Vereinstreffen der AQPA

20. Oktober 2022

Der AQPA-Vorstand:

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

Agenda

- 18:00 Begrüßung
- Präsentationen:
  - ~~Virussicherheit für Biopharmazeutische Produkte *(Walter Tabotta/ViruSure)*~~
  - Allfälliges:
    - Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
    - QP-Verantwortlichkeiten gemäß AMBO 2009 *(Georg Göstl/Takeda)*
    - QP Code of Conduct *(Georg Göstl/Takeda)*
- Teilnehmerliste *(Regine Tomasits/ViruSure)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

Allfälliges

EU GMP-Guide Annex 1:

- 59 pages (vs. 2008-version: 16 pages)
- The deadline for coming into operation of Annex 1 is **25 August 2023**,
- except for point **8.123** (sterilisation of lyophilizers) which is postponed until **25 August 2024**
- Additional responsibilities for the QP as "**person responsible for the certification/release**":
  - *Appropriate access to information and adequate knowledge and experience*
  - *All non-conformities adequately investigated before certification/release*
  - Test results of water system after disinfection/regeneration approved and results verified before batches considered for certification/release
  - Results of integrity test of gas or vent filters reviewed as part of batch certification/release process
  - Vacuum test for containers sealed under vacuum after predetermined period prior to certification/release
  - Conformity of sterilization records reviewed and approved as part of batch certification/release
  - Results of integrity test of vent filter at lyophilizer should be part of batch certification/release
  - Information from environmental monitoring, personnel monitoring, Temperature, humidity and other specific characteristics, APS should be used for routine batch certification/release
  - Environmental monitoring data and trend data should be reviewed as part of product batch certification/release

Annex 1 - Manufacture of Sterile Medicinal Products

PIC/S also published revised Annex 1:

- Almost simultaneously published with EU-Commission
- Identical to EU-GMP-Guide Annex 1 – with some very minor editorial differences
- https://picscheme.org/docview/4737

Allfälliges

EMA 3-year work plan for the Quality domain:

- Input from GMDP IWG
- EMA/563631/2022
- Among many other topics, the following is expected in relation to GMP-Guide and ICH:
    - Chapter 4 (Documentation): final text to EC by Q4/2023
    - Annex 11 (Computerised Systems): final text to EC by Q4/2022
    - Annex 15 (Qualification and Validation): review text by Q3/2023
    - **Annex 16 (QP Certification):** "Following up on LLE recommendations, consider revision of annex in order to provide additional guidance on batch traceability." By Q2/2023
    - Chapter 1 (PQS): final text to EC by Q4/2023
    - Annex 4 (Veterinary Medicines): final text to EC by Q4/2023
    - Annex 5 (Immunological veterinary medicines): final text to EC by Q4/2023
    - GMP for Autogenous Veterinary Vaccines: final text to EC by Q4/2023
    - ICH Q9 (QRM): develop training material by Q4/2023
    - **GMP and MAH:** revise paper (**strengthen guidance for MAHS in terms of having quality agreement with manufacturers**) by Q4/2023
    - ICH Q12 (Lifecycle Management): developing training material by Q4/202**1** (!)
    - ICH Q7 (GMP for API): make Annex 15 mandatory through inclusion in Q7 by Q4/2023
    - ICH Q13 (Continuous Manufacturing): developing guideline by Q4/2023

https://www.ema.europa.eu/en/documents/work-programme/work-plan-good-manufacturing-practice/good-distribution-practice-inspectors-working-group-2021-2023_en.pdf

Allfälliges

EMA draft Q&A on remote QP certification:

- Published 13 May 2022
- Consultation until 13 June 2022
- EQPA consolidated comments and submitted those to EMA

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/public-consultation-concerning-physical-attendance-location-personal-residency-qualified-person_en.pdf

EMA Q&A "Safety Features" (Delegated Regulation 2016/161):

- Version 20
- Published June 2022
- New entry Q 5.14: Verification of authenticity when product is not in physical possession
- https://health.ec.europa.eu/system/files/2022-06/qa_safetyfeature_en_0.pdf

EMA: New Update of the "IRIS" Documents:

- IRIS guide to registration and RPIs (version 2.9)
- IRIS guide for applicants (version 2.12)
- https://www.gmp-compliance.org/gmp-news/ema-new-update-of-the-iris-documents?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW39+-+MEU
- Also "What's New in IRIS" in the "IRIS Stakeholder Forums":
- https://iris.ema.europa.eu/forums/

Allfälliges

EC, HMA, EMA: Q&A "Regulatory Expectations during COVID-19 pandemic":

- Revision 5
- Published 11 August 2022
- Updated Q2.2 (GMP certificates in light of difficulties to conduct GMP inspections): **validity of GMP-certificates extended until end of 2023** (3rd extension) (for sites located in the EEA and outside EEA)

https://health.ec.europa.eu/system/files/2022-08/guidance_regulatory_covid19_en.pdf

EMA has published for public consultation the following concept papers:

- Concept Paper on the Establishment of a Guideline on the Development and Manufacture of Synthetic Oligonucleotides
- Concept Paper on the Establishment of a Guideline on the Development and Manufacture of Synthetic Peptides
- It is envisaged that two separate guidelines will be developed to address specific requirements for both synthetic peptides and oligonucleotides
- Comments should be provided using this template and sent to QWP@ema.europa.eu by **20 December 2022.**

EMA publishes comments received on ICH Q2(R2) and Q14:

- Large number of comments compiled in a 72 page PDF document for ICH Q2 (validation of analytical procedures" and a 54 page PDF document for ICH Q14 (analytical procedure development)
- FDA started consultation also on 26 August 2022
- https://www.ema.europa.eu/en/documents/comments/overview-comments-received-ich-guideline-q2r2-ich-guideline-q2r2-validation-analytical-procedures/chmp/ich/82072/2006_en.pdf
- https://www.ema.europa.eu/en/documents/comments/overview-comments-received-ich-guideline-q14-analytical-procedure-development-ema/chmp/ich/195040/2022_en.pdf
- https://www.ich.org/page/quality-guidelines

Allfälliges

EMA annual report of GMP and GDP Inspectors Working Group 2021:

- EMA/INS/GMP/706144/2021
- Published 19 APR 2022
- https://www.ema.europa.eu/en/documents/report/annual-report-good-manufacturing-distribution-practice-inspectors-working-group-2021_en.pdf

EMA annual report 2021:

- 148 pages
- Published: 10 June 2022
- https://www.ema.europa.eu/en/documents/annual-report/2021-annual-report-european-medicines-agency_en.pdf
- Annexes (157 pages) to the annual report 2021:
- **Lists all members in various EMA Committees, working parties and working groups**
- https://www.ema.europa.eu/en/documents/annual-report/annexes-2021-annual-report-european-medicines-agency_en.pdf

EMA 2020-2021 biennial report of EMA's interaction with industry:

- Describes EMA interactions with industry stakeholders
- https://www.ema.europa.eu/en/documents/report/european-medicines-agencys-interaction-industry-stakeholders-biennial-report-2010-2021_en.pdf

Allfälliges

EMA asks companies to register a Single Point of Contact:

- MAH to register an “Industry Single Point of Contact” (i-SPOC)
- All companies with centrally or nationally authorized medicinal product in the EU
- Facilitate rapid communication for drug shortages
- Companies must register their i-SPOC on the EMA IRIS online platform by 02 September 2022
- https://www.gmp-compliance.org/gmp-news/drug-shortages-ema-asks-companies-to-register-a-single-point-of-contact?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW27+-+MEU

EMA public consultation “Concept paper on revision of guideline on chemistry of active substances”:

- Published 11 July 2022
- Need was recognized during lessons learned from presence of Nitrosamine impurities in Sartan-medicines
- EMA/CHMP/600383/2022
- Deadline for public consultation: 31 OCT 2022
- Proposed guideline will replace current guideline EMA/454576/2016
- https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-guideline-chemistry-active-substances-revision-1_en.pdf

Allfälliges

EMA Guidance for applicants/MAHs involved in GMP and GCP inspections coordinated by EMA:

- EMA/274221/2021
- Version 1.0
- https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-applicants/mahs-involved-gmp-gcp-inspections-coordinated-ema_en.pdf

EMA Q&A on Nitrosamine Contamination updated:

- Rev. 12 (10 October 2022)
- 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

EMA new Q&A concerning titanium dioxide and its replacement in medicines:

- Published 01 JUL 2022
- https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/qa-quality/quality-medicines-questions-answers-part-2#replacement/removal-of-titanium-dioxide-(tio2)-in-medicines.-technical-and-procedural-guidance.-new-july-2022-section

EMA Update of the Q&A on Parallel Distribution:

- Updated May 2022
- https://www.ema.europa.eu/en/human-regulatory/post-authorisation/parallel-distribution/frequently-asked-questions-about-parallel-distribution

Allfälliges

EC amended labeling requirements for IMPs:

- Revised Annex VI to Regulation (EU) No 536/2014 (CTR)
- 06 SEP 2022
- Effective 20 days following publication in the official Journal of the EU
- Eliminating the obligation to include an expiry date on primary packaging in specific circumstances

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13421-Unauthorised-medicinal-products-used-in-clinical-trials-labelling-rules-_en

EC Q&A Regulation (EU) 536/2014 (Clinical Trial Regulation (CTR)):

- Version 6.2
- 142 pages(!)
- Published September 2022

https://health.ec.europa.eu/latest-updates/update-eudralex-volume-10-clinical-trials-guidelines-questions-and-answers-document-regulation-eu-2022-09-26_en

EC Q&A on the Interface between CTR (536/2014) and Regulation (EU) 2017/746 (in vitro diagnostic medical devices):

- MDCG 2022-10
- 25 May 2022

https://ec.europa.eu/health/latest-updates/qa-interface-between-regulation-eu-5362014-clinical-trials-medicinal-products-human-use-ctr-and-2022-05-25_en

Allfälliges

EMA has launched a public consultation for the first release of the Data Quality Framework for the EU medicines regulation (EMA news announcement).

- general considerations that can be applied to a wide range of data sources for the purpose of characterising and assessing data quality for decision making
- Intended to provide an overarching framework to identify, define and further develop data quality assessment procedures and recommendations for current and novel data types.
- Building a European Data Quality Framework for the regulatory use of data sources with associated quality metrics is one of the key 'Data Quality and Representativeness' deliverables set out in the joint HMA-EMA Big Data Steering Group workplan (2022-2025).
- Stakeholders and members of public are invited to submit comments on this framework using this template by **18 November 2022**. The completed form should be sent to dataqualityframework@ema.europa.eu.

EC draft Regulation on Substances of Human Origin (SoHO):

- Will be repealing Directives 2002/98/EC and 2004/23/EC
- Published 14 July 2022
- The text covers donation, collection, testing, processing, storage, and distribution of blood products including plasma
- You can find the document here: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2022:338:FIN
- The EC press release can be found here: https://ec.europa.eu/commission/presscorner/detail/en/ip_22_4403

EU whistleblowing directive (EU) 2019/1937:

- Deadline for implementation passed on 17 DEC 2021
- Overview of different implementation status in the member countries given in an article published by the TMF Group: https://www.tmf-group.com/en/news-insights/articles/2022/april/new-eu-whistleblowing-directive/

Allfälliges

Brexit: Legal Proposals adopted on Supply of Medicines in N-IRL, Cyprus and Malta:

- Q&A document by the European Commission
- Directive and Regulation are now in place (approved 12 April 2022)

https://www.gmp-compliance.org/gmp-news/brexit-legal-proposals-adopted-on-the-supply-of-medicines-in-northern-ireland-cyprus-ireland-and-malta?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW18+-+MEU

UK-MHRA introduces external consultants as " Compliance Monitors" in companies:

- The MHRA has published further details of the procedure, MHRA training and relevant documentation on a separate website.
- Source: MHRA Blog Part 1 and Part 2

UK MHRA now also full member of ICH:

- Press release published 16 June 2022

https://www.gov.uk/government/news/mhra-joins-international-partnerships-to-set-global-standards-for-medicines-and-medical-devices-regulation--2

UK consultation "future strategy for batch testing in GB":

- Assess policy options for batch testing where medicines are imported into GB from a third country
- List of consultation questions
- Consultation open until 11:45pm on 26 July 2022

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

Allfälliges

Interesting Reading: “Bioburden – Q and A on Biopharmaceutical Manufacturing”:

- Developed by ECA Academy
- More Q&A will follow shortly

https://www.gmp-compliance.org/gmp-news/bioburden-question-and-answers-on-biopharmaceutical-manufacturing?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW18+-+MEU

The ECA Foundation (not the Academy) has a new webpage:

- information about the different activities such as working groups, Guidances, annual Reports etc.
  https://www.linkedin.com/feed/update/urn:li:activity:6984040502601916416

ECA Good Practice Guide on Equipment Qualification – merging ASTM 2500 and EU Annex 15

- Qualification and validation based on Customer-Supplier Partnership
- Practical advice for leveraging equipment qualification
- Guide is in compliance with EU and US regulations and takes into account standard recommendations as those in ASTM E2500
- https://www.gmp-compliance.org/gmp-news/press-announcement/eca-good-practice-guide-on-equipment-qualification-merging-astm-2500-and-eu-annex-15?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW41+-+MEU

Allfälliges

New Version of ICH Q3D Guideline for Impurities published:

- Second revision published in April 2022
- PDEs for nickel, gold and silver adjusted and related monographs revised
- Annex 5 added for limits for the Cutaneous and Transcutaneous Route

https://database.ich.org/sites/default/files/Q3D-R2_Guideline_Step4_2022_0308.pdf

ICH Guideline S1B(R1) Testing for Carcinogenicity of Pharmaceuticals:

- 04 August 2022
- New addendum integrated (evaluation for assessing human carcinogenic risk of pharmaceuticals)
- https://database.ich.org/sites/default/files/S1B-R1_FinalGuideline_2022_0719.pdf

EFPIA published results of a member survey: current inspection trends 2021

https://www.efpia.eu/media/637001/efpia-2021-3-reg-inspection-survey.pdf

GAMP®5 2nd Edition released (end of July 2022)

- The new edition can be ordered on the ISPE website.
  https://www.gmp-compliance.org/gmp-news/gamp5-2nd-edition-released?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW32+-+MEU

Allfälliges

EDQM: EU Administrative Procedure for Official Authority Batch Release revised:

- Date of entry into force: 01 July 2022

https://www.edqm.eu/en/human-ocabr-guidelines#OCABR%20Administrative%20Procedures

EDQM: OMCLs participate in international regulatory collaboration on analysis of nitrosamines in metformin-containing medicines:

- https://www.edqm.eu/en/-/omcls-participate-in-international-regulatory-collaboration-on-the-analysis-of-nitrosamines-in-metformin-containing-medicines

EDQM published the 21st version of the Blood Guide for public consultation:

- *"Guide to the Preparation, Use, and Quality Assurance of Blood Components" (Blood Guide)*
- Separate documents providing background information and evidence to support parameters in the Guide
- Future editions of the *Blood Guide* may be explicitly referenced in the revised EU Blood, Tissues, and Cells legislation
- Deadline for submissions to EDQM: 15 September 2022.

Allfälliges

EDQM - Call for experts: join the Ph.Eur. network

- Every three years, the European Pharmacopoeia invites qualified candidates – scientists, academics, regulatory officials and other professionals working with medicines – to apply to join its network of experts and become a part of the safety net that promotes and protects public health in Europe and beyond.
- Apply to join the Ph. Eur. expert network, share your knowledge and passion for quality, participate in engaging debates and contribute to decisions that are critical to ensuring public health!
- In particular, the Ph. Eur. is seeking **experts with current expertise in pharmaceutical analytical procedures**, related to the **quality control** of **inorganic substances** and **synthetic and semi-synthetic organic substances**. **Active involvement** in laboratory verification and validation of test procedures **is essential**.
- Would you like to share your expertise with colleagues worldwide, collaborate with the EDQM staff, scientists and European regulators? Click here to apply!
- https://www.edqm.eu/en/-/call-for-experts-join-the-ph.-eur.-network-3

EDQM – Annual Report 2021 now available:

- Published 14 June 2022
- https://www.edqm.eu/en/-/2021-highlights-edqm-annual-report-now-available

Allfälliges

Ph. Eur. Chapter 5.21 “Chemometric methods Applied to Analytical Data”:

- Published in Ph. Eur. 11.1

https://www.edqm.eu/en/-/revised-general-chapter-5.21-chemometric-methods-applied-to-analytical-data-published-for-public-comment-in-pharmeuropa

New general chapter 5.26 “Implementation of Pharmacopoeial Procedures”:

- 2 step approach
- Text will be implemented on 01 January 2023

https://www.gmp-compliance.org/gmp-news/new-ph-eur-chapter-on-implementation-of-pharmacopoeial-procedures?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW32+-+MEU

New Ph. Eur. Chapter 5.27 “Comparability of alternative analytical procedures”:

- Proposed in Pharmeuropa 34.2
- Deadline for comments: 30 June 2022
- More information can be found after registration on the Pharmeuropa website.

https://www.gmp-compliance.org/gmp-news/how-to-demonstrate-comparability-of-analytical-procedures?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW19+-+MEU

Allfälliges

Ph. Eur. Revised several chapters on Chromatographic methods:

- The following general chapters are affected:
  - 2.2.27. Thin-layer chromatography
  - 2.2.28. Gas chromatography
  - 2.2.29. Liquid chromatography
  - 2.2.30. Size-exclusion chromatography
  - 2.2.45. Supercritical fluid chromatograpy
- Publication of Supplement 11.1
- Implementation by 01 April 2023

List of all texts adopted:
https://www.edqm.eu/documents/52006/340088/List+of+texts+adopted+at+the+March+2022+session+of+the+European+Pharmacopoeia+Commission.pdf/ae750fdc-fbe6-80b3-4648-e1c0d20b8404?t=1651670563446

- Ph. Eur. Revised General Chapter
  - 2.2.46. Chromatographic separation techniques
  - Published in 11th Edition (implementation date 01 JAN 2023)

https://www.edqm.eu/en/-/general-chapter-2.2.46.-chromatographic-separation-techniques-now-published-in-ph.-eur.-11th-edition

- EDQM publishes FAQs on revised Ph. Eur. General Chapter 2.2.46. Chromatographic Separation Techniques
  - Due to numerous queries received by EDQM help desk, selected Q&A now published
  - https://faq.edqm.eu/pages/viewpage.action?pageId=48201789

Allfälliges

Ph. Eur. – Revision of Chapter 2.6.30 Monocyte Activation Test:

- Further details on the revision can be found, after registration, on the Pharmeuropa website.
- Deadline for comments: 30 June 2022

https://www.gmp-compliance.org/gmp-news/pharmeuropa-revision-of-chapter-2-6-30-monocyte-activation-test?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW20+-+MEU

Ph.Eur. Revision of Heparin sodium (0333) and Heparin calcium (0332) monographs:

- control for absence of non-porcine source materials,
- In addition, it is proposed to lower the current limit for residual protein from ≤ 0.5 per cent to ≤ 0.1 per cent, a level considered more commensurate with a substance that is used in parenteral products.
- Feedback required via the Pharmeuropa platform by 30 September 2022

https://www.edqm.eu/en/-/revision-of-heparin-sodium-0333-and-heparin-calcium-0332-monographs-feedback-required

Nitrosamines – Deadline extension for CEP holders to complete step 3 Revision to the CEP:

- Now 01 October 2023
- To allow companies time to perform thorough investigation and establish any mitigating actions.
- Deadline for step 2 Confirmatory Testing remains unchanged: 26 SEP 2022

https://www.edqm.eu/en/-/nitrosamines-deadline-extension-to-all-cep-holders-to-complete-step-3-revision-to-the-cep-now-1st-october-2023-.

Allfälliges

European Pharmacopoeia 11th edition (EP 11.0):

- effective date 01 Jan 2023
- https://www.edqm.eu/en/european-pharmacopoeia-ph.-eur.-11th-edition
- 11th Edition of Ph. Eur. now available in print
- https://www.edqm.eu/en/-/11th-edition-of-the-european-pharmacopoeia-now-available-in-print-1

Ph. Eur. 11.1 published and will be effective 01-Apr-2023:

- Revised chapters/monographs of this supplement:
  - **(0169) sterilized Water for injections: Deletion of tests for acidity/alkalinity and inorganic compounds (Ca, Mg, NO_3, SO_4, NH_4, Cl, …) as conductivity testing is able to determine those. Please note test for Aluminum is maintained for sWFI**

Official Comments for the texts published

EDQM: Examples of Analytical Method Implementation:

- Following new Ph. Eur. Chapter 5.26 “Implementation of pharmacopoeial procedures” (Ph. Eur. 11.0)
- https://www.gmp-compliance.org/gmp-news/examples-of-analytical-method-implementation?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW38+-+MEU

Allfälliges

EDQM: updated List of Reference Standards:

- More than 3000 substances
- Several reference standards replaced by new batches
- Some substances have been removed from the list or will be removed in future
- Complete list under following links:

https://www.edqm.eu/en/-/24-replacement-batches-released-in-april-2022

https://www.edqm.eu/en/-/4-new-ph.-eur.-reference-standards-and-16-replacement-batches-released-in-september-2022

CEP holders invited to comment on draft monographs published in Pharmeuropa 34.3:

- https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-34.3

New Edition of Technical Guide for the Elaboration of Ph. Eur. Monographs:

- 8th edition
- More information is available in the EDQM Newsroom and under Ph. Eur. Technical Guides.

https://www.gmp-compliance.org/gmp-news/new-edition-of-the-technical-guide-for-the-elaboration-of-ph-eur-monographs?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW32+-+MEU

Allfälliges

FDA updated Guidance on Investing OOS results:

- Revision 1 Published in May 2022

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigating-out-specification-oos-test-results-pharmaceutical-production-level-2-revision

FDA plans Rating System for Pharmaceutical Companies:

- Objective assessment of "Quality Management Maturity" (QMM)
- White Paper published for download

https://www.fda.gov/media/157432/download

FDA office of Pharmaceutical Quality publishes Annual Report 2021:

https://www.fda.gov/media/156272/download

FDA Draft Guidance for Industry "Benefit-Risk Considerations for Product Quality Assessment":

- Published in May2022
- Deadline for comments: 10 JULY 2022

https://www.fda.gov/media/158204/download

FDA Draft Guidance for industry "Risk Management Plans to Mitigate the Potential for Drug Shortages":

- Deadline for comments: 19 July 2022

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/risk-management-plans-mitigate-potential-drug-shortages

Allfälliges

FDA Draft Guidance Q9(R1) Quality Risk Management:

- Deadline for comments: 15 July 2022

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q9r1-quality-risk-management

FDA Draft Guidance for Industry "Patient-Focused Drug Development, or Modifying Fit-for-Purpose Clinical Outcome Assessments":

https://www.fda.gov/media/159500/download

FDA Draft Guidance for Industry "Clinical Pharmacology Considerations for the Development of Oligonucleotide Therapeutics":

https://www.fda.gov/media/159414/download

FDA Draft Guidance for Industry "Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies":

- Deadline for comments: 14 September 2022

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-consensus-standards-recognition-program-regenerative-medicine-therapies

Allfälliges

FDA Draft Guidance for Industry "Considerations for Rescinding Breakthrough Therapy Designation":

https://www.fda.gov/media/159359/download

FDA revised draft guidances for Track and Trace:

- 2 revised draft guidances: "Standards for Track and Trace", "identifying Trading Partners under the DSCSA"
- Comments can be submitted to FDA by 05 SEP 2022
- DSCSA (Drug Supply Chain Security Act) will come into effect in November 2023
- https://www.fda.gov/media/90548/download
- https://www.fda.gov/media/159621/download

FDA published an interesting article "Is It Really "FDA Approved"?":

- posted on FDA website

https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved?utm_medium=email&utm_source=govdelivery

FDA Warning Letter: Potentially Carcinogenic Contaminants in Hand Sanitizers:

- During FDA laboratory testing hand sanitizers, the impurities benzene, acetaldehyde and acetal impurities were detected at unacceptable levels (California manufacturer)
- FDA has not received a response from the company regarding corrective actions to the observations identified during the inspection in the Form FDA 483. The company also failed to respond to previous inquiries from the FDA or responded only after repeated requests.
- https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/virgin-scent-inc-dba-artnaturals-631780-09012022

Allfälliges

FDA draft Guidance for Industry on preventing cross contamination:

- "Non-Penicillin Beta-Lactam Drugs: A CGMP Framework for Preventing Cross-Contamination"
- 15 pages including two appendices, published June 2022 for comments
- intended to replace an industry guideline from 2013 with the same title
- guidance on methods, design requirements for premises and control elements to prevent cross-contamination with components carrying a beta-lactam ring (e.g. Cephalosporines)

https://www.fda.gov/media/159358/download

FDA published 2022 Investigations Operations Manual (IOM)

- Regulated industry and stakeholders can better understand FDA operations
- 628 pages

https://www.fda.gov/media/113432/download

FDA Draft GfI "Conducting Remote Regulatory Assessments":

- Published for comments only (July 2022)
- Objective to continue use also after COVID-pandemic
- RRAs "complement" the inspection authority, but do not replace/substitute inspections

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

Allfälliges

USP draft chapters for plastic materials used in manufacturing:

- <382> *Elastomeric Component Functional Suitability in Parenteral Product Packaging/Delivery Systems*
- <383> *Cured Silicone Elastomers for Pharmaceutical Packaging and Manufacturing Components*
- Published for comments
- The proposed USP monographs on elastomers are available after registration to the Pharmacopeial Forum.

Revised USP Chapter <831> Refractive Index published for comments:

- The deadline for submitting comments is July 31, 2022.
- The draft of the revised chapter is available on PF Online. (Please note: a one-time registration is required to access the Pharmacopeial Forum)

https://www.gmp-compliance.org/gmp-news/revised-usp-chapter-831-refractive-index-published-again-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW21+-+MEU

Proposed revision of USP <711> Dissolution canceled:

- Initially published in March 2022, has now been canceled
- Expected that new proposed revision will be published in November 2022

https://www.gmp-compliance.org/gmp-news/proposed-revision-of-usp-chapter-711-dissolution-canceled?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW24+-+MEU

Allfälliges

USP publishes draft guideline on analytical methods for mRNA Vaccines:

- Available for public comments
- Opportunity to submit alternative methods and additional documentation, including validation documents, to the methods presented in the draft
- More detailed information on the draft guidance and the comments on it can be found on the USP website.

USP intends to review chapters on Microbiological Control on non-sterile medicinal products:

- With the current publication, the USP aims to inform stakeholders of the overall scope and nature of the expected changes and encourages them to comment before the Expert Committee begins its work in depth.
- For further information, please visit the USP website and log in for access at Refining Microbiological Control and Testing for Nonsterile Products.

Major Revision of USP Chapter <1724> Semisolid Drug Products Performance Tests:

- Published for comments
- Deadline: 31 July 2022
- The draft of the revised chapter is available on PF Online. (Please note: a one-time registration is required to access the Pharmacopeial Forum.

https://www.gmp-compliance.org/gmp-news/major-revision-of-usp-chapter-1724-semisoldrug-products-performance-tests-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW22+-+MEU

Allfälliges

USP Revision of <761> NMR Spectroscopy and <1761> Applications of NMR Spectroscopy:

- Revision proposed in Pharmacopoeial Forum, PF 48(4)
- Comments can be submitted until 30 SEP 2022
- Further information and a more detailed summary of the proposed revisions can be found in the two drafts published on PF Online.

Revision of USP <1094> Capsules – Dissolution Testing:

- Published for comments
- Deadline for comments is 30 SEP 2022
- Further information and a more detailed summary of the proposed revisions can be found in the document published on PF Online.

USP Article: In Vitro Test Methods for Continuous Manufacturing:

- Stimuli article published in Pharmacopoeial Forum 48(4)
- How release testing methods could be implemented in future
- The article "In Vitro Performance Tests for Continuous Manufacturing: The Impact on the Current Compendial Framework from the Viewpoint of the USP New Advancements in Product Performance Testing Expert Panel" in PF 48(4) is available free of charge after registration.

Allfälliges

Revision of USP Chapter <541> Titrimetry

- Revision proposed in Pharmacopoeial Forum, PF 48(5)
- The draft of the revised chapter is available on PF Online. Comments can be submitted until November 30, 2022.

USP-NF Stimuli Article on "Analytical Method Precision Comparisons"

- Published in Pharmacopoeial Forum, PF 48(5)
- Addressing a statistical strategy proposed to compare method precision during transfer of a validated analytical procedure
- Deadline for submitting comments is 30 NOV 2022
- The text written by Keith M. Bower is available on PF Online.

USP: Third Instrument Qualification Stimuli published for comments:

- "Analytical Instrument and System (AIS) Qualification: The Qualification Life Cycle Process"
- Posted on UPS Pharmacopoeial Fourm website for comments
- Deadline for comments: 30 NOV 2022
- Get and comment the Stimuli document after one-time registration on the Pharmacopeial Forum website.

Allfälliges

USP General Chapter <621> Chromatography: Delay of Implementation of two new requirements:

- Scheduled to be official on 01 DEC 2022
- Sections “Peak Sensitivity” and “Peak Symmetry” will be delayed
- Announced on 26 August 2022: delay based on comments received

https://www.uspnf.com/notices-gc-621-nitr-20220826

Upcoming USP-NF 2023 Issue 1:

- will be published 01-Nov-2022 (effective 01-May-2023)

USP Pharmacopeial Forum PF48(6):

- will also be available on 01-Nov-2022

Allfälliges

Egypt Drug Authorities Consultation: Lot Release for Biological Products:

- Draft Version: endorsed 19 MAY 2022
- Principles and Criteria of the risk-based classification level, including reliance possibility
- Documentation and testing policy required by risk level
- Timelines for each activity of the lot release process
- Situations when lot release may be expedited and the decision-making process for out-of-specification results
- No target date for final publication yet known
- OCABR by EU-authorities might be accepted (plasma, vaccines)
- But: not yet clear if other biologicals (which are not under OCABR in EU) could be in scope

Brazil Resolution RDC 672 “Criteria for Granting Certification of GMP and set the Inspection Programs for Foreign Manufacturers of APIs”

- New, published on 31 MAR 2022

https://alimentusconsultoria.com.br/resolucao-rdc-no-672-de-30-de-marco-de-2022-anvisa/

South Africa: new communication to stakeholders related to Nitrosamines:

- Published 29 JUN 2022

Allfälliges

ICMRA (International Coalition of Medicines Regulatory Authorities):

- **Regulatory Collaboration Pilot for facility inspections**
- Industry planning to file an application to more than one Regulatory Agency
- Sponsors planning to submit a proposal and ensuring the facility is inspection ready
- First pilot to start in September 2022

https://www.icmra.info/drupal/strategicinitatives/pqkms/pq_pilots_call_for_industry_applications

EMA re-elected as chair of ICMRA

- Emer Cooke, Executive Director of EMA elected as chair from October 2022
- vice chair will be Dr Yasuhiro Fujiwara, Chief Executive of Japan PMDA

https://www.ema.europa.eu/en/news/ema-re-elected-chair-icmra-october-2022

NMPA (China) “GMP for Pharmaceutical Packaging Materials”:

- Draft issued for public comments

https://www.nmpa.gov.cn/xxgk/zhqyj/zhqyjyp/20220602170512112.html

China GMP: New Annex 13 for IMPs

- Published by NMPA in May 2022
- GMP for Investigational Medicinal Products
- Incorporated into Chinese GMP guidelines on 01 July 2022
- So far, the guideline is only available in Chinese language and can be checked on the NMPA website.

Allfälliges

QP-Verantwortlichkeiten gemäß AMBO 2009:

- Umfrage der EQPA: relative Unsicherheit bezüglich nationaler zusätzlicher gesetzlicher Anforderungen
- Aber: auch noch zusätzliche Erwartungen durch Inspektoren (die nicht genauso in der AMBO gefordert sind)
- Artikel der EQPA zu den Umfrage-Ergebnissen aktuell in Ausarbeitung
- Tabellarische Übersicht durch AQPA bereits verteilt nach Veröffentlichung der AMBO 2009
- Aktualisierte Übersicht:
  - Beinhaltet auch Kontrolllaborleiter und Herstellungsleiter, sowie QS
  - Persönliche Genehmigung/Unterschrift durch die **QP in rot**
  - Kopie für Teilnehmer
  - Download auf der AQPA-website (spätestens nächste Woche)

AMBO 2009	Forderung/Aufgaben/Verantwortlichkeiten	QP	KLL	HL	QS	Anmerkungen
§ 2. (6)	"Fertigprodukt" ist ein AM dass von einer QP freigegeben wurde.	X				
§ 2. (7)	"Freigabe" die von den QP erteilte Genehmigung zum Inverkehrbringen	X				
$ 2. (21)	"Sachkundige Person": eine Person gemäß " 2 Abs. 13b des AMG	X				
§ 5. (3)	QS System von entsprechend qualifizierter Person zu leiten, muss unabhängig von Herstellung sein				X	
§ 5. (5)	Betriebsbeschreibung muss Verantwortlichkeiten enthalten.	X	X	X	X	Site Master File
§ 5. (7)	Valdierungsmasterplan ist von der QP zu genehmigen	X				
§ 5. (9)	Change Control ist Teil des QS-Systems				X	
§ 5. (11)	Jede Abweichung von einer in QS verantwortlichen Person zu unterfertigen				X	
§ 6. (4)	Arbeitsplatzbeschreibungen, einschließlich der QP	X	X	X	X	Job Description
§ 7. (1)	Jeder Betrieb muss ständig und ununterbrochen über mindestens eine QP verfügen	X				
§ 7. (9)	jede Charge gemäß GMP und Zulassung hergestellt und kontrolliert, jede Charge von Prüfpräparaten gemäß GMP und CTA hergestellt und kontrolliert, jede Charge aus Drittländern nach gleichwertigen GMP Standards hergestellt und kontrolliert	X				
§ 7. (10)	die QP hat die Einhaltung aller Vorschriften gemäß (8) in einem Register zu bescheinigen	X				
§ 7. (11)	die QP muss mit den Verfahren zu Herstellung und Kontrolle jeder Charge vertraut sein	X				
§ 7. (12a)	sicherstellen, dass die Sicherheitsmerkmale ggf. auf der Außenverpackung angebracht worden sind	X				
§ 7. (13)	jede Charge vor dem In-Verkehr-Bringen oder vor dem Export freigeben	X				
§ 7. (14)	Delegation der ihr obliegenden Aufgaben nur an eine andere QP	X				
§ 8. (1)	Für jeden Betrieb ist ein HL zu bestellen			X		
§ 8. (8)	Herstellung gemäß den entsprechenden Anweisungen, Genehmigung der Anweisungen für Herstellungsvorgänge und Sicherstellung, dass diese genau eingehalten werden, Überprüfung und Unterschrift der Herstellungsprotokolle vor Weitergabe an QC, Kontrolle der Wartung der Räumlichkeiten und Ausrüstung, Sicherstellung, dass die notwendige Validierungen durchgeführt werden, Sicherstellung der anfänglichen und fortlaufenden Schulung des Personals in der Herstellung und Anpassung der Schulung entsprechend den jeweiligen Erfordernissen.			X		
§ 9. (1)	Für jeden Betrieb ist ein KLL zu bestellen		X			
§ 9. (8)	Billigung oder Zurückweisung von Ausgangsmaterial, Zwischenprodukten, Bulkware, Verpackungsmaterial und Endprodukten, Auswertung der Protokolle über Herstellung und Prüfung, Sicherstellung dass alle erforderlichen Prüfungen durchgeführt werden, Genehmigung von Spezifikationen, Probennahmeanweisungen, Prüfmethoden, Zustimmung zur Beauftragung von Analysenlabors im Auftrag sowie deren Überwachung, Kontrolle der Wartung der Räumlichkeiten und Ausrüstung der QC, Sicherstellung, dass alle notwendigen Validierungen durchgeführt werden, Sicherstellung der anfänglichen und fortlaufenden Schulung des Personals der QC und Anpassung der Schulung entsprechend den jeweiligen Erfordernissen		X			
§ 16. (1)	Genehmigung der Herstellungsvorschrift durch HL und QP durch Unterschrift	X		X		
§ 17. (2) 10.	Bestätigung am Herstellungsbericht, dass alle Schritte entsprechend der HVO durchgeführt wurden			X		
§ 18. (1)	Genehmigung der Prüfvorschrift durch KLL und QP durch Unterschrift	X	X			
§ 18. (3)	Unterschrift des Prüfprotokolls		X			
§ 19. 7.	Unterschrift des APR	X				
§ 23. (11)	Abweichungen bei Zeit- oder Wertbegrenzungen jedes Herstellungsschrittes sind von einer im Rahmen des QS-Systems verantwortlichen Person zu begründen und zu dokumentieren				X	

AMBO 2009	Forderung/Aufgaben/Verantwortlichkeiten	QP	KLL	HL	QS	Anmerkungen
§ 24. (4)	Aufgaben des Kontrolllabors: Festlegung, Validierung und Ausführung aller QC-Verfahren, Aufbewahrung von Rückstellmustern und Referenzproben, Sicherstellung der ordnungsgemäßen Kennzeichnung der Behältnisse, die Materialien und Produkte enthalten, Überwachung der Stabilität, Mitwirkung bei Reklamationsuntersuchungen, Überprüfung der Umgebungsbedingungen, Mitwirkung bei Aufklärung von Abweichungen, Untersuchung von Abweichungen und Erstellung von Abweichungsberichten		X			
§ 24. (5)	Mitwirkung bei Kontrolle der Einhaltung der Lagerungsvorschriften, Reinigung der Ausrüstung, Reinigung und Desinfektion der Arbeitsräume, allgemeine hygienische Bedingungen, Validierung von Betriebsanlagen, Maschinen, Instrumenten, Prüfeinrichtungen und Verfahren, Erstellung des APR		X			
§ 24. (6)	Billigung von Ausgangsmaterial, Zwischenprodukten, Bulkware, Endprodukten oder Verpackungsmaterial		X			
§ 25. (4)	Unterschrift bei Abweichungen im Rahmen der Prüfung durch KLL oder QS		X		X	
§ 29. (2)	Beschreibung der Verantwortlichkeiten der QP bei Arbeiten im Auftrag	X				
§ 33. (4)	Überprüfung und Genehmigung von Umarbeitungen durch die QP	X				
§ 33. (6)	Prüfung von Arzneimitteln vor Wiederverwertung, bei Vorliegen eines Verdachtes auf unsachgemäße Lagerung oder Transport, Untermischung oder Austausch, oder deren Qualität sonst negativ beeinflusst worden sein könnte				X	

Allfälliges

QP Code of Conduct:

- Art. 52 in Dir 2001/83/EC
  - *"Member States shall ensure that the duties of qualified persons referred to in Article 48 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a **professional code of conduct**.*
  - *Member States may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary procedures against him for failure to fulfil his obligations."*
- EQPA: keine einzige Behörde eines EU-Mitgliedslandes hat bislang einen derartigen "Code of Conduct" veröffentlicht
- EQPA: ***"Ethics for the QP – A Professional Code of Conduct"***
- Veröffentlichung geplant Ende 2022
- Bis EU-Länder einen "Code of Conduct" etablieren werden
- Zweck:
  - Provide guidance to EQPA-member QPs
  - Define what constitutes professional conduct with QP-role
  - May serve as reference and standard
  - Ethical training of QPs
  - Underpin decision making by QPs

- Präsentationen werden wieder im Internet abrufbar sein:
  www.austria-qp.at
- 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
- Nächstes **Vereinstreffen** der AQPA: **24. Mai 2023**
- **Austrian QP Forum 2023**: **24.-25. Mai 2023**
- **Qualified Person Forum 2022 der EQPA:**
  30 November - 02 December 2022 in Berlin

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

Bleiben Sie gesund!

Der AQPA-Vorstand!

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