Generalversammlung und Vereinstreffen der AQPA

22. November 2017

Agenda

- Begrüßung
- Rechnungsprüfung
- Wahl des Vorstandes:
  - Wahlvorschlag:
    - Obmann – Georg Göstl
    - Obmann Stellvertreterin – Gabriela Schallmeiner
    - Kassier – Markus Thiel
    - Schriftführerin – Regine Tomasits
  - Alternative Vorschläge?
- Präsentationen:
  - Safety Features – Einführung bis zum 9.2.2019 *(Jürgen Idinger/Shire)*
  - Anforderungen an die Fachtechnisch Verantwortliche Person in der Schweiz *(Ina Bach)*
- Allfälliges – Neuigkeiten von den Behörden *(Georg Göstl)*
- Teilnehmerliste bitte unterschreiben
- Termine (Vereinstreffen, AQPA-Forum 2018)
- Gemütliches Beisammensein

Allfälliges

- Neue EU-CT Regulation nicht vor 2019
  - Technical difficulties with the development of the IT systems

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp

- Neuer Annex 1: erwartet für 2018 (Schwerpunkt-Thema beim AQPA-Forum 2018)
- Annex 21 (Import): Konsultation nicht vor 2018
- EMA Guideline on Manufacture of the finished dosage form (EMA/CHMP/QWP/245074/2015): coming into effect: 04 January 2018

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/08/WC500233239.pdf

- Auswirkungen des Brexit:
  - MAH must be in the EU/EEA
  - Sponsor of an orphan medicinal product in the EU/EEA
  - QPPV and PSMF in the EU/EEA
  - Import from UK (API or medicinal product) = 3rd country!
  - All batches analysed in the EU/EEA
  - Batch release and QP in the EU/EEA

    -> Rechtzeitig Variations einreichen!!!

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500228739.pdf

Allfälliges

- EMA Brexit Plan:
  - Category 1 (highest priority)
  - Category 2 (continued as long as possible)
  - Category 3 (already suspended activities)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/07/news_detail_002789.jsp&mid=WC0b01ac058004d5c1

- HM Government „Position Paper“ zum Brexit (21.8.2017):
  - Defines proposed future state which will be negotiated between London and Brussels:
    - Continued mutual recognition of licenses and certification of goods
    - Continued mutual recognition of inspections and QPs
    - Prevent duplication of activities

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/638958/Continuity_in_the_availability_of_goods_for_the_EU_and_the_UK_Position_Paper.pdf

- EMA-Implementation Plan Safety Features
  - Safety features können auch bereits vor dem 9. Februar 2019 implementiert werden
  - CHMP opinion or EMA notification … shall occur **no later than 09.02.2019**

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/02/WC500201413.pdf

Allfälliges

- New EU-GMP-Guideline for IMPS:
  - EU- Clinical Trial Regulation 536/2014 (ersetzt Directive 2001/20)
  - GMP for IMPs Delegated Act 2017/1569 (ersetzt Annex 13)
  - GMP-Directive NEU 2017/1572 (ersetzt Directive 2003/94)

https://www.gmp-compliance.org/gmp-news/new-eu-gmp-guideline-for-imps

- MRA EU-USA: operational 1. Nov. 2017!!!
  - 11.8.2017: EU-assessment of US-FDA abgeschlossen
  - 23.08.2017: Confidentiality Commitment signed (FDA, EC, EMA)
  - FDA-assessment of first 8 EU member countries: Austria, Croatia, France, Italy, Malta, Spain, Sweden, UK
- Erweiterung des MRA EU-Japan:
  - Discussions ongoing to broaden the scope (include sterile and biological products and APIs)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001843.jsp&mid=WC0b01ac058005f8ac

- PIC/S News:
  - Iran, Turkey, Mexico accede to PIC/S (50th, 51st and 52nd participating authorities from 1 January 2018)
  - Russia and Saudi Arabia applied for pre-accession

https://picscheme.org/en/news

Allfälliges

- EMA Reflection Paper „selection and justification of starting materials“
  - Applicant has to define, from here on subject to GMP (ICH Q7A)

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/10/WC500175228.pdf

- New version of EudraVigilance launched on 22 November 2017
- ICH Q11 „Development and Manufacture of Drug Substances“
  - Questions & Answers

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q11/Q11IWG_Step4_QA_2017_0823.pdf

- ICH Q12 „Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management”
  - 2500 comments
  - Legal review by EC
  - Public comments (ab ???)
  - 2018/2019 global expectation for submissions and potentially separate life cycle document

Allfälliges

- EMA Draft guideline „Notification of servious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol“
  - Details on the notification process
  - Possible actions by member states in response to such notifications

http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/05/WC500228199.pdf

- EMA Q&A: WFI by non-distillation methods – Reverse Osmosis
  (EMA/INS/GMP/443117/2017)
- EMA and EC: guideline on excipients in labelling: updated annex
  - Implement wording in compliance with revised annex (first opportunity or within 3 years)

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/10/news_detail_002825.jsp&mid=WC0b01ac058004d5c1

- MHRA FAQ: Annex 16 QP Certification and Batch Release – part 2

https://mhrainspectorate.blog.gov.uk/2017/08/14/annex-16-qp-certification-and-batch-release-frequently-asked-questions-part-2/

  - Part 2 is focussing on application of Annex 16 to IMPs
- MHRA-inspectorate blog: z.B. „Use of Freezers“
  - Design considerations
  - Conditioning of cold packs

https://mhrainspectorate.blog.gov.uk/2017/06/20/use-of-freezers/

Allfälliges

- FDA Warning Letters

https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/

- WHO Prequalification of Medicines website:

https://extranet.who.int/prequal/

- Relocation of EMA -> Decision Nov 20, 2017: Amsterdam
  - Take up operations on 30 March 2019 at the latest
- ECA Good Practice Guide No. 2

  „Duties and Responsibilities for Qualified Persons in the EU“

  Version 4.0

  Verfügbar auf der Website der European QP Association:

  http://www.qp-association.eu/qpag_index.html
- Änderungen im Board of Directors der EQPA
  - Georg Göstl neues Mitglied im Board of Directors der EQPA

Allfälliges

- Präsentationen werden wieder im Internet abrufbar sein: www.austria-qp.at
- **NEU:** In Zukunft auch Kurzprotokolle
- Teilnehmerliste bitte unterschreiben
- Vorschläge zur Verbesserung/Aufwertung der AQPA-Homepage?
- Themenliste für zukünftige Treffen / Forum?
- **AQPA feiert 10. Geburtstag in 2018!!!**
- Nächstes Vereinstreffen: **16. 05. 2018**

  Beginn: 18:00, Begrüßungskaffee ab 17:30
- Austrian QP Forum 2018: **16./17. Mai 2018**

  Austria Trend Parkhotel Schönbrunn, Hietzinger Hauptstr. 10-14, 1130 Wien

Noch einen schönen Abend und viele angeregte und hilfreiche Diskussionen wünscht

Der AQPA-Vorstand!

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