Vereinstreffen der AQPA

24. Oktober 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:
  - Qualifizierung vs. Validierung Refresher *(Gabriela Schallmeiner/ Inspection-Ready)*
  - Kommentierte Gesetze nutzen! *(Markus Thiel/ Roche)*
  - Allfälliges: Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
- Teilnehmerliste *(Winfried Chang/AOP)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

Allfälliges

EU Commission releases "Assessment of the Supply Chain Vulnerabilities":

- ✓ For the first tranche of the Union List of Critical Medicines
- ✓ Published 10 July 2024
- ✓ https://health.ec.europa.eu/document/download/67294e68-3a9a-4a73-8c9f-899338bac7f9_en?filename=hera_scv-critical-medicines_1t_assessment_en.pdf

EU Commission Report on Trends in Falsification of Medicines:

- ✓ Some important points:
  - Expensive prescription medicines and high-demand products such as "lifestyle medicines" most frequently counterfeited
  - Online sales increases risk
  - No specific regions of origin identified
  - Still incomplete implementation and lack of standard procedures
- ✓ https://www.gmp-compliance.org/gmp-news/report-on-trends-in-the-falsification-of-medicines?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU_KW31

Allfälliges

EU adopts Supply Chain Law:

- ✓ 24 MAY 2024
- ✓ Applicable to companies with more than 1000 employees and turnover of more than 450 million euros
  - Risk based system to remediate and prevent human rights and environmental impacts
  - Ensure that entire supply chain meets these obligations
  - Take appropriate measures to prevent and remedy abuses
  - Implement climate change transition plan
- ✓ https://www.gmp-compliance.org/gmp-news/eu-adopts-supply-chain-law-implications-for-pharmaceutical-companies?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW24-2024-MEU

Allfälliges

EMA issued templates for Shortage Prevention and Mitigation Plans:

- ✓ 18 JUN 2024
- ✓ MAH in the EEA encouraged to create SPP and SMP
- ✓ SPPs and SMPs should be submitted to Competent Authorities upon request
- ✓ https://www.gmp-compliance.org/gmp-news/templates-for-shortage-prevention-and-mitigation-plans-issued-by-ema?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW27-2024

EMA update of Q&A on "Parallel Distribution"

- ✓ https://www.gmp-compliance.org/gmp-news/ema-update-of-the-q-as-on-the-topic-of-parallel-distribution?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW25-2024

EMA: Update of Module 1 of the eCTD:

- ✓ Version 3.1 published in June 2024
- ✓ Large number of revisions and updates (listed in the "release notes")
- ✓ M1 Validation Criteria also updated (version 8.0)
- ✓ Transition period should be completed by end of March 2025
- ✓ https://www.gmp-compliance.org/gmp-news/ema-update-of-module-1?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW36-2024

Allfälliges

EMA Q&A for Centralized Procedure updated again:

- ✓ June 2024
- ✓ Topics before and during the application
- ✓ Including updates related to "Transfer of Marketing Authorization"
- ✓ https://www.gmp-compliance.org/gmp-news/ema-q-a-document-for-centralised-procedures-updated-again?utm_source=Newsletter&utm_medium=email&utm_campaign=MEU_KW29

EMA Comments on Q&A for "Co-processed Excipients":

- ✓ Comments can be submitted until 31 DEC 2024
- ✓ https://www.gmp-compliance.org/gmp-news/ema-comments-on-q-as-for-co-processed-excipients-possible?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-EN-MEU-KW39-2024

EMA Reflection Paper on Artificial Intelligence:

- ✓ Use of AI in medicinal product lifecycle
- ✓ Principles relevant to safe and effective application of AI and machine learning across various stages of medicine's development
- ✓ Introduction of new technology must not undermine trust in medicines regulatory decision making and patient safety
- ✓ Should you have any questions on this reflection paper, please contact AIreflectionpaper@ema.europa.eu
- ✓ https://www.ema.europa.eu/en/about-us/how-we-work/big-data/artificial-intelligence#ai-in-medicinal-product-lifecycle-reflection-paper-68368

Allfälliges

CMDh/EMA: Appendix 1 for Nitrosamines updated again:

- ✓ New substances added in July 2024:
  - 1-diphenylmethyl-4-nitrosopiperazine
  - 3-(dimethylamino)propyl 2-[benzyl(nitroso)amino]benzoate
  - Nitroso-STG-19
  - N-Nitroso-bilastine impurity 2
  - N-nitroso-caspofungin
  - N-Nitroso-desformyl-riociguat
  - N-nitroso-desmethyl-clarithromycin
  - N-nitroso-desmethyl-citalopram
  - N-nitroso-desmethyl-tramadol
  - N-nitroso-desvaleryl-valsartan
  - N-nitroso-diisopropylamine
  - N-nitroso-ethylisopropylamine
  - N-nitroso-N-desmethyl-diphenhydramine
  - N-nitroso-N-methyl-4-aminobutyric acid
  - N-nitroso-tigecycline
  - N-nitroso-trandolapril
- ✓ Letztes Update am **1. September 2024**
- ✓ EMA/393815/2024/Rev. 6
- ✓ Please visit the EMA website to take a look at the Annexes 2 and 3 as well as Appendix 1 and the Q&A document for nitrosamines

Allfälliges

EMA/CMDh: Q&A Document Nitrosamines revised again:

- ✓ "Nitrosamines EMEA-H-A5(3)-1490 - Questions and answers for marketing authorization holders / applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products"
- ✓ Revised again in July 2024, version 21
- ✓ https://www.gmp-compliance.org/gmp-news/ema-cmdh-q-a-document-nitrosamines-revised?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU_KW34

EMA draft guideline on the chemistry of active substances:

- ✓ Draft Revision 1 published for comments
- ✓ Until 31 JAN 2025
- ✓ New guidance will be applicable to existing and new APIs

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-chemistry-active-substances-revision-1_en.pdf

Allfälliges

EMA published revised veterinary guidelines for public consultation:

- ✓ Guideline for the demonstration of efficacy for veterinary medicinal products containing antimicrobial substances . revision 2
- ✓ Guideline on the conduct of efficacy studies for intramammary products for use in cattle – revision 3
- ✓ For each guidance, comments should be provided using this template and sent to vet-guidelines@ema.europa.eu by 31 October 2024
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-demonstration-efficacy-veterinary-medicinal-products-containing-antimicrobial-substances-revision-2_en.pdf
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-conduct-efficacy-studies-intramammary-products-use-cattle_en.pdf-1

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:

- aktuell (18. Oktober 2024) 23 Dokumente unter „open consultations“

https://www.ema.europa.eu/en/news-events/open-consultations

Allfälliges

Ireland:

HPRA Q and A on the Windsor Framework and medicines for human use:

- ✓ Brexit impact and Windsor Framework; update by HPRA
- ✓ Will be live 01 JAN 2025
- ✓ Topics include labelling, QP batch release and QC test results from UK
- ✓ https://www.hpra.ie/docs/default-source/default-document-library/questions-and-answers-on-the-windsor-framework.pdf?sfvrsn=2

Swissmedic:

Interesting Reading: Swissmedic Technical Interpretation of QP in Switzerland:

- ✓ Responsibilities, Qualification, Education and Knowledge, Experience, Trustworthiness, Independence, Language, Deputies, etc.
- ✓ https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/responsible-person-requirements.html

Swissmedic launched own GMDP database

- ✓ GMP and GDP certificates
- ✓ Public access
- ✓ https://www.gmp-compliance.org/gmp-news/swissmedic-launched-own-gmdp-database

Allfälliges

MHRA: New guidance after Brexit:

- ✓ Wholesaler & manufacturers guidance following agreement of the Windsor Framework
- ✓ Effective by 01 JAN 2025
- ✓ Labelling “UK Only”
- ✓ No FMD bar codes
- ✓ MHRA responsible for N-IRL
- ✓ Shared/common packaging for UK and EU not possible anymore
- ✓ QPs in N-IRL can continue to certify for UK and EU
- ✓ QP listed in MHRA-license have to be resident in UK
- ✓ EU/EEA storage not for “UK only”
- ✓ https://www.gov.uk/government/publications/wholesalers-manufacturers-guidance-following-agreement-of-the-windsor-framework/wholesalers-manufacturers-guidance-following-agreement-of-the-windsor-framework

British Pharmacopoeia 2025 was published

- ✓ Will get effective on 01 JAN 2025

Allfälliges

Zimbabwe applies for PIC/S pre-accession:

- ✓ 20 OCT 2023
- ✓ Medicines Control Authority of Zimbabwe (MCAZ) applied for PIC/S pre-accession
- ✓ Pre-accession application complete on 06 DEC 2023
- https://picscheme.org/en/news

Allfälliges

EDQM published updated Ph.Eur. Water Monographs:

- ✓ Published for comments
- ✓ TOC limit restricted from 0.5 mg/L to max 0.50 mg/L
- ✓ Deadline for comments: 30 SEP 2024
- ✓ https://www.gmp-compliance.org/gmp-news/edqm-publishes-updated-ph-eur-water-monographs-for-comment?utm_medium=email&utm_campaign=NL-MEU_KW30

New Ph. Eur. Chapter on Elemental Impurities in Plastic Materials:

- ✓ Draft chapter 2.4.35 published in Pharmeuropa
- ✓ New chapter published in Ph. Eur. Supplement 11.7
- ✓ https://www.gmp-compliance.org/gmp-news/new-ph-eur-chapter-on-elemental-impurities-in-plastic-materials?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW28-2024

Ph. Eur. bids adieu to rabbit pyrogen test in its monographs

- ✓ https://www.edqm.eu/en/-/ph.-eur.-bids-adieu-to-rabbit-pyrogen-test-in-its-monographs

Allfälliges

- **The European Pharmacopoeia Ph. Eur. 11.6 was published and will get effective on 01-January-2025**
  - Some chapters/monographs highlight here:
  - **NEW chapters** of this supplement:
    - ✓ 5.31. Phage therapy medicinal products
  - **Revised chapters/monographs** of this supplement:
    - ✓ 2.2.46. Chromatographic separation techniques
    - ✓ 2.6.12. Microbiological examination of non-sterile products: microbial enumeration tests
    - ✓ 3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion
    - ✓ Polysorbate 20 (0426)
    - ✓ Polysorbate 40 (1914)
    - ✓ Polysorbate 60 (0427)
    - ✓ Polysorbate 80 (0428)
    - ✓ Propylene glycol (0430)

Allfälliges

The European Pharmacopoeia Ph. Eur. 11.7 was published and will get effective on 01-April-2025

✓ Some chapters/monographs highlighted here:

- **NEW General Chapters / Monographs** of this supplement:
  - 2.4.35. Extractable elements in plastic materials for pharmaceutical use
  - 5.33. Design of experiments
  - 5.34. Additional information on gene therapy medicinal products for human use
  - Gene therapy medicinal products for human use (3186)
- **Revised General Chapters / Monographs**:
  - 4. Reagents
  - 5.2.12. Raw materials of biological origin for the production of cell-based and gene therapy medicinal products
  - 5.22. Names of herbal drugs used in traditional Chinese medicine
  - Recombinant DNA technology, products of (0784)

Allfälliges

EDQM: Monthly CEP Overview

- ✓ Certification monthly report on CEPs
- ✓ Published in the newsroom of EDQM website
- ✓ https://www.edqm.eu/en/-/certification-monthly-report-of-activities-end-of-july-2024

EDQM: CEP holders invited to comment on draft monographs published in Pharmeuropa 36.3

- ✓ Gabapentin (2173)
- ✓ Nifedipine (0627)
- ✓ Oxygen (0417)
- ✓ Pregabalin (2777)
- ✓ Sodium hyaluronate (1472)
- ✓ Testosterone enantate (1048)
- ✓ https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-36.3

Allfälliges

Pharmeuropa: 2 revised chapters on Dissolution Testing published for comments:

- ✓ 2.9.42 Dissolution test for lipophilic solid dosage forms
- ✓ 2.9.43 Apparent dissolution
- ✓ Deadline for submitting comments: 30 SEP 2024
- ✓ https://www.gmp-compliance.org/gmp-news/pharmeuropa-two-revised-chapters-on-dissolution-testing-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW28-2024

Allfälliges

US-Congress puts Pressure on FDA:

- ✓ US congress raised significant concerns about effectiveness and integrity of FDA foreign drug inspection program
- ✓ Two letters from Congress to the FDA Commissioner
- ✓ Primary concerns: significant variability in inspection outcomes, potential issues of inspector's competence and misconduct
- ✓ Seriously evaluating the possibility that some of the variation could be the result of bribery or fraud
- ✓ https://www.gmp-compliance.org/gmp-news/congressional-scrutiny-on-fdas-foreign-inspection-program-puts-pressure-on-agency?utm_source=Newsletter&utm_medium=email&utm_campaign=MEU_KW29

Allfälliges

FDA updated GfI "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection"

- ✓ Revision 1
- ✓ June 2024
- ✓ Defining types of behaviors (actions, inactions, and circumstances)
- ✓ Not an exhaustive list, rather illustrating most common situations that FDA anticipates may occur
- ✓ A drug or device is "deemed to be adulterated" if … delays, denies, or limits and FDA inspection or refuses to permit entry or inspection
- ✓ Delay of Inspections
  - Delay Scheduling Pre-announced Inspections
  - Delay During an Inspection
  - Delay Producing Records
- ✓ Denial of Inspection
- ✓ Limiting of Inspection
  - Limiting Access to Facilities and/or Manufacturing Processes
  - Limiting Photography
  - Limiting Access to or Copying of Records
  - Limiting or Preventing Collection of Samples
- ✓ Refusal to Permit Entry or Inspection
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/circumstances-constitute-delaying-denying-limiting-or-refusing-drug-or-device-inspection

Allfälliges

FDA published Fiscal Year 2023 Report on the State of Pharmaceutical Quality:

- ✓ Published 12 JUL 2024
- ✓ Some key information:
  - FDA Fiscal Year 2023 was from 01 OCT 2022 to 30 SEP 2023
  - CDER site catalogue included 4819 manufacturing sites (42% thereof located in US)
  - 776 drug QA inspections
  - 187 MRA partner inspections
  - 94% of all sites received NAI or VAI (highest in EU: 98%, US: 94%, lowest in India: 89%)
  - Number of recalls similar to 5 year average
  - 17% of recalled products associated with ophthalmic drug products
  - 94 Warning Letters; More than half related to hand sanitizers or contamination with DEG or EG
  - 71.6% of manufacturers of hand sanitizers tested in a study had violative products
- ✓ https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/report-state-pharmaceutical-quality

Allfälliges

10 points on how FDA CDER monitors the Quality of Medicinal Products:

- ✓ Interesting reading
- ✓ https://www.gmp-compliance.org/gmp-news/10-points-on-how-the-fdas-cder-monitors-the-quality-of-medicinal-products?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW26-2024

FDA publishes final rule on Medical Gases:

- ✓ Introducing certification requirements and amending existing GMP requirements
- ✓ https://www.gmp-compliance.org/gmp-news/fda-publishes-final-rule-on-medical-gases?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW27-2024

FDA inspection guidance for BIMO inspections:

- ✓ Bioresearch Monitoring Inspections (BIMO)
  - Information to assist the agency in planning inspections
  - Best practices for communicating to the FDA before, during and after an inspection
- ✓ https://www.fda.gov/media/179136/download?utm_source=substack&utm_medium=email
- ✓ https://www.fda.gov/media/179027/download?utm_source=substack&utm_medium=email

Allfälliges

FDA issues revised guidance on Container Closure System and Component Changes for Glass Vials and Stoppers:

- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/container-closure-system-and-component-changes-glass-vials-and-stoppers?utm_medium=email&utm_source=govdelivery

FDA revises control of Nitrosamines:

- ✓ Control of Nitrosamine Impurities in Human Drugs
- ✓ Revision of February 2021 guidance
- ✓ Including information about NDSRIs (nitrosamine drug substance related impurities)
- ✓ Recommending implementation of new control strategies
- ✓ Updated timeline for manufacturers and applicants to implement these recommendations
- ✓ Associated information will be updated periodically at the FDA web page
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/control-nitrosamine-impurities-human-drugs?utm_medium=email&utm_source=govdelivery

Allfälliges

USP-NF 2024 Issue 3:

- ✓ Published and will get effective on 01 DEC 2024
- ✓ Some new chapters and monographs highlighted:
  - <2800> Multi-Ingredient Dietary Supplement Products—Product Quality Tests
  - Polyethylene Glycol 40 Castor Oil
  - Soybean Phosphatidylcholine
  - Soybean Phospholipids
  - Carbamazepine Extended-Release Capsules
  - Choline Fenofibrate
- ✓ Some revised chapters and monographs:
  - <2> Oral Drug Products - Product Quality Tests
  - <87> Biological Reactivity Tests, In Vitro
  - <88> Biological Reactivity Tests, In Vivo
  - <781> Optical Rotation
  - <782> Vibrational Circular Dichroism Spectroscopy
  - Antithrombin III Human
  - Cyclophosphamide Capsules
  - Dimethyl Sulfoxide
  - Dimethyl Sulfoxide Irrigation

Allfälliges

USP Proposal for Elastomeric Packaging Components:

- ✓ Revised chapter <381> published for comments until 30 SEP 2024
- ✓ https://www.gmp-compliance.org/gmp-news/usp-proposal-for-elastomeric-packaging-components?utm_source=Newsletter&utm_medium=email&utm_campaign=MEU_KW29

USP Proposal for Metallic Packaging Systems:

- ✓ <662> Metallic Packaging Systems and Their Materials and Components of Construction
- ✓ <1662> Materials and Manufacturing Processes for Metallic Packaging Systems
- ✓ Deadline for comments: 30 SEP 2024
- ✓ https://www.gmp-compliance.org/gmp-news/usp-proposal-for-metallic-packaging-systems?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW28-2024

USP proposed revision of Endotoxin Test:

- ✓ <1085> Guidelines for Testing for Endotoxins
- ✓ Include recombinant reagents
- ✓ Further details on the changes can be found in the revision proposal on the USP website after registration.
- ✓ https://www.gmp-compliance.org/gmp-news/revision-of-usp-1085-guidelines-on-endotoxin-test?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU_KW34

Allfälliges

USP Update Excipient List

- ✓ published for comments until 30 SEP 2024
- ✓ You can view and comment on this draft 'Excipients, USP and NF Excipients, Listed by Functional Category' after a one-time registration on the website of the Pharmacopeial Forum
- ✓ https://www.gmp-compliance.org/gmp-news/usp-updated-excipient-list-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU-KW35-2024

USP revised chapter <1033> validation of biological assays

- ✓ Open for commenting

USP revised general chapter on Biocompatibility of Pharmaceutical Packaging Systems

- ✓ <1031>
- ✓ Biocompatibility of Pharmaceutical Packaging Systems and their Materials of Construction
- ✓ Effective date: 01 DEC 2024

Allfälliges

Australian TGA introduces shorter Surveillance Inspections:

- ✓ Under defined conditions, so-called “surveillance inspections” are carried out
- ✓ Starting 01 JUL 2024
- ✓ This applies to both domestic and foreign manufacturers
- ✓ Primary aim to reduce overdue inspections and reduce business disruptions caused by delays in re-inspection
- ✓ https://www.gmp-compliance.org/gmp-news/tga-introduces-shorter-surveillance-inspections?utm_source=Newsletter&utm_medium=email&utm_campaign=NL-MEU_KW33
- ✓ Please note: there is an MRA in operation between EU and Australia since 01 JUN 1999 for human medicines (excluding ATMPs)

Allfälliges

Japanese Pharmacopoeia 18th Edition Supplement II:

- ✓ Will get effective on 31 DEC 2025
- ✓ Some changes highlighted:
  - **New chapters** added to this supplement:
    - 3.07 Particle Size Determination in Liquid by Dynamic Light Scattering
  - **Revised chapters** of this supplement:
    - 2.03 Thin-layer Chromatography
    - 2.46 Residual Solvents
    - 2.66 Elemental impurities
    - 3.01 Determination of Bulk Density
    - 4.02 Microbial Assay for Antibiotics
    - 5.01 Crude Drugs Tests
- ✓ The official English translated version is expected to be released in the future by the Japanese PMDA.

Allfälliges

The EAEU Pharmacopoeia Volume 1 Part 2:

- ✓ Published with transition period until January 2026

China NMPA announcing applicability of ICH Q2(R2) and Q14:

- ✓ Studies required in accordance with requirements on ICH guidelines Q2 (validation of analytical procedures) and Q14 (analytical procedure development) for studies starting from 24 November 2024
- ✓ Published in Chinese language on 28 MAY 2024
- ✓ https://www.gmp-compliance.org/gmp-news/nmpa-announcement-on-application-of-ich-q2r2-and-q14-principles?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW24-2024-MEU

China Counterespionage Law – what is Industry Thinking?

- ✓ Survey by EQPA and EU GMP Auditor Association
- ✓ Survey results available in the member's area of EQPA
- ✓ https://www.qp-association.eu/qpag_members_survey.html?utm_source=Newsletter&utm_medium=email&utm_campaign=Sonder-KW27-2024-EQPA

Allfälliges

Clinical Trial Regulation – A QP's Perspective:

- ✓ CTR is applicable since 31 JAN 2022
- ✓ Transition phase will end on 31 JAN 2025
- ✓ German QP Association (GQPA) summarized its perspective in an article in the English edition of the GMP Journal
- ✓ https://www.gmp-journal.com/current-articles/details/ctr-implementation-a-qps-perspective.html

- Präsentationen werden wieder im Internet abrufbar sein:
  www.austria-qp.at
- Teilnehmerliste/Schulungsdokumentation: *Winfried Chang*
- 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

  Programm in wenigen Tagen unter:

  https://www.austria-qp.at/qpaus_events.html

- **Nächstes Vereinstreffen der AQPA:**

  Donnerstag, 15. Mai 2025

Wir wünschen einen schönen Abend,
viel Spaß beim Netzwerken und
hoffen auf zahlreiches reales Wiedersehen am
15. Mai 2025

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