✓ Draft published for commenting
- ✓ Management and reporting of changes
- ✓ Comparability studies to assess changes
- ✓ Deadline 13 NOV 2023
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/manufacturing-changes-and-comparability-human-cellular-and-gene-therapy-products?utm_medium=email&utm_source=govdelivery

FDA's Guidance on Track & Trace Standards:

- ✓ https://www.gmp-compliance.org/gmp-news/fdas-guidance-on-track-trace-standards?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW38-2023

Allfälliges

New FDA draft Guidance on Remote Oversight Tools:

- ✓ Use of risk based decisions (e.g., requesting additional information, remote assessments, or using information from other authorities)
- ✓ In preparation for, or in lieu of inspections in pending applications
- ✓ To provide operational flexibility to facilitate timely approval of drugs
- ✓ Complement inspections, but do not replace them
- ✓ This does not apply to other inspection programs
- ✓ Comments can be submitted online
- ✓ https://www.fda.gov/media/172290/download

FDA draft Q&A: Conducting Remote Regulatory Assessments:

- https://www.fda.gov/media/160173/download

Allfälliges

FDA CDER Small Business & Industry Assistance (SBIA)

- A Comprehensive Resource for Information on Human Drug Development in Regulation
- Access to resources, education and training
- No Cost conferences
- Newsletter and audio podcast “SBIA Chronicles”
- Direct Communications Services (available to everyone)
- https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/about-cder-small-business-and-industry-assistance-sbia
- Conference and webinar recordings available on YouTube: CBER SBIA YouTube Learning Library: https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/cder-sbia-youtube-learning-library

FDA Guidance Document “Potency Assay Consideration for Monoclonal Antibodies and Other Therapeutic Proteins Targeting Viral Pathogens”

- March 2023
- Draft document, not for implementation
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/potency-assay-considerations-monoclonal-antibodies-and-other-therapeutic-proteins-targeting-viral

Allfälliges

FDA updated risk factors for prioritizing inspections:

- ✓ Updated Manual of Policies and Procedures (MAPP) for staff
- ✓ How FDA prioritize inspections und the Site Selection Model (SSM)
- ✓ Effective date: 26 JUN 2023
- ✓ Adding a risk factor for establishments in countries where there is a “history of violations”

https://www.fda.gov/media/116004/download

US-congress criticized FDA over inadequate GMP-inspections in India and China

- ✓ Letter sent to FDA Commissioner Robert Califf
- ✓ 18 JUL 2023

https://d1dth6e84htgma.cloudfront.net/Letter_to_FDA_on_Foriegn_Drug_Inspections_dc7bf60a6d.pdf

US DHHS ended COVID-19 flexibilities

- In response to the WHO IHE declaration, on January 31, 2020, the U.S. Department of Health and Human Services declared a public health emergency (PHE). After 13 renewals, the PHE expired on May 11, 2023, which results in the end of a range of COVID-19 regulatory flexibilities afforded by the FDA to the pharmaceutical industry, which were implemented to mitigate the impact of COVID-19.

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-procedures-blood-and-blood-components-during-covid-19-public-health-emergency

Allfälliges

Revised USP Chapters

- <2> Oral Drug Products – Product Quality Tests
- <711> Dissolution (harmonized document EP, JP, and USP)
- <781> Optical Rotations
- <782> Vibrational Circular Dichroism Spectroscopy
- <1782> Vibrational Circular Dichroism Spectroscopy – Theory and Practice
- Published for comments in Pharmacopeial Forum PF 49(3)
- Deadline for comments: 31 JUL 2023
- The drafts are available after registration to the Pharmacopeial Forum
- https://www.uspnf.com/pharmacopeial-forum

2nd Version of USP draft on mRNA-based Therapeutics:

- ✓ USP seeking input on the draft
- ✓ Deadline for submission: 25 JUL 2023
- ✓ https://www.gmp-compliance.org/gmp-news/2nd-version-of-the-usp-draft-guidance-on-mrna-based-therapeutics?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW24-2023

Allfälliges

Revised USP Chapter <31> and new chapter <1331>

- ✓ Volumetric Apparatus
- ✓ Published for comments until 30 NOV 2023
- ✓ https://www.gmp-compliance.org/gmp-news/revised-usp-chapter-31-and-new-chapter-1331-on-volumetric-apparatus-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW38-2023

USP: Weighing on an Analytical Balance <1251>:

- ✓ Comments can be submitted until 30 NOV 2023
- ✓ https://www.gmp-compliance.org/gmp-news/usp-chapter-weighing-on-an-analytical-balance-1251-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW39-2023-MEU

USP: Balances <41>:

- ✓ Revised following update to USP <1251> “Weighing on an Analytical Balance”
- ✓ Comments can be submitted until 30 NOV 2023
- ✓ https://www.gmp-compliance.org/gmp-news/usp-comments-possible-on-the-topic-balances-41?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW38-2023

Allfälliges

USP Draft of harmonized Chapter <701> Disintegration

- ✓ Published for comments in Pharmacopoeial Forum PF 49(5)
- ✓ Commenting period until 30 NOV 2023
- ✓ International harmonization of European, Japanese, and US Pharmacopoeias
- ✓ The draft chapter is available on PF Online via the USP Website Access Point

New Proposals for Revision of USP Chapters <761> and <1761> on NMR Spectroscopy

- ✓ Published for comments in Pharmacopoeial Forum PF 49(5)
- ✓ Commenting period until 30 NOV 2023
- ✓ Update content with modern technologies and contemporary practices
- ✓ Expand coverage of quantitative NMR
- ✓ The two draft chapters are available on PF Online via the USP Website Access Point.

New USP Chapter: <1243> Wetting Properties of Pharmaceutical Systems:

- ✓ Draft can be found in Pharmacopoeial Forum 49(5)
- ✓ The draft is free to view, requires a free registration on the USP/NF site, though
- ✓ https://www.gmp-compliance.org/gmp-news/new-usp-chapter-wetting-properties-of-pharmaceutical-systems?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW40-2023

USP: Excipient Stimuli document published for comments

- ✓ Comments can be submitted until 30 NOV 2023
- ✓ The draft can be viewed and commented after one-time registration on the Pharmacopoeial Forum website
- ✓ https://www.gmp-compliance.org/gmp-news/usp-excipient-stimuli-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW40-2023

Allfälliges

USP adopted revised general chapters for Semisolids:

- ✓ <1724> Semisolid Drug Products – Performance Tests
- ✓ <1912> Measurement of Yield Stress of Semisolids

https://www.gmp-compliance.org/gmp-news/semisoldrug-product-quality-and-performance-tests?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW29-2023

- ✓ <670> Auxiliary Packaging Components
- ✓ Including desiccants and odor adsorbents

https://www.gmp-compliance.org/gmp-news/auxiliary-packaging-components?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW29-2023

USP-NF Stimuli Article on Chromatographic Screening for Extractables and Leachables

- ✓ Pharmacopoeial Forum, PF 49(4)
- ✓ Deadline for comments: 30 SEP 2023

https://www.gmp-compliance.org/gmp-news/usp-nf-stimuli-article-on-chromatographic-screening-for-extractables-and-leachables?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW30-2023-MEU

Allfälliges

Indonesia:

- ✓ Vaccine Batch/Lot Release Certificate issued by NADFC (National Agency for Drug and Food Control)
- ✓ Requirement for distribution within the territory of Indonesia
- ✓ Date effective: 10 Jan 2022

Korean MFDS publishes Revision of Comparative Dissolution Test Guideline:

- ✓ https://www.gmp-compliance.org/gmp-news/korean-mfsd-publishes-revision-7-of-comparative-dissolution-test-guideline?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-2023-KW25-MEU

South-Korea Data Integrity Guidance for ATMPs:

- ✓ contains some very special requirements:
  - Photos of all micro-lab plates, turbidity checks, visual confirmation, … (to prove result and allow reconstruction)
  - Second reviewer's confirmation record alone not considered sufficient
  - Photos/videos of all interventions in sterile areas (at least a plan should be prepared to introduce recording equipment)
  - Media Fills/APS: photos or videos of all sample vials before and after incubation
  - Reasonable sample plan to take photos of visual inspection to store evidence; in the long term have a plan to introduce automatic foreign body testers to guarantee evidence for the result
- ✓ Describing position of Korean MFDS
- ✓ Guide-1269-01 (30 JAN 2023)
- ✓ 135 pages
- ✓ Currently only in Korean language, no official English translation yet

Allfälliges

EAEU (Russia, Belarus, Kazakhstan, Kyrgyzstan, Armenia) heading towards a kind of harmonized/central licenses:

- ✓ Conversion to be complete by end 2025
- ✓ Rather like an MRP (one country approving as reference, others to approve same dossier content in second step)
- ✓ Please be aware that by DEC 2025 some of the current licenses might be terminated

On May 5, the World Health Organisation (WHO) declared the end of the COVID-19 international health emergency (IHE)

- ✓ in place since early 2020, and is responsible for approximately 7 million deaths, 700 million confirmed cases of COVID-19, and more than 65 million cases of long COVID-19.

WHO draft working document: Good Practices for QC Laboratories:

- ✓ QAS/21.882
- ✓ Published for comments by 06 OCT 2023
- ✓ 83 pages
- https://www.gmp-compliance.org/gmp-news/who-draft-working-document-on-good-practices-for-quality-control-laboratories-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW39-2023-MEU

WHO Draft Working Document on Biowaiver Project:

- ✓ Biowaivers are a way of waiving bioequivalency studies, when those are considered not necessary
- ✓ Published for comments by 10 SEP 2023
- ✓ https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/working-documents-public-consultation

Allfälliges

Interesting Reading:

- **“QPs in a Time of Electronic Data”**
  - ✓ Published in GMP Journal
  - ✓ 22 June 2023
  - ✓ https://www.gmp-journal.com/current-articles/details/qps-in-a-time-of-electronic-data.html
- **“Advanced Data Analysis as an enabler to near real-time Contamination Control Strategy Evaluation”**
  - ✓ Published in GMP Journal
  - ✓ 22 June 2023
  - ✓ https://www.gmp-journal.com/current-articles/details/advanced-data-analysis-as-an-enabler-to-near-real-time-contamination-control-strategy-evaluation.html
- **New Issue of EQPA Membership Newsletter**
  - Issue 18, June 2023
  - Issue 18 and all previous issues available in the member area of EPQA-website: “EQPA Download Area -> 6. EPQA Members Newsletters”:
  - https://www.qp-association.eu/qpag_index.html
- **„Extended QP responsibilities based on national legislation”:**
  - ✓ Survey by EQPA
  - – https://www.gmp-journal.com/current-articles/details/extended-qp-responsibilities-based-on-national-legislation.html

- Präsentationen werden wieder im Internet abrufbar sein: www.austria-qp.at
- **2 Rechnungsprüfer** -> *Markus Thiel*
- 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 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 Schönbrunn

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

  13. Juni 2024

  Doubletree by Hilton Vienna Schönbrunn

Wir wünschen einen schönen Abend,
viel Spaß beim Netzwerken und
hoffen auf zahlreiches reales Wiedersehen am
13. Juni 2024

Bleiben Sie gesund!

Der erweiterte AQPA-Vorstand:

Georg Göstl, Obmann
Gabriela Schallmeiner, Obmann-Stellvertreterin
Regine Tomasits, Schriftführerin
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Winfried Chang
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