Vereinstreffen der AQPA

5. Mai 2021

Der AQPA-Vorstand:

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

Agenda

- Begrüßung
- Besondere Regeln aufgrund COVID-19-Situation: 100 % online
- Präsentationen:
  - Nutzen und Risiken von COVID-Tests *(Markus Thiel)*
  - Erfahrungen mit und Tipps für virtuelle Audits und Inspektionen *(Georg Göstl)*
  - Allfälliges – Neuigkeiten von den Behörden *(Georg Göstl)*
- Teilnehmerliste / Schulungsdokumentation
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Gemütliches Beisammensein

  -> leider nicht für remote Teilnehmer in Zeiten von COVID-19

Allfälliges

Aussendung der AMVS zu FMS/Serialisierung:

- Rückmeldungen zu allen **Level 5-Alarmen**: Auch in der Startphase sollte die zeitnahe Meldung an die AMVS innerhalb der vom BASG für den Echtbetrieb geforderten **3 Werktagen** erfolgen
- Rückmeldung zu den Alarmen sollte zumindest enthalten:
  - **Alert ID**
  - **Time Stamp**
  - **Fehlercode**
  - **Produktcode**
  - **Produkt Name**
  - **Chargennummer abgefragt**
  - **Verfalldatum abgefragt**
  - **Seriennummer abgefragt**
  - **Root Cause Analyse**
- Neue Revision AMVO Coding Rules 4.0:
  https://www.amvs-medicines.at/en/infothek/press-news/version-40-of-amvo-coding-rules-released/
- Verifizierung darf nur von jenem User vorgenommen werden, welcher tatsächlich zum Zeitpunkt der Verifizierung im physischen Besitz der Arzneimittelpackung ist.
- Standort der Verifizierung muss eindeutig durch die User-Daten des Benutzers identifizierbar sein
- Weitergabe von Zugangsdaten und Passwörtern ist nicht gestattet
- Großhandelsaktivitäten dürfen nicht über einen OBP-User durchgeführt werden

Allfälliges

- Brexit:
  - EMA/520875/2020, Rev. 3
    - **14.3: both sides recognize the results of GMP inspections of the other party.** National documents from UK authority (e.g. GMP certificates, inspection reports) for locations in the UK will continue to be accepted in the EU (e.g. for regulatory submissions and/or import applications). **The same applies to inspections in third countries.**
    - **https://www.ema.europa.eu/en/documents/other/questions-answers-stakeholders-implementation-protocol-ireland/northern-ireland_en.pdf**
  - UK recognition of EU/EEA Batch Testing does not end on 1 Jan 2023:
    - "Letter to medicines and medical products suppliers" by British Government states **"…continued recognition of EU/EEA batch testing will not be ending on 1 January 2023"**
    - **https://www.gmp-compliance.org/gmp-news/uk-recognition-of-eu-eea-batch-testing-does-not-end-on-1-january-2023?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW14+-+MEU**

Allfälliges

- EU Delegated Regulation (EU) 2021/457: “Derogation from Obligation of Wholesalers to Decommission the Unique Identifier of Products to the UK” (amending 2016/161)
  - Applicable from 01 Jan 2021
  - Published 17 March 2021
  - *“By way of derogation from point (a), from 1 January 2021 to 31 December 2021 the obligation to decommission the unique identifier of medicinal products which the wholesaler intends to distribute outside of the Union **shall not apply** to products which he intends to distribute in the United Kingdom.”*
  - https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2021:091:FULL&from=EN
- Clinical Trial Regulation (EU) No 536/2014: new draft Q&A (version 3) published in February 2021

  https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/regulation5362014_qa_en.pdf
- EMA and HMA (Heads of Medicines Agencies) published joint strategy to 2025 (08 DEC 2020): Strategic goals, goals and objectives by focus area -> see link:

  https://www.ema.europa.eu/en/news/joint-strategy-sets-direction-ema-eu-medicines-regulatory-agencies-2025
- EC: COM(2020) 761 final (published 25 NOV 2020): “Communication from the commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions”: Pharmaceutical Strategy for Europe: Flag ship initiatives and other actions -> see link:
  https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2173

Allfälliges

- EMA Revision of Q&A Documents regarding **Centralized Procedure**:
  - New Q 7.2.14: "Do I need to record in the dossier a **new manufacturing site for physical importation**?": A: "… **no variations** applications are required for changes in physical importation sites. The MIA holder responsible for batch certification should ensure the site of physical importation is appropriately authorized for this operation."
  - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure-track_en-0.pdf
- EMA assessment report for Nitrosamines in Sartans defines limits and reporting deadlines:
  - https://www.ema.europa.eu/en/documents/variation-report/angiotensin-ii-receptor-antagonists-sartans-article-31-referral-chmp-assessment-report-impact/83/ec_en.pdf
- New EMA "guideline on quality, non-clinical and clinical aspects of medicinal products containing genetically modified cells" will become effective on 01 June 2021 https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-quality-non-clinical-clinical-aspects-medicinal-products-containing-genetically-modified_en-0.pdf
- EU Commission Notice to **notified bodies' audits** due to COVID-19 pandemic (2021/C 8/01) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2021:008:FULL&from=EN
- New EMA-guideline on GMP/GDP distant assessment & PMF distant assessment (EMA/335293/2020)

  https://www.ema.europa.eu/en/documents/scientific-guideline/guidance-related-gmp/gdp-pmf-distant-assessments_en.pdf

Allfälliges

- EMA Q&A zu “principles of GMP for manufacturing of starting materials of biological origin used to transfer genetic materials for manufacturing of ATMPs”:
  - EMA/246400/2021
  - 24 February 2021
  - GMP certificate not required for manufacturing and testing sites of starting materials for ATMPs
  - ATMP manufacturers have responsibility to verify that appropriate GMP requirements are implemented for manufacturing/testing of the starting materials
  - Neither recurring inspections nor GMP certifications are required (for starting materials)
  - “Risk Based Approach” zur Festlegung der relevanten GMP-Anforderungen
  - Keine QP erforderlich “in connection with the manufacturing of starting materials”
  - https://www.ema.europa.eu/en/documents/other/questions-answers-principles-gmp-manufacturing-starting-materials-biological-origin-used-transfer_en.pdf
- Swissmedic clarifies validity of GMP-certificates during COVID-19 pandemic (20 NOV 2020): certificates issued by Swissmedic and based on a routine GMP-inspection in 2017 or 2018 will remain fully valid until end of 2021 (or next routine inspection) -> see link: https://www.swissmedic.ch/swissmedic/en/home/news/coronavirus-covid-19/gueltigkeit_gmp_zertifikaten.html#:~:text=Swissmedic%20would%20like%20to%20make,corresponds%20to%20the%20currently%20valid

Allfälliges

- PIC/S:
  - Russia (MIT, Roszdravnadzor, FSI SID & GP, and FSBI SCEMD) and Jordan applied for membership
  - Brazil ANVISA joins PIC/S (as 54th authority)
  - Azerbaijan MoH applies for pre-accession (August 2020)
  - Saudi Arabia (SFDA) applies for PIC/S membership (February 2020)
- ICH Final Concept Paper: ICH Q9(R1) – Quality Risk Management (Endorsement by Management Committee on 13 NOV 2020): Harmonization Action proposed including specific official ICH training materials will be developed to facilitate implementation of proposed revisions. -> see link: https://database.ich.org/sites/default/files/Q9-R1_Concept%20Paper_2020_1113.pdf
- WHO publishes draft guideline for Medical Gases:
  - comments until end of March,
  - Completion scheduled for end of 2021
  - https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/working-documents-public-consultation
- WHO Draft Document on GMP for IMPs and WHO Draft Document on GxP for R&D facilities
  - Published November 2020
  - Comments until 6 January 2021

Allfälliges

- FDA Launches New Webpage for CDER Scientific Review Documents Supporting **Emergency Use Authorizations** for Drug and Biological Therapeutic Products for **COVID-19**:
  - https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological?utm_medium=email&utm_source=govdelivery
- USP proposal for new General Chapter "Supplier Qualifications"
  - Input deadline 25 April 2021
  - https://www.gmp-compliance.org/gmp-news/supplier-qualification-for-packaging-material?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW14+-+MEU
- FDA GfI "Manufacturing, Supply Chain, and Drug and Biological Product Inspection During COVID-19 Public Health Emergency – Questions and Answers"
  - https://www.fda.gov/media/141312/download
- FDA GfI "Remote Interactive Evaluations (RIE) … during COVID-19 …":
  - RIE ist keine Inspektion (die muss vor Ort erfolgen)
  - Dokumentation, aber kein Form 483 oder EIR
  - Antwort ebenfalls binnen 15 Tagen erwartet
  - https://www.fda.gov/news-events/press-announcements/fda-provides-guidance-remote-interactive-evaluations-oversight-drug-facilities-during-covid-19
- New FDA Guidance for COVID-19 packaging changes: glass vials and stoppers (due to supply chain issues)
  - https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-container-closure-system-and-component-changes-glass-vials-and-stoppers-guidance-industry?utm_medium=email&utm_source=govdelivery

Allfälliges

- FDA: BPDR (Biological Product Deviation Report) also required / applicable to human tissue and cellular tissues and tissue based products
  - https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations?utm_campaign=Untitled%20Email&utm_medium=email&utm_source=Eloqua
- FDA Guideline "Manufacturing Considerations for Licensed and Investigational Cellular and Gene Therapy Products During COVID-19 Public Health Emergency"
  - https://www.fda.gov/media/145301/download
- GAO (US Government Accountability Office) asks FDA to review their current inspections approach
  - https://www.gmp-compliance.org/gmp-news/gao-criticizes-fdas-current-inspections-approach?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW07+-+MEU
- ISO 22519 (ED.2) „Membrane Based Generation of WFI"
  - Neuer Entwurf
  - Permission request from copyright@iso.org
  - 2nd Edition cancels and replaces the 1st edition (ISO 22519:2019)
  - Any feedback or questions should be directed to the user's national standards body. Complete listing of these can be found at www.iso.org/members.html
  - In Österreich: Austrian Standards
  - https://www.austrian-standards.at/en

- Präsentationen werden wieder im Internet abrufbar sein:
  www.austria-qp.at
- Schulungsdokumentation (remote Teilnehmer): *Regine Tomasits*
- Vorschläge zur Verbesserung/Aufwertung der AQPA-Homepage?
- Themen für zukünftige Treffen / Forum?
- Nächstes **Vereinstreffen** der AQPA:
  23. September 2021, Beginn: 18:00
  Hotel des AQPA Forums 2021 oder Live-online
- **Generalversammlung** (gemäß Vereinsgesetz): **4. November 2021**
  Voraussichtlich als Live-online-Veranstaltung
- **Austrian QP Forum 2021**: **23.-24. September 2021**
  Radisson Blu Park Royal Palace Hotel; Schlossallee 8; 1140 Wien
  oder Live-online
- **Qualified Person Forum 2021 der EQPA** in Berlin/online:
  01.-03. Dezember 2021

Wir wünschen einen schönen Abend und hoffen auch ein Wiedersehen am 23. September 2021!

Bleiben Sie gesund!

Der AQPA-Vorstand!

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