Vereinstreffen der AQPA

13. Juni 2024

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 und Eröffnung des online-Meetings über MS-Teams
- 18:00 Begrüßung
- Präsentationen:
  - Review Prozess für elektronische Batch Records *(Carina Rappel/Stefan Schneider/Boehringer Ingelheim)*
  - SwissMedic – Technische Interpretation zum Versand unter Quarantäne *(Markus Thiel/Roche)*
  - Allfälliges: Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
- Teilnehmerliste *(Regine Tomasits/ViruSure)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

Allfälliges

EMA relaunching their corporate website:

- ✓ **05 DEC 2023**
- ✓ **What's staying the same:**
  - First of all, you will still be able to find us at https://www.ema.europa.eu/en.
  - Also, most pages, documents and visuals will work as before.
  - If any links to current pages change, we will ensure that redirects are put in place to guide you towards the information you need.
- ✓ **What's changing:**
  - EMA's new website will have a fresh look and feel, will be more secure and simpler to navigate, and will help better meet your needs.
    - ***Improved medicines search and simplified navigation***
    - ***Key pages will have different URLs***
    - ***Outdated links will no longer work***
    - ***Improvements in 2024 and beyond***
- ✓ **Find out more:** If you want to learn more about our corporate website relaunch and ask us questions, don't miss our presentation to the EMA Patients' and Consumers' and Healthcare Professionals' Working Parties on 15 November 2023.
- ✓ **Get in touch:** For any questions you may have on our corporate website relaunch, please contact us at newwebsite@ema.europa.eu.

Allfälliges

EMA annual report 2023:

- ✓ Insights into initiatives and priority areas that guided the agency's work in 2023 plus a selection of key figures and trends
- ✓ https://www.ema.europa.eu/en/documents/annual-report/2023-annual-report-european-medicines-agency_en.pdf

EU and Korea have signed a Confidentiality arrangement

- ✓ Came into effect on 25 APR 2024
- ✓ Exchange of confidential information
- ✓ Including information on safety, quality and efficacy, as well as inspections, regulatory guidance and legislation
- ✓ https://www.ema.europa.eu/en/news/confidentiality-arrangement-between-eu-republic-korea

Allfälliges

EMA-extension of GMP-certificates:

- ✓ Several revisions to automatically extend validity of GMP-certificates (without the need for further action by the holder of the certificate)
- ✓ Explanatory footer also introduced in EudraGMDP database
- ✓ Extension until 31 DEC 2021, then 31 DEC 2022, and 31 DEC 2023
- ✓ Another extension published on 07 DEC 2023:
  - https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance-research-and-development/good-manufacturing-practice#ema-inpage-item-10391
  - *"The GMP/GDP Inspectors Working Group has decided to **continue the extension of the validity date until 2024 or the conclusion of the next on-site inspection**, whichever comes first, except where clarifying remarks in the document state otherwise."*
  - *"The inspections will be prioritised based on risk"*
  - *"Questions about the validity date of a GMP or GDP certificate should be addressed to the competent authority that issued the certificate."*

UK-MHRA published also extended validity date of MHRA-issued GMP and GDP-certificates until 2024:
https://mhrainspectorate.blog.gov.uk/2023/12/11/gmp-gdp-certificates-validity-period-extended/

Allfälliges

EMA published new Q&A for Annex 1:

- ✓ What is the maximum acceptable bioburden level?
- ✓ Is rapid method valid for the detection of microorganism within grade A and B?
- ✓ Is an isolator considered as a “closed isolator” if the semi-continuous ingress and/or egress of materials during operations is conducted via reproducible bio-decontamination steps (active VHP material airlock)?
- ✓ What are the requirements for the bioburden sampling to support parametric release?
- ✓ The answers can be found under the following link (scrolling down to the Annex 1 section):

https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance-research-and-development/good-manufacturing-practice/guidance-good-manufacturing-practice-and-good-distribution-practice-questions-and-answers

EMA updated Annex of Excipients Guideline:

- ✓ “Excipients and Information for the Package Leaflet”
- ✓ Revision 4
- ✓ https://www.ema.europa.eu/en/annex-european-commission-guideline-excipients-labelling-package-leaflet-medicinal-products-human-use#document-history-revision-3-66675

Allfälliges

Annex 1:

Swissmedic publishes Q&A on Interpretation of Annex 1

- ✓ 46 questions and corresponding answers
- ✓ Download at: https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/bewilligungen_zertifikate/authorisations/inspectorates.html

Free Presentation by GMP Inspector on Contamination Control Strategy

- ✓ Rainer Gnibl (Germany)
- ✓ Inspector's view on an overarching strategy
- ✓ https://www.pharma-congress.com/gmp-onlineforum.html

PIC/S-EMA-WHO Joint Implementation Working Group on Revised Annex 1

- ✓ 19 JAN 2024 inaugural kickoff meeting of PIC/S-EMA-WHO joint working group
- ✓ Goal: to achieve harmonized interpretation of new Annex 1
- ✓ PIC/S invites to follow on **LinkedIn (!)**

Allfälliges

EMA published new Q&A on Annex 16:

- ✓ Unexpected Deviations: the role of the QP
- ✓ https://www.gmp-compliance.org/gmp-news/unexpected-deviations-the-role-of-the-qp?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW17-2024
- ✓ "In the context of handling unexpected deviations, what is included in the scope of registered specifications for medicinal products?"
- ✓ Per the answer this includes IPC, bulk and finished product specifications which have been included in the MAA
- ✓ But: *"It may therefore be possible to accept deviation from an in-process specification where risk assessment confirms that there is no impact to manufacturing process or product quality."*
- ✓ *"Non-compliance with registered specifications (except where excursions from in-process specifications can be accepted based on quality risk management principles) therefore fall outside the scope of Annex 16 section 3, and the QP would not be able to certify the affected batches under the Annex 16 provisions for handling unexpected deviations."*
- ✓ https://www.ema.europa.eu/en/human-regulatory-overview/research-and-development/compliance-research-and-development/good-manufacturing-practice/guidance-good-manufacturing-practice-and-good-distribution-practice-questions-and-answers#eu-gmp-guide-annexes:-supplementary-requirements:-annex-16-section

Allfälliges

EMA published new Q&A on Annex 8:

- ✓ Sampling of starting and packaging materials: Glycerol and other excipients at high risk of DEG/EG contamination
- ✓ Answers provided to the following questions:
  - What is the background regarding international incidents of contamination of drug components with diethylene glycol (DEG) and ethylene glycol (EG)?
  - How is the EU patient protected from similar contamination occurring in EU products?
  - Can I use the derogations of Annex 8 of the GMP to sample only a portion of incoming containers of for glycerol, propylene glycol and macrogols (polyethylene glycol) with a relative molecular mass below 1000?
  - What steps are expected of manufacturers and importers when purchasing excipients at high-risk of DEG/EG contamination?
  - The European Pharmacopoeia limit test for DEG/EG involves a gas chromatographic method, which may be difficult to perform on a large number of containers.
  - Are there any considerations applicable to the pharmaceutical assessment of marketing-authorisation applications?
  - My company manufactures products for external use. Does this guidance apply?

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers

Allfälliges

EU Commission: Strategy Paper with Measures against Medicines Supply Shortages:

- ✓ Most important planned measures:
  - Establishment of a voluntary EU solidarity mechanism
  - A Union list of critical medicines
  - Regulatory flexibility
  - EU guidelines for the procurement of medicines in the interest of greater security of supply
  - Joint procurement at EU level of antibiotics and respiratory virus treatments
- ✓ Setting up a “Critical Medicines Alliance”
- ✓ https://ec.europa.eu/commission/presscorner/detail/en/ip_23_5190

EMA published “Toolkit” for Shortages of Medicinal Product

- ✓ EMA has published a so called "*MSSG Toolkit on recommendations on tackling shortages of medicinal products*"
- ✓ You can find more details here: MSSG Solidarity Mechanism.
- ✓ https://www.gmp-compliance.org/gmp-news/ema-publishes-toolkit-for-shortages-of-medicinal-products?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW45-2023

Allfälliges

EMA published Union list of critical medicines to help avoid potential shortages in the EU:

- ✓ Version 1 of list published
- ✓ Methodology to identify critical medicines for the Union list
- ✓ Q&A on the Union list
- ✓ https://www.ema.europa.eu/en/news/first-version-union-list-critical-medicines-agreed-help-avoid-potential-shortages-eu#ema-inpage-item-64290

EMA recommendations to strengthen supply chains of critical medicines:

- ✓ Published 23 APR 2024
- ✓ Measures aiming to assure availability and securing supply of critical medicines whose supply chain was identified as vulnerable
- ✓ https://www.gmp-compliance.org/gmp-news/recommendations-from-ema-to-strengthen-supply-chains-of-critical-medicines-published?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW19-2024

EC updated Q&A on Safety Features:

- ✓ Version 21
- ✓ New questions:
  - What are the safety features?
  - If a pack bearing the safety features is lawfully opened, can it be resealed?
  - Is it possible to market products with packaging showing visible signs of opening/intrusion, but where the ATD has been replaced by a new ATD?
  - Is it acceptable to use stickers to place UI on the outer/immediate packaging?

https://health.ec.europa.eu/document/download/2e49010a-0071-4f39-8b00-c90a266aba76_en

Allfälliges

EMA/CHMP/CVMP: New Q&A “How to use a CEP”:

- ✓ Published 13 FEB 2024
- ✓ https://www.ema.europa.eu/en/questions-answers-how-use-cep-context-marketing-authorisation-application-or-marketing-authorisation-variation

EU Commission finally approved SoHO Regulation:

- ✓ “Quality and safety standards for substances of human origin for human use”
- ✓ Approved on 24 April 2024
- ✓ Including regulations on blood, tissue, cells, and breast milk
- ✓ EU Commission also published a Q&A document on its website
- ✓ https://www.gmp-compliance.org/gmp-news/final-approval-of-soho-regulation?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW18-2024-MEU

ECHA (European Chemicals Agency) next steps for “PFAS”:

- ✓ PFAS = per- and polyfluoroalkyl substances

https://echa.europa.eu/de/-/next-steps-for-pfas-restriction-proposal#msdynttrid=qB2hu3t2P1ewyWN1YqBIxfl_cQHlm2QOjaV4-8f8h9M

Allfälliges

EMA/CMDh: several update in Q&A for Nitrosamines:

- ✓ Appendix 1 updated in December 2023 to contain five additional substances
  - N-nitroso-cinacalcet
  - N-nitroso-desmethyl-citalopram
  - N-nitroso-desmethyl-nintedanib
  - N-nitroso-imatinib
  - N-nitroso-quetiapine HEEP Impurity
- ✓ Q&A document updated again in January 2024, now available as Revision 20, 3 questions added:
  - *3. For the 'call for review' for chemically synthesised and biological medicinal products, when and how should MAHs report steps 1 and 2 to competent authorities?*
  - *9. What are the requirements of the analytical method(s)?*
  - *10. Which limits apply for nitrosamines in medicinal products?*
- ✓ Appendix 1 also revised in January and following substances added:
  - 1-(2,3-dichlorophenyl)-4-nitrosopiperazine
  - N-nitroso-azacyclonol
  - N-nitroso-betaxolol
  - N-nitroso-dabigatran etexilate
  - N-nitroso-desmethyl-sildenafil
  - N-nitroso-desmethyl-sumatriptan
  - N-nitroso-desmethyl-terbinafine
  - N-nitroso-dorzolamide
  - N-nitroso-mirtazapine
  - N-nitroso-ranolazine impurity 1
  - N-nitroso-ribociclib impurity 1
  - N-nitroso-rivaroxaban amide
  - N-nitroso-rivaroxaban open-ring acid
  - N-nitroso-terbinafine degradant
  - N-nitroso-terbinafine impurity A
  - N-nitroso-urapidil

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/CMDh: several update in Q&A for Nitrosamines:

- ✓ Appendix 1 again updated in February 2024 and 15 new substances added:
  - 2,2,5-trimethyl-3-nitroso-1,3-oxazolidine
  - N-nitroso-apixaban Impurity B
  - N-nitroso-clozapine
  - N-nitroso-clozapine EP Impurity C
  - N-nitroso-desmethyl-tamoxifen
  - N-Nitrosodiisopropanolamine
  - N-nitroso-flecainide
  - N-nitroso-folic acid
  - N-nitroso-masitinib
  - N-nitroso-meglumine
  - N-nitroso-meropenem
  - N-nitroso-ritalinic acid
  - N-nitroso-silodosin
  - N-nitroso terazosin Impurity C
  - N-nitroso terazosin Impurity N

https://www.gmp-compliance.org/gmp-news/ema-cmdh-appendix-1-for-nitrosamines-updated-again?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW12-2024-MEU

Allfälliges

EMA/CMDh: Update of Appendix 1 for Nitrosamines:

- ✓ Sixteen substances were added and are marked in red and clearly recognizable in the list of acceptable intakes (AIs). These include:
  - 2-(4-nitrosopiperazin-1-yl)ethanol
  - 3-((ethyl(nitroso)amino)methyl) benzenesulfonate
  - 4-nitroso-methyl piperazine-1-carboxylate
  - N-(2-hydroxy-2-phenylethyl)-N-(4-nitrophenethyl)nitrous amide
  - N-(4-aminophenethyl)-N-(2-hydroxy-2-phenylethyl)nitrous amide
  - N-nitroso-articaine
  - N-nitroso-desmethyl-edoxaban
  - N-nitroso-fenfluramine
  - N-nitroso-furosemide
  - N-nitroso-N-desmethyl-dextromethorphan
  - N-nitroso-posaconazole Impurity 1
  - Rivaroxaban Nitroso Impurity 1
  - Rivaroxaban Nitroso Impurity 2
  - Rivaroxaban Nitroso Impurity 5
  - N-nitroso-trientine Impurity 1
  - N-nitroso-vibegron
- ✓ The entries for the substances "N-nitroso-folic acid" and "N-nitroso-lisinopril" have been updated.
- ✓ https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/referral-procedures-human-medicines/nitrosamine-impurities

Allfälliges

EMA updated Q&A – Clinical Trials Regulation (EU) No 536/2014:

- ✓ Version 6.6
- ✓ Published 29 SEP 2023
- ✓ 154 pages
- ✓ https://health.ec.europa.eu/system/files/2023-09/regulation5362014_qa_en.pdf

EMA published "Guideline on Development and Manufacture of Synthetic Peptides"

- ✓ Public consultation until 30 APR 2024
- ✓ https://www.ema.europa.eu/en/development-and-manufacture-synthetic-peptides-scientific-guideline

EMA published ICH Q14 Guideline on Analytical Procedure Development – Step 5

- ✓ 26 JAN 2024
- ✓ Date for coming into effect: 14 JUN 2024
- ✓ https://www.ema.europa.eu/en/ich-q14-analytical-procedure-development-scientific-guideline

Allfälliges

EMA concept paper on development and manufacture of human medicinal products specifically designed for phage therapy:

- ✓ EMA/CHMP/BWP/486838/2023
- ✓ Public consultation started 22 DEC 2023
- ✓ End of consultation: 31 MAR 2024
- ✓ Bacteriophages considered a promising alternative to antibiotics for treatment of infections not responding to conventional antibiotic treatment
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-establishment-guideline-development-and-manufacture-human-medicinal-products-specifically-designed-phage-therapy_en.pdf

EMA published a draft assessment guide for SmPC section 5.1

- ✓ EMA/CHMP/566497/2023, published 15 DEC 2023
- ✓ Deadline for comments: 04 MAR 2024
- ✓ Section 5.1 should be limited to indication, target population and posology that are authorized. No information should be given on indications/populations that were not applied for or were rejected (except for paediatrics)
- ✓ https://www.ema.europa.eu/en/assessment-smpc-section-51-guide-assessors-centralised-applications-scientific-guideline

EMA Concept Paper on Revision of guideline on clinical evaluation of medicinal products intended for treatment of Hepatitis B

- ✓ Revision 1
- ✓ End of consultation: 30 APR 2024
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-guideline-clinical-evaluation-medicinal-products-intended-treatment-hepatitis-b-revision-1_en.pdf

Allfälliges

EU added Taiwan to list of third countries for APIs imported to the EU

- ✓ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202302484&qid=1704698812889

FAQ on medicinal products development and assessment involving companion diagnostics (CDx):

- ✓ EMA/CHMP/821321/2022
- ✓ To be read in conjunction with IVDR regulation 2017/746
- ✓ https://www.ema.europa.eu/en/documents/other/frequently-asked-questions-medicinal-products-development-and-assessment-involving-companion-diagnostic-cdx_en.pdf

EMA and FDA publish Q&A on Expediting Quality Drug Development:

- ✓ EMA and FDA sharing experience and regulatory expectations in the context of breakthrough therapy designation (FDA) and Priority Medicines Programs (EMA) for patients with unmet medical needs
- ✓ https://www.fda.gov/drugs/pharmaceutical-quality-resources/european-medicines-agency-fda-questions-answers-expediting-quality-development-fdas-breakthrough?utm_medium=email&utm_source=govdelivery

EMA to support establishment of the African Medicines Agency

- ✓ EMA received grant of 10 Million Euros from EU Commission to support regulatory systems in Africa
- ✓ AMA (African Medicines Agency) will be a specialized agency of African Union
- ✓ 27 member countries already ratified AMA treaty (as per 26 JAN 2024)
- ✓ https://www.ema.europa.eu/en/news/ema-support-establishment-african-medicines-agency

Allfälliges

EMA: Q&A on "Centralised Procedures" revised:

- ✓ Topics before and during application: (147 pages): https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure-document_en.pdf
- ✓ Topics after the granting of the authorisation: (307 pages): 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: First Electronic Product Information (ePI) for Human Medicines:

- ✓ One year pilot from July 2023
- ✓ https://www.ema.europa.eu/en/news/first-electronic-product-information-epis-published-selected-human-medicines

EMA revised Guideline on Good Agricultural and Collection Practice (GACP):

- ✓ Starting materials of herbal origin
- ✓ Open for comments until 15 JUL 2024
- ✓ https://www.gmp-compliance.org/gmp-news/revised-gacp-guideline?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW17-2024

Allfälliges

EMA: Implementation strategy of ICH M10 on bioanalytical method validation:

- ✓ EMA/449486/20233
- ✓ Deadline for comments: 31 JAN 2024
- ✓ If method development started after 21 JAN 2023, all validation should be based on ICH M10
- ✓ If method development started shortly before 21 JAN 2023, you should consider segueing to M10
- ✓ If study was near to completion on 21 JAN 2023, studies may be completed if EMA guideline has been applied throughout
- ✓ If development was complete before 21 JAN 2023 there is no need to change or revalidate (also when submission is after this date), if EMA guideline was used
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/implementation-strategy-ich-guideline-m10-bioanalytical-method-validation_en.pdf

EMA Guideline on clinical requirements for non-replacement therapy in hemophilia A and B:

- ✓ EMA/136018/2023
- ✓ Deadline for comments: 30 APR 2024
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-clinical-requirements-non-replacement-therapy-haemophilia-and-b_en.pdf

EMA communication:

- ✓ EU medicines agency reflect on lessons learned from COVID-19
- ✓ Joint report by EMA and HMA (Heads of Medicines Agencies)
- ✓ Published on 01 DEC 2023
- ✓ This communication and related content are published here

Allfälliges

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

Ireland: HPRA updated Guide for Attainment of QP status

- ✓ AUT-G0080-5: Guide to the Attainment of Qualified Person Status in Ireland: Educational Requirements, Training and Licensing, 11-Apr-2024
- ✓ https://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0080-guide-to-attainment-of-qualified-person-status-in-ireland-v3.pdf?sfvrsn=19

Swissmedic: Nitrosamine Requirements updated:

- ✓ Q&A updated
- ✓ https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/aktualisierte-anforderungen-umgang-nitrosamin-verunreinigungen.html

Allfälliges

China applies for PIC/S membership

- ✓ On 22 SEP 2023 China NMPA submitted membership application
- ✓ Status of Applicant granted on 03 NOV 2023
- ✓ NMPA representing all Chinese Authorities involved in Chinese GMP programs
- ✓ https://picscheme.org/en/news

Egypt applies for PIC/S pre-accession

- ✓ On 22 SEP 2023 Egyptian Drug Authority (EDA) applied for PIC/S pre-accession

https://picscheme.org/en/news

Allfälliges

China tightens Counterespionage Law – Risk for Audits and Inspections?

- ✓ Revised law came into force on 01 JUL 2023
- ✓ New version expanding government's counterespionage powers
- ✓ Including now "*Stealing, prying into, purchasing, or illegally providing …* ***other documents, data, materials, or items related to national security and interests*** …"
- ✓ Now some EU-GMP-inspectorates have unofficially suspended inspections in China due to legal uncertainty
- ✓ Considering that many GMP-certificates will probably only be valid until 2024, there is a risk for increased shortages of medicines
- ✓ Risk for auditors from industry is also increased
- ✓ This is currently a challenge that cannot be solved with legal certainty.
- ✓ https://www.gmp-compliance.org/gmp-news/china-tightens-counterespionage-law-risk-for-audits-and-inspections?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW49-2023-MEU
- ✓ After German associations and newspapers took up the matter, another article appeared now in Financial Times
- ✓ Western companies concerned about denial of access to risk of arrest; companies now refusing to go to China for audits
- ✓ EU regulatory authorities also expect difficulties when inspecting facilities in China
- ✓ US FDA inspections could not be carried out in over 150 cases since 2021 because they were rejected.
- ✓ And there has already been an incident in which a Japanese executive from Astellas Pharma was arrested in China
- ✓ https://www.gmp-compliance.org/gmp-news/chinese-anti-espionage-law-causes-quite-a-stir?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW18-2024-MEU

Allfälliges

ICH adopts final text of Q2(R2) and Q14 guidelines:

- ✓ Q2 “Validation of Analytical Procedures”
- ✓ Q14 Analytical Procedure Development”
- ✓ Final texts adopted at ICH Assembly Meeting
- ✓ Final documents now available for download

https://www.gmp-compliance.org/gmp-news/ich-guidelines-q2r2-validation-of-analytical-procedures-and-ich-q14-analytical-procedure-development-published?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW02-2024

ICH Q3C: Residual Solvents

- ✓ New Version published
- ✓ 9th revision
- ✓ Revision and adjustments in section 3.4 Analytical Procedures

https://www.gmp-compliance.org/gmp-news/ich-q3c-new-version-of-the-guideline-for-residual-solvents-published?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW20-2024

Allfälliges

EDQM Newsroom: Reminder: Use of EMA SPOR/OMS ORG_ID and LOC_ID mandatory for any CEP applications:

- ✓ CEP 2.0
- ✓ Since 01 JUL 2023 applicants must provide EMA SPOR/OMS ORG_ID and LOC_ID in application forms of any type of submission (new dossier, sister files, revisions, and renewals)
- ✓ Companies that do not have an ORD_ID and LOC_ID must therefore register as soon as possible
- ✓ It is the CEP holder's responsibility to ensure that this is also available for intermediate manufacturers
- ✓ https://www.edqm.eu/en/-/cep-2.0-reminder-use-of-ema-spor/oms-org_id-and-loc_id-mandatory-for-any-cep-applications

EDQM publishes News on CEP 2.0: Specifications

- ✓ https://www.edqm.eu/en/-/cep-2.0-new-requirements-for-the-content-of-the-chemical-purity-and-herbal-drugs/herbal-drug-preparation-dossiers

EDQM: Supplement 11.4 to Ph. Eur. available:

- ✓ Implemented on 1st APR 2024
- ✓ https://www.gmp-compliance.org/gmp-news/edqm-supplement-11-4-to-the-european-pharmacopoeia-available?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW46-2023

Allfälliges

New Ph. Eur. Chapter Comparability of Alternative Analytical Procedures:

- ✓ New general chapter 5.27
- ✓ Published in Supplement 11.5
- ✓ No new requirements, but useful information
- ✓ https://www.gmp-compliance.org/gmp-news/new-ph-eur-chapter-comparability-of-alternative-analytical-procedures?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW04-2024

Ph. Eur. Nitrosamine-monograph:

- ✓ 2.5.41 N-Nitrosamines in active substances and medicinal products
- ✓ Open for comments until 31 MAR 2024
- ✓ Draft can be viewed and commented following one-time registration at:
- ✓ https://pharmeuropa.edqm.eu/home

Ph. Eur.: New strategy for N-nitrosamine impurities in Ph. Eur. Monographs:

- ✓ Delete Production section covering N-nitrosamine impurities from existing individual monographs
- ✓ General requirement for these impurities in monograph 2034 applies to all substances for pharmaceutical use within given scope
- ✓ In addition, clear rules defined on when a specification for N-nitrosamine impurities should be added

- https://www.edqm.eu/en/-/new-strategy-for-n-nitrosamine-impurities-in-ph.-eur.-monographs

Allfälliges

EDQM updated list of reference substances:

- ✓ More than 3100 substances
- ✓ Complete list, including also batch validity statements, safety data sheets, and leaflets (downloadable PDFs) at:
- ✓ https://www.edqm.eu/en/-/8-replacement-batches-released-in-december-2023

European Pharmacopoeia welcomes Egyptian Drug Authority as observer:

- ✓ EDA has been granted observer status to the European Pharmacopoeia Commission
- ✓ Ph.Eur. has now 33 observers in addition to 39 European countries
- ✓ https://www.edqm.eu/en/-/european-pharmacopoeia-welcomes-egyptian-drug-authority-as-observer

EDQM: CEP holders invited to comment on draft monographs published in Pharmeuropa 36.1

- ✓ Feedback before 31 MAR 2024
- ✓ For companies located in a Ph.Eur. member state: please send comments through the relevant National Pharmacopoeial Authority
- ✓ For companies located in a county which is not a member state of Ph.Eur.: please send comments directly using EDQM HelpDesk

https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-36.1

Allfälliges

EDQM: Top Ten Deficiencies for CEPs:

- ✓ Published in February 2024
- ✓ Help applicants to avoid such deficiencies in future
- ✓ Recommended to use EDQM guideline "Content of dossier for chemical purity and microbiological quality"

https://www.gmp-compliance.org/gmp-news/edqm-top-ten-deficiencies-for-ceps?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW11-2024

EDQM draft guideline on Requirements for Sterile Packaging Material:

- ✓ "Content of the dossier for sterile substances"
- ✓ Public consultation until 15 AUG 2024

https://www.edqm.eu/en/-/draft-guideline-on-content-of-the-dossier-for-sterile-substances-released-for-public-consultation

Ph.Eur. new Draft Chapter „High-Throughput Sequencing for detecting Viral Extraneous Agents":

- ✓ NGS (Next Generation Sequencing)
- ✓ Rapid and cost effective sequencing of DNA or RNA
- ✓ Draft of new Chapter 2.6.41 published for comments in Pharmeuropa 36.2
- ✓ Open for comments until 30 June 2024
- ✓ Accessible after free registration on Pharmaeuropa website

https://www.gmp-compliance.org/gmp-news/hts-ngs-draft-ph-eur-chapter-high-throughput-sequencing-for-detecting-viral-extraneous-agents?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW14-2024

Allfälliges

VICH: Guideline for APIs in Veterinary Medicinal Products:

- ✓ Comments until end of March 2024
- ✓ VICH is an association of EU, USA, and Japan
- ✓ Download and commenting e.g., on FDA-website:
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-286-vich-gl60-good-manufacturing-practice-active-pharmaceutical-ingredients-used-veterinary?utm_medium=email&utm_source=govdelivery

Allfälliges

FDA launches new Webpage for searching Pharmaceutical Quality Documents:

- ✓ New search function on FDA's Office of Pharmaceutical Quality webpage
- ✓ The new webpage scans existing FDA guidance documents, manuals of policies and procedures, and compliance programs to provide users with relevant and up-to-date resources and information
- ✓ https://www.fda.gov/drugs/pharmaceutical-quality-resources/search-pharmaceutical-quality-documents?utm_medium=email&utm_source=govdelivery

FDA Revised Draft Guidance "Conducting Remote Regulatory Assessments":

- ✓ Q&A reflecting comments to the 2022 draft guidance
- ✓ Open for public comments until 26 MAR 2024
- https://www.federalregister.gov/documents/2024/01/26/2024-01589/conducting-remote-regulatory-assessments-questions-and-answers-revised-draft-guidance-for-industry

FDA revised Draft Guidance for Industry "Conducting Remote Regulatory Assessments – Q&A"

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

FDA Office of Compliance published Annual Report FY 2023:

- ✓ https://www.fda.gov/media/175379/download?utm_medium=email&utm_source=govdelivery

Allfälliges

FDA issues final guidance on developing drugs for COVID-19 treatment and prevention

- ✓ FDA's current recommendations on the design of phase 2 and phase 3 trials with a focus on trial population and design, efficacy endpoints, as well as safety and statistical considerations.
- ✓ The guidance does not provide recommendations on the development of preventative vaccines, convalescent plasma, or Long COVID-19 as these development programs raise different considerations
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/covid-19-developing-drugs-and-biological-products-treatment-or-prevention?utm_medium=email&utm_source=govdelivery

FDA Revision of Guidance on Quality Considerations for Ophthalmic Drug Products:

- ✓ Recent cases of microbiologically contaminated products and recent recall
- ✓ Revised draft includes information about product sterility, extractables and leachables, and preservative use
- ✓ Any FDA-regulated drug products that are used for topical delivery in and around the eye such as solutions, suspensions, emulsions, gels, ointments or creams
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/quality-considerations-topical-ophthalmic-drug-products

FDA Office of Pharmaceutical Quality (OPQ) issues Annual Report for 2023

- ✓ View the full report

Allfälliges

FDA issues guidance on translation of GLP study reports

- ✓ This question-and-answer document is intended to clarify FDA's recommendations concerning the translation of study reports **from a non-English language** into English for studies conducted in compliance with GLP regulations.
- ✓ Questions & Answers: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/translation-good-laboratory-practice-study-reports-questions-and-answers?utm_medium=email&utm_source=govdelivery
- ✓ Guidance snapshot: https://www.fda.gov/media/174062/download?attachment=&utm_medium=email&utm_source=govdelivery
- ✓ Recap podcast (13:39 min): https://www.fda.gov/media/174061/download?attachment=&utm_medium=email&utm_source=govdelivery
- ✓ For more information and to submit a comment regarding this guidance, please visit Translation of GLP Study Reports: Questions and Answers; Draft Guidance for Industry; Request for Comments

Allfälliges

FDA issues final rule on preventing risk information in prescription drug television and radio ads:

- ✓ These advertisements must present the drug's major side effects and risk information, known as the "major statement," in a clear, conspicuous, and neutral manner.
- ✓ https://www.federalregister.gov/documents/2023/11/21/2023-25428/direct-to-consumer-prescription-drug-advertisements-presentation-of-the-major-statement-in-a-clear

FDA issued final guidance on developing monoclonal antibodies for COVID-19 under EUA:

- ✓ Although the health emergency has expired, SARS-CoV-2 continues to circulate and COVID-19 remains a serious health risk for some individuals
- ✓ Guidance for manufacturing, nonclinical, virological, and clinical considerations
- ✓ Data and information to support Emergency Use Authorization (EUA)
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-monoclonal-antibody-products-targeting-sars-cov-2-emergency-use-authorization?utm_medium=email&utm_source=govdelivery

Allfälliges

FDA issues guidance for industry "Rare Diseases: Considerations for the Development of Drugs and Biological Products":

- ✓ Clarifying FDA's thinking on important considerations in rare disease drug development
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rare-diseases-considerations-development-drugs-and-biological-products?utm_medium=email&utm_source=govdelivery

FDA guidance for industry „Reformulating Drug Product That Contain Carbomers Manufactured with Benzene":

- ✓ Published in December 2023
- ✓ Certain United States Pharmacopeia (USP) carbomer monographs currently allow for unacceptable levels of benzene, which raises safety concerns.
- ✓ FDA has requested that the USP omit (or remove) these monographs, and applicants and manufacturers may need to reformulate their drug products to avoid using these carbomers.
- ✓ This will probably cause some headache in industry (similar to DEG/EG or nitrosamines)
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reformulating-drug-products-contain-carbomers-manufactured-benzene?utm_medium=email&utm_source=govdelivery

Allfälliges

FDA new draft guidance regarding Use of Human- and Animal-derived Materials:

- ✓ manufacturing cell and gene therapy products, as well as Tissue Engineered Medical Products (TEMPs)
- ✓ It details the requirements for chemistry, manufacturing, and control (CMC) information that should be included in an investigational new drug application (IND).
- ✓ Deadline for comments: 29 JUL 2024
- ✓ https://www.gmp-compliance.org/gmp-news/new-fda-draft-guideline-regarding-the-use-of-human-and-animal-derived-materials?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW22-2024

FDA new draft guidance regarding safety testing of human allogeneic Cells:

- ✓ Deadline for comments is 29 JUL 2024
- ✓ https://www.gmp-compliance.org/gmp-news/new-fda-draft-guideline-regarding-safety-testing-of-human-allogeneic-cells?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW121-2024-MEU

FDA guidance for industry "Drug Products, including Biological Products, that Contain Nanomaterials":

- ✓ April 2022
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/drug-products-including-biological-products-contain-nanomaterials-guidance-industry?utm_medium=email&utm_source=govdelivery
- ✓ Podcast and Transcript published recently: https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/considerations-drug-products-contain-nanomaterials?utm_medium=email&utm_source=govdelivery

Allfälliges

FDA draft guidance for industry „Potency Assurance for Cellular and Gene Therapy Products“:

- Published in December 2023
- Open for comments until 27 MAR 2024
- As potency testing of CGT is difficult and can provide inconsistent results, an overal potency assurance strategy is being proposed
- Risk Management principles are emphasized throughout the product lifecycle
- For a high-level overview of this guidance document, please view this recorded webinar featuring Dr. Matthew Klinker, Cell Therapy Branch 2 Chief, Office of Cellular Therapy and Human Tissues, Office of Therapeutic Products, CBER.
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/potency-assurance-cellular-and-gene-therapy-products?utm_medium=email&utm_source=govdelivery

FDA Draft on Data Integrity for bioavailability and bioequivalence studies:

- ✓ Published in April 2024, open for comments for 60 days
- ✓ https://www.gmp-compliance.org/gmp-news/us-fda-draft-on-data-integrity-for-be-ba-studies-published?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW15-2024-MEU

Allfälliges

FDA issued a final rule to amend its regulations concerning the use of master files for biological products:

- ✓ A master file is a submission to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.
- ✓ Information contained in a master file can be used to support a submission to FDA by an applicant or sponsor.
- ✓ Drug master files (DMFs) are master files that contain certain information, such as drug substance, drug substance intermediate, or drug product (DS/DSI/DP) information, that is relevant to applications for drug products regulated under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA's current thinking on KPIs and Quality Metrics:

- ✓ https://www.gmp-compliance.org/gmp-news/fdas-current-thinking-on-kpis-and-quality-metrics?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW15-2024-MEU

Allfälliges

USP-NF 2024 Issue 1

- ✓ Effective on 01 MAY 2024
- ✓ Some new chapters:
  - <1079.4> Temperature Mapping for the Qualification of Storage Areas
  - <1117.1> Microbiological Chapters – Glossary
- ✓ Some revised chapters:
  - <232> Elemental Impurities / Limits
  - <789> Subvisible Particulate Matter in Intraocular Solutions
  - <1059> Excipient Performance

Allfälliges

USP-NF 2024 Issue 2

- ✓ Will get effective on 01 Aug 2024
- ✓ Some chapters highlighted:
  - ✓ New chapters:

    <312> Molecular Weight Determination for Alginates

    <383> Cured Silicone Elastomers for Pharmaceutical Packaging and Manufacturing Components

    <1023> Evaluation Strategy for Trace Elements in Cell Culture Media Used in the Manufacture of Recombinant Therapeutic Proteins

    <1035> Potency Assays to Evaluate Coagulation Factor VIII and Factor IX
  - ✓ Revised chapters:

    <471> Oxygen Flask Combustion

    <541> Titrimetry

    <661> Plastic Packaging Systems and Their Materials of Construction

    <791> pH

Allfälliges

Revised USP Chapter <660> Glass Containers

- ✓ Final version published and made official on 01 OCT 2023
- ✓ Glass type change from “composition based” to “performance based”
- ✓ Important to note that compendial chapters USP <660> and Ph. Eur. 3.2.1 are currently not harmonized in this point (Ph. Eur. Still refers to borosilicate glass for Type 1)
- ✓ For more information please see USP Chapter <660> *Containers – Glass*.

USP <621> “Chromatography”

- ✓ Published for comments
- ✓ Deadline for comments: 31 JAN 2024
- ✓ https://www.gmp-compliance.org/gmp-news/usp-chapter-621-chromatography-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW45-2023

New USP chapter on PAT (Process Analytical Technology) planned

- ✓ https://www.gmp-navigator.com/gmp-news/usp-plant-neues-kapitel-ueber-process-analytical-technology-pat?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-QKMIBI-KW16-2024

Allfälliges

Proposal for new USP Chapter <317> ICP OES Testing for Sodium Hyroxide and Potassium Hydroxide

- ✓ Published for comments until 31 JUL 2024
- ✓ Content of Sodium in Sodium Hydroxide
- ✓ Content of Potassium in Potassium Hydroxide
- ✓ Potassium as an Impurity in Sodium Hydroxide
- ✓ https://www.gmp-compliance.org/gmp-news/proposal-for-new-usp-chapter-317-icp-oes-testing-for-sodium-hydroxide-and-potassium-hydroxide-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW19-2024

USP stimuli document "Responses to Comments for Stimuli Articles on Analytical Instrument and System (AIS) Qualification"

- ✓ Comments and observations on this summary can be submitted until 31 JUL 2024
- ✓ https://www.gmp-compliance.org/gmp-news/usp-responses-to-instrument-qualification-stimuli-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW19-2024

Allfälliges

Revision of USP Chapter <1053> Capillary Electrophoresis published for comments:

- ✓ Pharmacopoeial Forum, PF 50(1)
- ✓ Reason for change: harmonization with Ph. Eur. and JP
- ✓ Comments until 31 MAR 2024
- ✓ https://www.gmp-compliance.org/gmp-news/revision-of-usp-chapter-1053-capillary-electrophoresis-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW04-2024

USP new chapter on cured Silicone elastomers:

- ✓ USP <383>
- ✓ Final text published
- ✓ Will become official on 01 DEC 2027
- ✓ Relevant for closures, but also for silicone parts in manufacturing processes (e.g., O-rings, tubings, membranes, etc.)
- ✓ https://www.gmp-compliance.org/gmp-news/new-usp-chapter-on-cured-silicone-components?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW09-2024-MEU

USP: <11> Reference Standards

- ✓ New draft published for comments until 31 JUL 2024
- ✓ You can access and comment on the new draft of the monograph "<11> USP REFERENCE STANDARDS" after registering once on the Pharmacopeial Forum website
- ✓ https://www.gmp-compliance.org/gmp-news/usp-11-reference-standards-draft-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW20-2024

Allfälliges

India's Health Ministry revises GMP-Rules and replaces the "GMP"-Term:

- ✓ Published on 06 JAN 2024
- ✓ "GMP" replaced by "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products"
- ✓ Aim to ensure production of high quality, globally acceptable drugs
- ✓ Changes introduced include:
  - Introduction of PQS
  - QRM
  - PQR
  - Qualification and Validation
  - Computerized storage system for all drug products

- https://www.gmp-compliance.org/gmp-news/indias-health-ministry-revises-gmp-rules-and-replaces-the-gmp-term?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW06-2024

State Pharmacopoeia of the Russian Federation XV Edition:

- ✓ Published with transition period until September 2026

Allfälliges

Changes planned for Water in Chinese Pharmacopoeia:

- ✓ Monograph 0261
- ✓ Comment period until 24 JUL 2024
- ✓ Planned changes welcome, as they represent further harmonization between various global pharmacopoeias

• https://www.gmp-compliance.org/gmp-news/changes-planned-for-pharmaceutical-water-in-the-chinese-pharmacopoeia?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW22-2024

WHO Draft Working Document on Bioanalytical Method Validation and Study Sample Analysis published for Comments:

- ✓ QAS/23.925
- ✓ Text is based on ICH M10 Guideline (May 2022)
- ✓ Comments by 21 JAN 2024

✓ https://www.gmp-compliance.org/gmp-news/who-draft-working-document-on-bioanalytical-method-validation-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW46-2023

Allfälliges

GMP Update 2023/2024:

- ✓ Article in the GMP Journal summarizes a few selected highlights
- ✓ https://www.gmp-journal.com/current-articles/details/the-gmp-update-2023-2024.html

ECA published Q&A Document on Annex 1:

- ✓ https://www.eca-foundation.org/news/questions-and-answers-on-annex-1.html

New ECA Academy Website:

- ✓ Largest search engine for GMP-related information
- ✓ New GMP search function
- ✓ https://www.gmp-compliance.org/gmp-news/new-eca-academy-website?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW19-2024

New EQPA Newsletter issue:

- ✓ Download section of the member's area
- ✓ Topics:
  - How EQPA Members make use of QPSHARE
  - EQPA Engagement Board – first Experiences
  - Summary Report: The Position of the QP within the Organization of the MIAH
  - New EMA Q&As on Remote Certification – EQPA Survey Results
- ✓ https://www.qp-association.eu/qpag_download.html?utm_source=Newsletter&utm_medium=email&utm_campaign=Sonder-KW23-2024-EQPA

- Präsentationen werden wieder im Internet abrufbar sein:
  www.austria-qp.at
- 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 2024 der EQPA:**

  27-29 NOV 2024 in Amsterdam, Leonardo Royal Hotel

  Programm: https://www.qp-forum.org/

- **Austrian QP Forum 2025:**

  15.-16.Mai 2025

- **Nächstes Vereinstreffen der AQPA:**

  Donnerstag, 24.10.2024

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

Wir wünschen einen schönen Abend,
viel Spaß beim Netzwerken und
hoffen auf zahlreiches reales Wiedersehen am
24.10.2024

Bleiben Sie gesund!

Der erweiterte 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