Generalversammlung und Vereinstreffen der AQPA

04. November 2021

Der AQPA-Vorstand:

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

Agenda

- Begrüßung
- Rechnungsprüfung: bereits am 23.9.2021 abgeschlossen
- Wahl des Vorstandes:
  - Abstimmung zur Erweiterung des Vorstandes
  - Wahlvorschlag:
    - Obmann – Georg Göstl
    - Obmann Stellvertreterin – Gabriela Schallmeiner
    - Kassier – Markus Thiel
    - Schriftführerin – Regine Tomasits
  - Alternative Vorschläge?
- Präsentationen:
  - mRNA-basierte Covid-19-Impfstoffe: Besondere Herausforderungen bei Herstellung und Freigabe *(Richard Vasicek)*:
  - Allfälliges – Neuigkeiten von den Behörden *(Georg Göstl)*
- Teilnehmerliste / Schulungsdokumentation *(Regine Tomasits)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum

Generalversammlung 04. Nov 2021

- Eingereichte Vorschläge zur Änderung des Vorstands:
  - _____

- Abstimmung zur einer Erweiterung des Vorstands:
  1. Ich bin damit einverstanden, dass der Vorstand der AQPA erweitert wird.
  2. Ich bin NICHT damit einverstanden, dass der Vorstand der AQPA erweitert wird.

- Wahl des Vorstandes:
  1. Ich bestätige den Vorstand
  2. Ich bestätige den Vorstand NICHT

Allfälliges

EMA Q&A "Regulatory Expectations … during COVID-19 Pandemic":

- Revision 4 – July 2021 (published 30 SEP 2021)
- most important aspect: **extension of GMP-certificates until 31 December 2022** without the need for further action from the holder of the certificate.
- 3 new Q&As added under "Pharmacovigilance Activities"
- https://ec.europa.eu/health/sites/default/files/human-use/docs/guidance_regulatory_covid19_en.pdf

EMA: New Updates of Templates for Reporting Nitrosamine Contamination

- The ***Nitrosamine detected response template*** has now been revised again
- In addition, question 10 was amended in the Q&A document by the EMA and CMDh (EMA/409815/2020 Rev.5, published 21 September 2021)
- https://www.hma.eu/620.html

EMA Reflection Paper on interpretation of Article 18(7) or Regulation (EU) 2019/6 (VMP-Regulation)

- Marketing authorizations for generic veterinary medicinal products
- Draft published for comments (17 SEP 2021)
- End of consultation: 17 DEC 2021
- https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-interpretation-article-187-regulation-eu-2019/6_en.pdf

Allfälliges

EMA implements new measures to minimize animal testing during medicines development:

- EMA's Innovation Task Force (ITF)
- Development and implementation of NAMs (New Approach Methodologies)
- Dedicated forum for early dialogue between regulators and developers
- Discuss innovative aspects such as emerging therapies, methods and technologies
- ITF's service is free of charge and any NAMs adhering to 3Rs (replace, reduce, refine) principles that can be used to fulfil testing requirements are eligible for consideration
- https://www.ema.europa.eu/en/news/ema-implements-new-measures-minimise-animal-testing-during-medicines-development

Brexit:

- On 13 October, the European Commission proposed further arrangements to respond to possible difficulties in the movement of goods between Northern Ireland and Great Britain
- willingness to hold intensive talks with the British government in order to find a mutually agreed permanent solution as soon as possible
- This is laid down in a new so-called non-paper, which replaces the document from July. Whether this will be accepted by the British government remains to be seen.
- https://ec.europa.eu/info/strategy/relations-non-eu-countries/relations-united-kingdom/eu-uk-withdrawal-agreement/protocol-ireland-and-northern-ireland_en#october-2021-package%20

Allfälliges

EMA to coordinate GMP Inspections via Online Portal

- 01 October 2021
- **MAH and applicants** need to use EMA's secure online platform IRIS for communicating on all GMP inspections
- IRIS: Guidance and Support:
  - https://iris.ema.europa.eu/homenews/
- IRIS guide for applicants:
  - EMA/444925/2018 (published 17 SEP 2021)
  - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf
- Guidance for applicants/MAHs involved in GMP inspections coordinated by EMA:
  - Published 02 SEP 2021
  - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-applicants/marketing-authorisation-holders-involved-gmp-inspections-coordinated-ema_en.pdf

Change for Entries in EudraGMDP Database:

- New regulatory framework for veterinary medicinal products requires changes to EudraGMDP database
- Integration of EudraGMDP into EMA'S OMS (Organisation Management System)
- Ab **28. Jänner 2022** wird für sämtliche **neu erstellte oder aktualisierte GMDP-Zertifikate** im Zusammenhang mit der **EudraGMDP-Datenbank** die **Nutzung der OMS-Daten verpflichtend**. Dies betrifft Hersteller, Importeure und Großhändler sowohl von Veterinär- als auch Humanarzneimitteln. Dem Vernehmen nach kann das BASG somit ab diesem Zeitpunkt neue oder geänderte GMDP-Zertifikate nur noch dann in die EudraGMDP-Datenbank hochladen, wenn das jeweilige Unternehmen in OMS registriert ist.
- Zulassungsinhaber müssen somit fristgerecht sicherstellen, dass Ihre Organisation für das EMA-OMS registriert ist
- https://www.gmp-compliance.org/gmp-news/important-change-for-entries-in-eudragmdp-database?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW40+-+MEU

Allfälliges

European Commission launched public consultation step on the revision of the EU Pharmaceutical legislation:

- Questionnaire format
- Feedback Period: 28 SEP – 21 DEC 2021
- Target audience: includes general public and patients as well
- Focusing on 6 key priorities:
  - Unmet medical needs and market failures for medicines other than medicines for rare diseases and children;
  - Unequal access to available and affordable medicines for patients across the EU;
  - The current legislative framework may not be fully equipped to respond quickly to innovation;
  - Inefficiency and administrative burden of regulatory procedures;
  - Vulnerability of supply of medicines, shortages of medicines;
  - Environmental challenges and sustainability;
- https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation/public-consultation_en

Allfälliges

Delegated Regulation (EU) 2021/1686 (of 7 July 2021) to amend Regulation 2016/161

- Article 47 amended: “citizens of the EU” replaced by “people in the Union” (all adverse events regardless of citizenship)
- Annex 1 amended (list of prescription only that may not bear a safety feature): product category “cicatrizants with ATC code D03AX” with pharmaceutical form “fly larvae” included
- https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1686&from=EN

EMA published a reflection paper for medical device classifications:

- MDCG 2021-24 (October 2021)
- https://ec.europa.eu/health/sites/default/files/md_sector/docs/mdcg_2021-24_en.pdf

ICH guideline M7 (control of mutagenic impurities) – addendum

- Draft version endorsed 06 October 2021
- Deadline for comments: 08 DEC 2021
  - https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-m7-assessment-control-dna-reactive-mutagenic-impurities-pharmaceuticals-limit_en.pdf

Allfälliges

Ph.Eur. New general Chapter 2.1.7 “Balances for Analytical Purposes”:

- Supplement 10.6, published in July 2021
- “filling a long-standing gap … for a piece of equipment that is the cornerstone of every analytical procedure…”
- https://www.edqm.eu/en/news/publication-new-general-chapter-balances-european-pharmacopoeia-supplement-106

EDQM updates Guidance for Electronic Submission of CEP Applications:

- PA/PH/CEP (09) 108, 6R (July 2021)
- Implementation date: 01 October 2021
- https://www.edqm.eu/sites/default/files/medias/fichiers/Certification_of_Suitability/About_the_procedure/paphcep091086r.pdf

OECD: GLP: New Data Integrity Guideline:

- ENV/CBC/MONO(2021)26, published 20 September 2021
- Industry comments collected and partially incorporated in 2020
- Strongly based on MHRA guideline (2018)
- The "OECD 22" is a comprehensive, well-written, fluidly readable guide to data integrity in the GLP field.
- https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/cbc/mono(2021)26&doclanguage=en

Allfälliges

PIC/S Aide-Memoire "guidance to GMP inspectors on the inspection of QRM systems in the pursuit of harmonization"

- PI-038-2
- https://picscheme.org/docview/3823

China/NMPA (National Medicinal Products Administration) applied for PIC/S pre-accession

- 24 September 2021
- Nächster Schritt: "2 years to identify gaps between PIC/S and system used by China CA"
- https://picscheme.org/en/news

Strategic Plan of "Access Consortium" published:

- "Access Consortium": Australia (TGA), Canada (HBFB), Switzerland (Swissmedic), Singapore (HAS) UK (MHRA)
- Strategic Plan for 2021-2024
- "Reduced effort and duplication for both regulators and industry"
- "Increased collaboration on global GxP inspections"
- https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/995111/Access_Strategic_Plan_2021-2024_Final__with_graphic_.pdf

Allfälliges

New FDA draft guidance – Microbiological Quality Control on Non-Sterile Medicinal Products:

- 30 SEP 2021
- Open for comments until 20 NOV 2021
- Reflects lessons learned from Adverse Events and Recalls due to contamination (2014 – 2017: 197 AE related to bacterial or fungal contamination, FDA assumes that the number of unreported cases is significantly higher)

https://www.fda.gov/media/152527/download

FDA: GfI "Q&A on Quality Related Controlled Correspondence"

- Published September 2021
- New Q&As on **Endotoxin Testing**
- Also addressing answers related to **Bracketing and Matrixing** during generic drug development
- https://www.gmp-compliance.org/gmp-news/new-fda-q-as-on-endotoxin-testing?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW39+-+MEU

FDA'S final Q&As on Field Alert Reports:

- Published in July 2021 (supersedes draft guidance issued in 2018)
- https://www.fda.gov/media/114549/download

FDA: new draft GfI on Bioequivalency Studies

- Published in August for comment purposes only (60 days)
- https://www.fda.gov/media/87219/download

Allfälliges

FDA-CBER has launched a redesign of SBIA (Small Business and Industry Assistance) webpage:

- Condensed approach for easily accessible and relevant information on human drug development and regulations, which includes:
  - Calendar of upcoming SBIA webinars and conferences
  - Regulatory References
  - Online Training (including conference/webinar presentations and recordings
  - Learning library on YouTube
- https://www.fda.gov/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia?utm_medium=email&utm_source=govdelivery

FDA to do list for PDUFA VII (below only a couple of interesting topics):

- Advancing development of Drug-Device and Biologic-Device Combination Products Regulated by CBER and CDER.
  - New draft or revised guidance to provide comprehensive, systematic and stepwise approach
  - Deadline: 30 September 2024
- Alternative tolls to assess manufacturing facilities named in pending applications
  - Draft guidance will be issued
  - Deadline: 30 September 2023
- https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vii-fiscal-years-2023-2027

Allfälliges

USP: new chapter on Supplier Qualification and associated Risk Assessments

- <1083>
- “discuss the importance of supplier qualification and the application of a quality risk-based approach to select, assess, approve, and monitor suppliers of materials and services”
- The draft can be viewed in the Pharmacopeial Forum. (Please note: a one-time registration is required to access the Pharmacopeial Forum.)

USP Chapter on Impurities in Food Supplements:

- <2760>
- Proper control of unwanted impurities (e.g. heavy metals (UPS <2232> currently includes elemental contaminants in dietary supplements))
- expected to be published in Pharmacopeial Forum (PF) 48(5) [Sept.-Oct. 2022]
- https://www.uspnf.com/notices/gc-2760-prospectus-20210924

USP New Chapter “Analytical Procedure Life Cycle”:

- <1220>
- Final version announced for 01 November 2021 (Official: May 1, 2022)
- The chapter will be included in USP-NF 2022, Issue 1
- Relevant elements of this life cycle concept are already known from the Guidance for Industry Analytical Procedures and Methods Validation for Drugs and Biologics of the FDA.
- https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-notices/gc-1220-pre-post-20210924.pdf

Allfälliges

4 JP drafts related to Chromatography published for comments:

- Chromatography
- Liquid Chromatography
- Gas Chromatography
- Change Control in Lifecycle of Chromatography
- Available on PMDA's website
- Comments can be submitted until 30 NOV 2021
- https://www.gmp-compliance.org/gmp-news/four-jp-drafts-related-to-chromatography-published-for-public-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW39+-+MEU

New JP draft 2.28 "Circular Dichroism Spectroscopy" published for comments:

- Available on PMDA's website
- Comments submitted until 30 SEP 2021
- https://www.gmp-compliance.org/gmp-news/new-jp-draft-2-28-circular-dichroism-spectroscopy-published-for-public-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW39+-+MEU

- 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: **4. Mai 2022**
- **Austrian QP Forum 2022**: **04.-05. Mai 2022**
- **Qualified Person Forum 2021 der EQPA 100 % online:**
  01.-03. Dezember 2021

Wir wünschen einen schönen Abend und hoffen auf zahlreiches reales Wiedersehen am 04. Mai 2022

Bleiben Sie gesund!

Der AQPA-Vorstand!

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