Generalversammlung und Vereinstreffen der AQPA

16. Oktober 2025

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
- 18:00 Begrüßung
- Rechnungsprüfung (*Markus Thiel/Roche*)-> 2 Freiwillige
- Wahl des Vorstandes
- Präsentationen:
  - Pharmig: Vorstellung und zukünftige Zusammenarbeit mit AQPA *(Birgit Krimmel/Pharmig)*
  - Praxisbeispiel: mikrobiologische Kontamination eines Arzneimittels *(Klaus Hofstädter/AOP)*
  - Allfälliges: Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
  - Mitglieder-Umfrage *(Carina Rappel/Boehringer Ingelheim)*
- Teilnehmerliste *(Regine Tomasits/ViruSure)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

Wahl des Vorstandes

- Wahlvorschlag:
  - **Obmann – NEU: Stefan Schneider**
  - **Obmann Stellvertreterin – Gabriela Schallmeiner**
  - **Kassier – Markus Thiel**
  - **Schriftführerin – Regine Tomasits**
  - Erweiterter Vorstand:
    - **Winfried Chang**
    - **Klaus Hofstädter**
    - **Carina Rappel**
    - **Richard Vasicek**
- Alternative Vorschläge?
  - Keine alternativen Vorschläge eingereicht
- Abstimmung durch Handzeichen

aqpa
Austrian Qualified Person Association

Background

- 15+ years in Biopharmaceutical Industry (various positions at Baxter/Baxalta and Boehringer Ingelheim)
- Qualified Person since 2014

Education

- Pharmaceutical Quality Management (university course)
- Bioprocess Technology (Master's Degree)
- Biomedical Engineering (Bachelor's Degree)
- Economic Engineer (Secondary School)

Personal

- Happily married, 2 Kids
- 20+ years club work (treasurer)

Ing. Stefan Schneider, MSC

HoU Product Release Mammalian

T +43 (00) 1 80105-5383

E stefan_2.schneider@boehringer-ingelheim.com

PHARMIG

PHARMIG

Verband der pharmazeutischen Industrie Österreichs

Wien, 16.Oktober 2025

PHARMIG – **DIE** Interessensvertretung

- gegründet vor rund 70 Jahren
- eigene Interessenvertretung in Ergänzung zur WKO
- ca. 120 Mitgliedsunternehmen
- etwa 96 % Marktabdeckung
- Klein-, Mittel- und Großunternehmen
- forschende, produzierende und Vertriebsunternehmen
- Originale, Generika, Biologika, Biosimilars, Phyto-pharmaka


PHARMIG
Verband der pharmazeutischen Industrie Österreichs
Public Affairs & Market Access
Rainer Thomas
Head
Silvia Bauernhofer
Expert Market Access
Yasmin Huber
Senior Assistant
Andreas Weinseiss
Public Affairs Manager
International Affairs
Claudia Obernhuber
Head
Markus Miller
Project Manager
Finance, Human Resources & Administration
Astrid Schlegel
Head
Petra Glaser
General Assistant
Duska Hauser
Senior Assistant HR & Event Management
Andrea Marek
Senior Assistant Finance
Karin Schröfl
Medical Representatives Manager
WIR ARBEITEN FÜR RUND 120 MITGLIEDSUNTERNEHMEN UND 18.000 BESCHÄFTIGTE.
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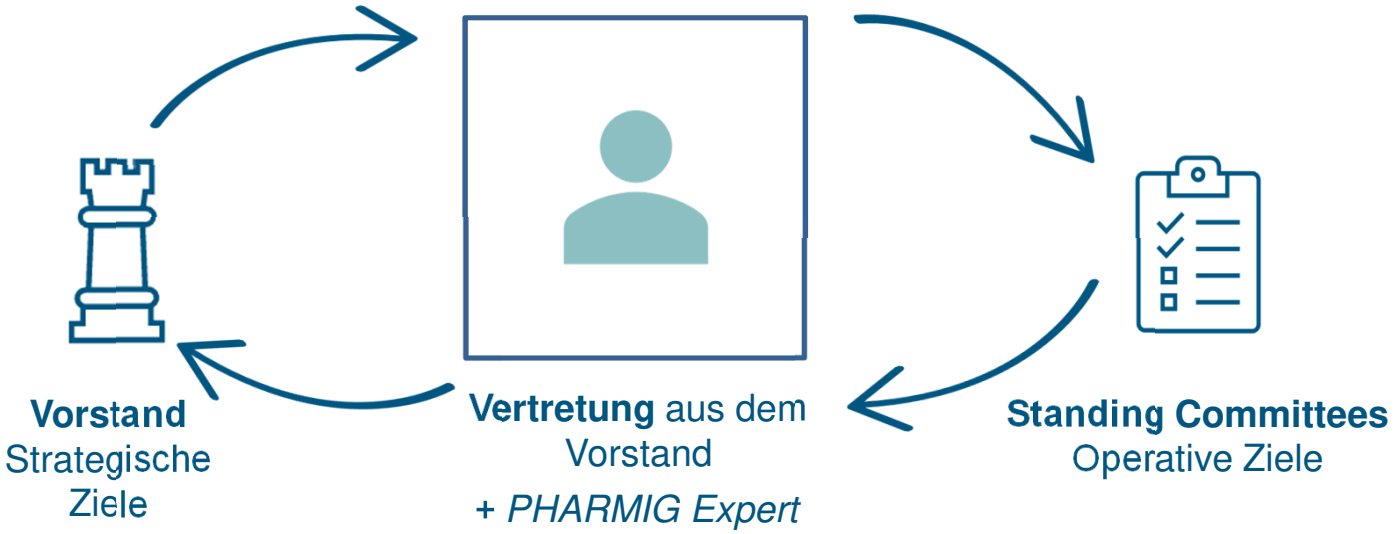
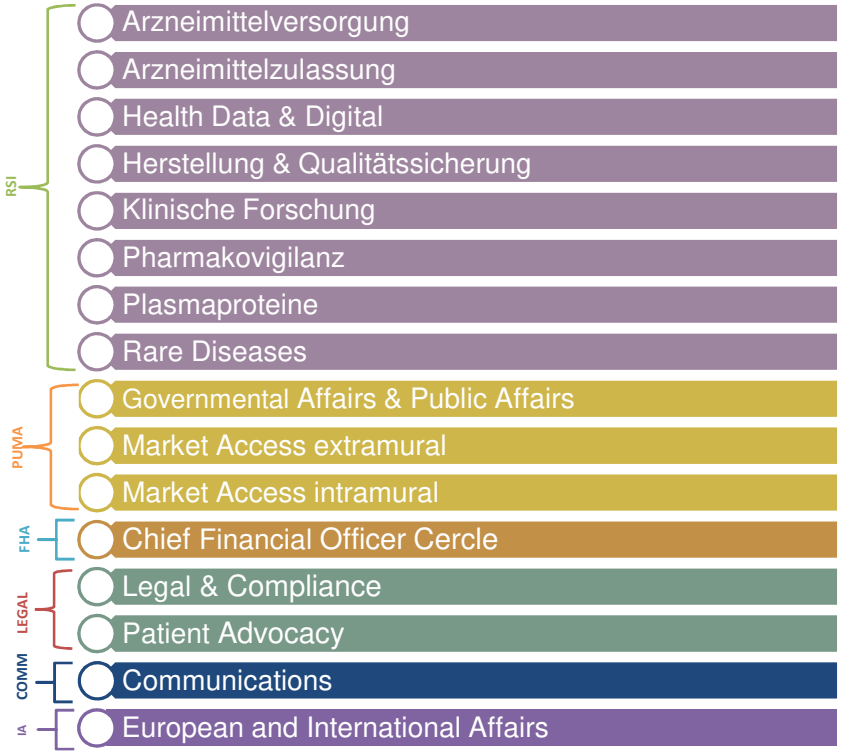
Alexander Herzog
Klaudia Pulka
Executive Assistant
Transition Management
Ronald Pichler
Transition Manager
Public Affairs & Market Access
Regulatory Affairs, Supply & Innovation
Linda Krempl
Head
Susanne Baumgartner
Expert Regulatory Affairs
Christa Holzhauser
Expert Clinical Research & Development, Rare Diseases
Birgit Krimmel
Expert Quality, Production & Distribution
Michael Kunze
Health Innovation Manager
Legal Affairs & Compliance
Barbara Bos
Head
Yulia Kals
Legal Expert
Communications & Public Relations
Peter Richter
Head
Martina Dick
Communications Expert
Stefan Prims
Communications Expert
PHARMIG Academy
Eva Waldmann
Head
Georgina Vargas de Novak
Senior Events & Marketing Manager
Alexander Fritsch
Junior Assistant Events
N.N.
Learning and Knowledge Manager

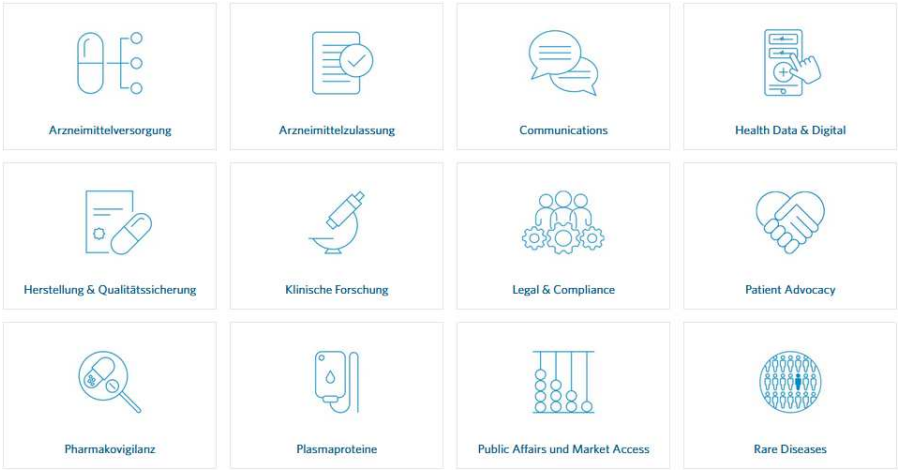
PHARMIG Standing Committees

Grundsätze und Regeln der PHARMIG SCs



PHARMIG Standing Committees

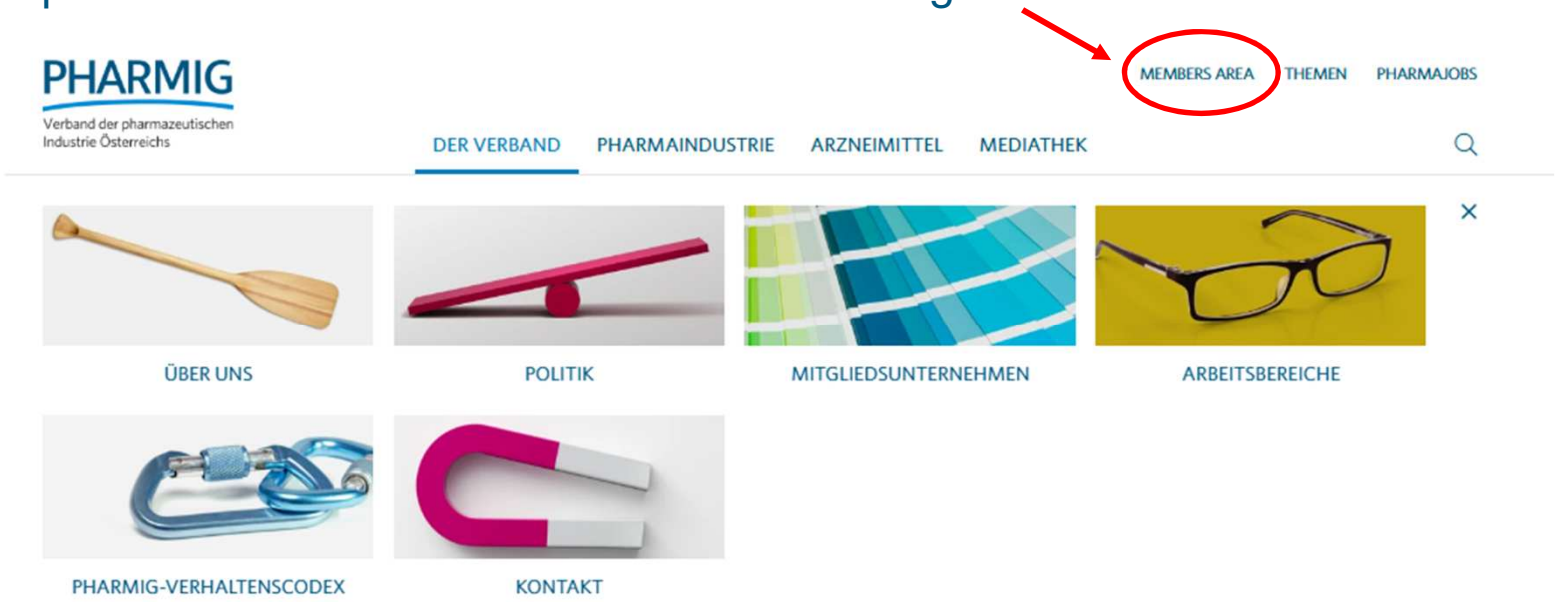




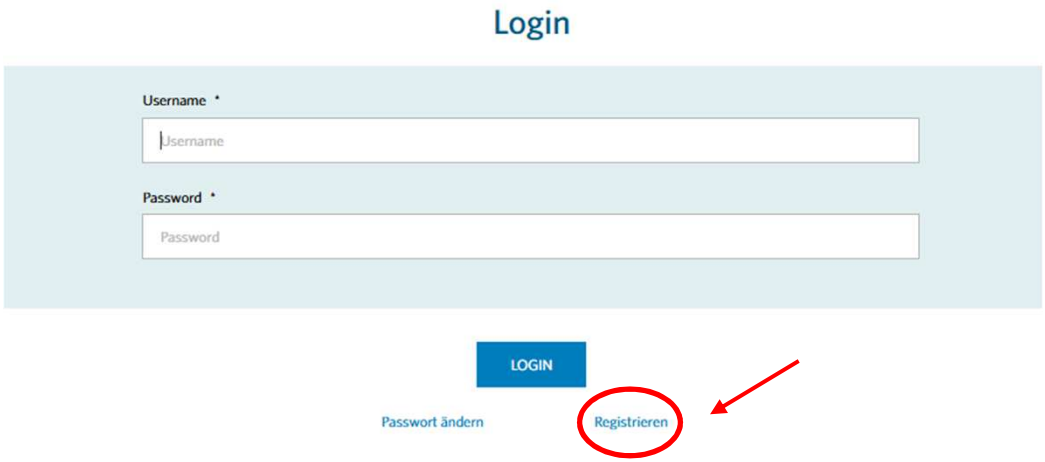
pharmig.at/der-verband/arbeitsbereiche/

PHARMIG Members Area

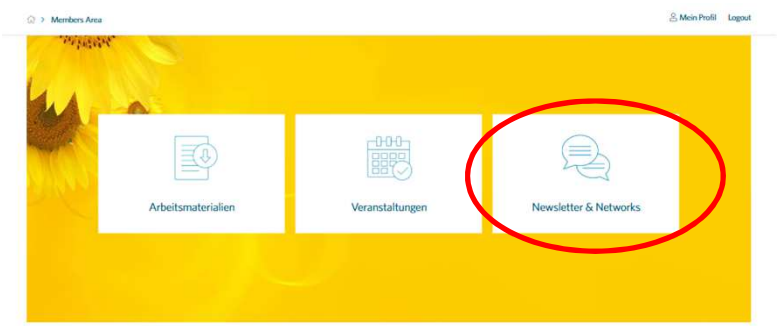
Um Informationen zugesendet zu bekommen, können sich interessierte Mitarbeiter:innen eines Mitgliedunternehmens persönlich auf der PHARMIG Webseite registrieren!

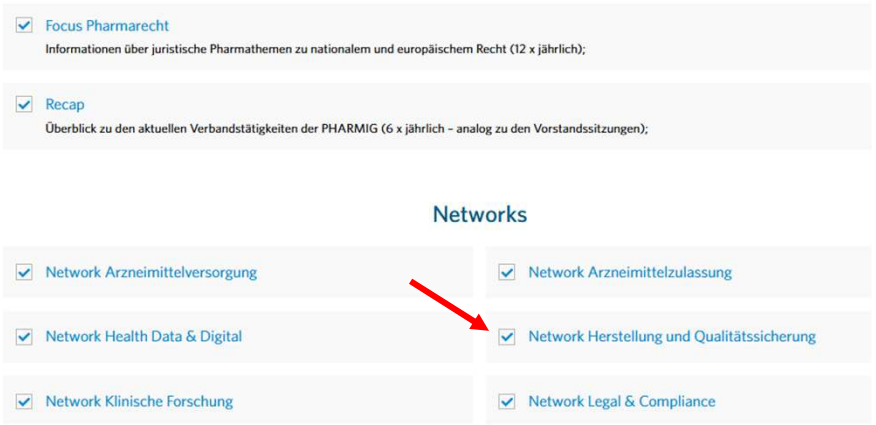


PHARMIG Members Area



PHARMIG Members Area





Regulatory Affairs, Supply & Innovation

PHARMIG RSI Team

Susanne Baumgartner
Expert Regulatory Affairs

Linda Krempl
Head of Regulatory Affairs, Supply & Innovation

Christa Holzhauser
Expert Clinical Research & Development, Rare Diseases

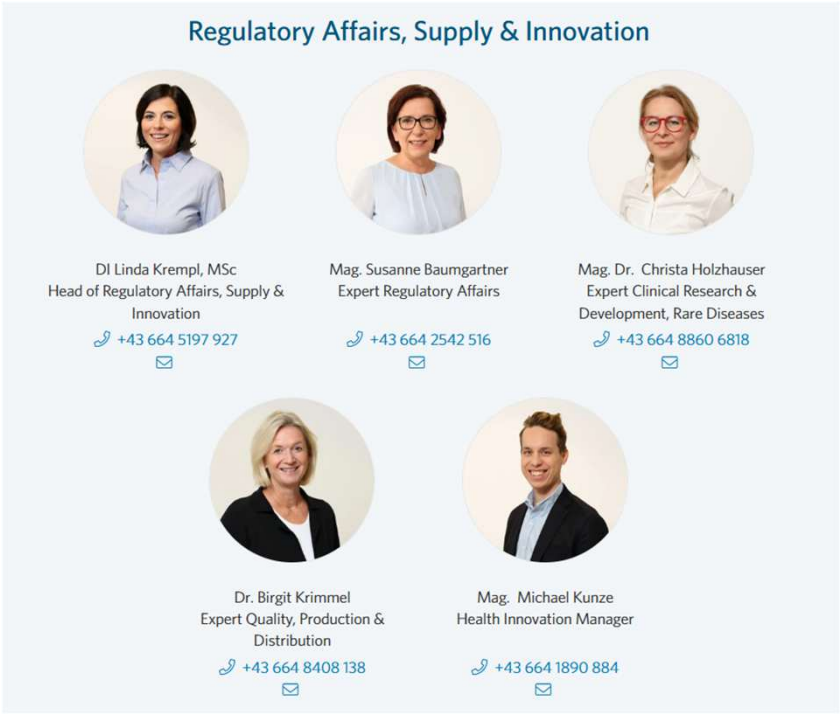
Birgit Krimmel
Expert Quality, Production & Distribution

Michael Kunze
Health Innovation Manager

PHARMIG RSI Leitung der SCs

PHARMIG RSI / SC Leitung

- Klinische Forschung
- Herstellung & Qualitätssicherung
- Arzneimittelzulassung
- Pharmakovigilanz
- Arzneimittelversorgung
- Plasmaproteine
- Rare Diseases
- Health Data & Digital



RSI Standing Committees

Standing Committee HSQS

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[Takeda Manufacturing Austria AG]

Co-Chair
DI Werner Giefing
[Octapharma Pharmazeutka Produktionsgesellschaft m.b.H.]

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Nora Kampitsch, MSc, MBA
[Merck Sharp & Dohme Ges.m.b.H.]

DI Dr. Markus Klingler
[Gebro Pharma GmbH]

DI Claudia Koban
[Boehringer Ingelheim RCV GmbH & Co KG]

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Mag. Katherina Schmidt
[Pharmazeutische Fabrik Montavit Ges.m.b.H]

Ing. Doris Sturm
[Fresenius Kabi Austria GmbH]

Standing Committee HSQS

Dr. Bernhard Wittmann
[Sigmapharm Arzneimittel GmbH]

Jörg Zimmermann
[Vetter Development Services]

Interesse an Mitarbeit?

Kontakt: birgit.krimmel@pharmig.at

Disclaimer

Bei den gegenständlichen Folien handelt es sich um eine aus Stichworten bestehende Unterlage, welche keinen Anspruch auf Vollständigkeit erhebt.
Dieses Dokument enthält Verlinkungen zu externen Dokumenten.

Bilder: Fotolia

Die Verwendung von Inhalten dieser Folien bedarf der vorherigen schriftlichen Zustimmung der Pharmig.

Praxisbeispiel: mikrobiologische Kontamination eines Arzneimittels

(Klaus Hofstädter/AOP)

AQPA Vereinstreffen Oktober 2025

Praxisbeispiel mikrobiologische Kontamination und Chargenfreigabe ?

16. Oktober 2025

Dr. Klaus Hofstädter, Qualified Person
AOP Orphan Pharmaceuticals GmbH

Disclaimer

Der Inhalt der Folien ist ausschließlich Eigentum von AOP Health. Diese Folien dürfen nur an die Teilnehmer der Konferenz für deren Eigengebrauch verteilt werden. Die Folien dürfen nicht an Dritte weitergegeben werden.

Diese Präsentation erfolgt in meinem eigenen Namen. Ich spreche nicht im Namen meines Arbeitgebers. Alle geäußerten Ansichten, Einschätzungen und Inhalte sind unabhängig erstellt und stellen keine offizielle Position meines Unternehmens dar.

INHALT

Hintergrund

Aktuelle Problematik

Lösungs-möglichkeiten ?

Hintergrund

Hintergrund

Produkt

- Small molecule
- Fertigprodukt Lyophilisat, 50 ml Vial
- Akuttreatment
- Befüllung 12,5 ml vor Lyophilisation

Herstellung:

- Ansatzlösung 39 L
- Bestandteile: 1,95 kg API / 1,95 kg Mannitol / WFI
- Zeit Ansatzlösung vor Filtration: max. 6 h

Aktuelle Problematik

Aktuelle Problematik (1)

Daten

- **<u>Mikrobiologische Belastung der Ansatzlösung:</u>**
  - In einer 1:100 Verdünnung „too numerous to count“
  - Das bedeutet in unserem Fall > 25.000 CFU/100 ml
  - Dauer max. 6 h
- Gefundene Spezies: Burkholderia cepacia complex (Bcc)
- Reinigungsprobleme im Ansatztank (multi-use, händische Reinigung), Verkeimung der Ansatzlösung
- Ev. Biofilm ?

Freigabeanalytik

- Doppelte Sterilfiltration, vor Sterilfilter 0 CFU/100 ml (durch Filtervalidierung abgedeckt)
- Produktanalytik compliant, keine Auffälligkeiten
- Endotoxinlimit NMT 1.0 IU/mg
- Sterilitätstest OK

Zulassung erfüllt – 5 betroffene Bulkchargen wurden von der QP des CMO freigegeben.
Ein Problem und die Systematik dahinter wird nicht gesehen.

Aktuelle Problematik (2)

AMBO 2009 sagt folgendes:

§7 (12)

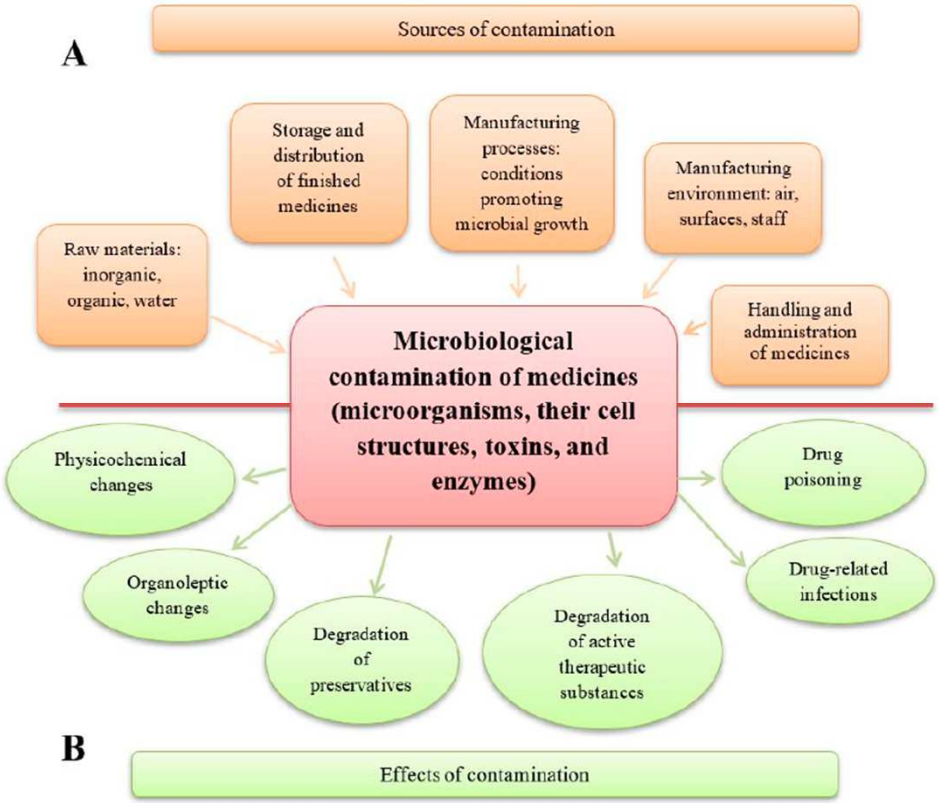
Bei der abschließenden Kontrolle vor der Freigabe gemäß Abs. 13 sind zusätzlich zu den analytischen Ergebnissen die **Produktionsbedingungen**, die Ergebnisse der **Inprozesskontrollen**, die Überprüfung der Herstellungsunterlagen und die Übereinstimmung der Produkte mit ihren Spezifikationen, einschließlich der Endverpackung, zu berücksichtigen.

Aktuelle Problematik (3)

Aber:

Mögliche Kontamina-tionsquellen

Eine Kontamination der Ansatzlösung durch Metabolismus der Bakterien kann nicht ausgeschlossen werden.
Daten hierzu können praktisch nicht erhoben werden. Und somit ist eine Erfassung und Bewertung des toxikologischen Risikos nicht möglich.



Lösungsmöglichkeiten ?

Lösungsmöglichkeiten ?

- Freigabe der Chargen dennoch möglich?

Wie würden Sie entscheiden?

- <u>Berechnung einer möglichen Kontamination - Annahmen:</u>
  - Gewicht 1 Bakterie Burkholderia: 0,25–0,30 pg (Annahme aus Internet)
  - Kontamination: min. 25.000 CFU/100 ml Lösung
  - Volumen Lösung 39 L → 12,5 ml Lösung/Vial (equal to 300 mg API)
  - 4 g Tagesdosis
    → **12,5 ng/max. Dosis**
    → **0,25 ng/kg Körpergewicht** (Annahme: 50 kg)
    Zum Vergleich, stärkstes Toxin z.B. Botulinum Toxin LD_{50}-Wert 1 ng/kg IV

Weiteres Thema

Weiteres Thema

Bioburdenlimit Ansatzlösung vor erster Filtration

- Reference: EMA/CHMP/CVMP/QWP/850374/2015

„Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container”

In most situations, a limit of NMT 10 CFU/100 ml (TAMC) would be acceptable for bioburden testing. If a pre-filter is added as a precaution only and not because the unfiltered bulk solution has a higher bioburden, this limit is applicable also before the pre-filter and is strongly recommended from a GMP point of view. A bioburden limit of higher than 10 CFU/100 ml before pre-filtration may be acceptable if this is due to starting material known to have inherent microbial contamination. In such cases, it should be demonstrated that the first filter is capable of achieving a bioburden of NMT 10 CFU/100 ml prior to the last filtration. Bioburden should be tested in a bulk sample of 100 ml in order to ensure the

- Acceptable maximum limit: **NMT 100 cfu/100ml***

* if requested by authorities, lower limit may be required

Allgemeine Fragen

Allgemeine Fragen

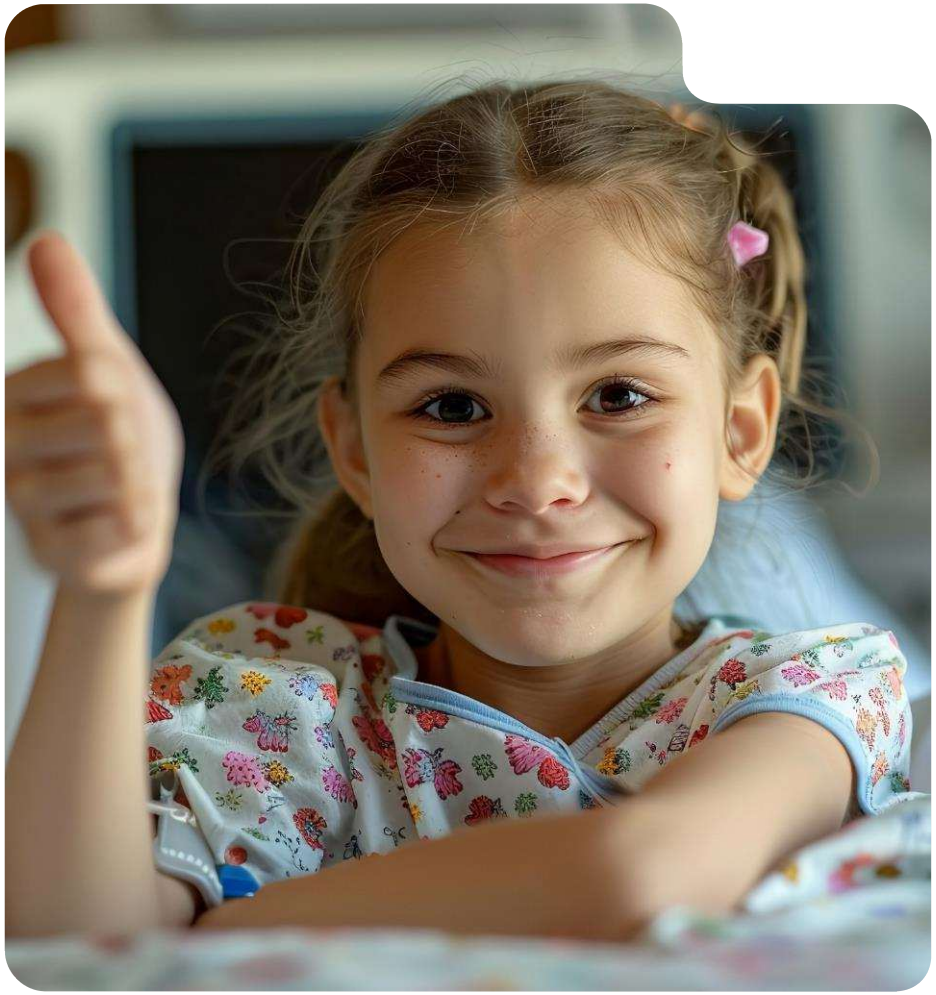
- Wer kennt freiberufliche Mibi-Experten für Risk Assessments/Expert Statements?

- Wie sind die Erfahrungen anderer QPs mit neuen, noch nicht erfassten Risiken bei der Chargenfreigabe? Gibt es hierzu bewährte Untersuchungsstrategien oder Informationsquellen?

Danke für Ihre Aufmerksamkeit

Our Vision

The most trusted company for integrated therapies for rare diseases and critical care in Europe ***& world wide.***



Contact

AOP Orphan Pharmaceuticals GmbH
Member of the AOP Health Group

Leopold-Ungar-Platz 2
1190 Vienna
Austria

aop-health.com
+43 1 503 72 44
office@aoporphan.com

Allfälliges:
Neuigkeiten von den Behörden
(Georg Göstl/Takeda)

50 Jahre QP!

- Direktive 75/319/EEC

  (am 17.12.2001 abgelöst durch 2001/83/EC -> voraussichtlich 2026 abgelöst durch neue EU-Arzneimittelgesetzgebung Dir. 2023/192)

  10 Seiten (1975) -> 62 Seiten (2001) -> 181 Seiten (Draft 2023)

EQPA-Newsletter
Special Edition:
50 years Qualified Person

- Im “Download Area” (Members Area)
- https://www.qp-association.eu/qpag_index.html

Österreich

- **BASG „All-in-one-Register“:**
  - Alte BASG-Register nur noch bis November 2025, danach „All-in-One Register“ (Info BASG Gespräch 11.06.2025) :

    BASG All-in-One Register

- **Anpassung Antragsformular für QP, Herstellungsleiter, Kontrolllaborleiter nach AMBO 2009 und TAMBO:**
  F_I220_Antrag_auf_Ausstellung_einer_Bestaetigung_Sachkundige_Person.docx

Allfälliges

BASG/AGES FAQs:

- Anpassung FAQs zu den meldepflichtigen Fachpersonen:
  FAQ - Meldepflichtige Fachpersonen – BASG

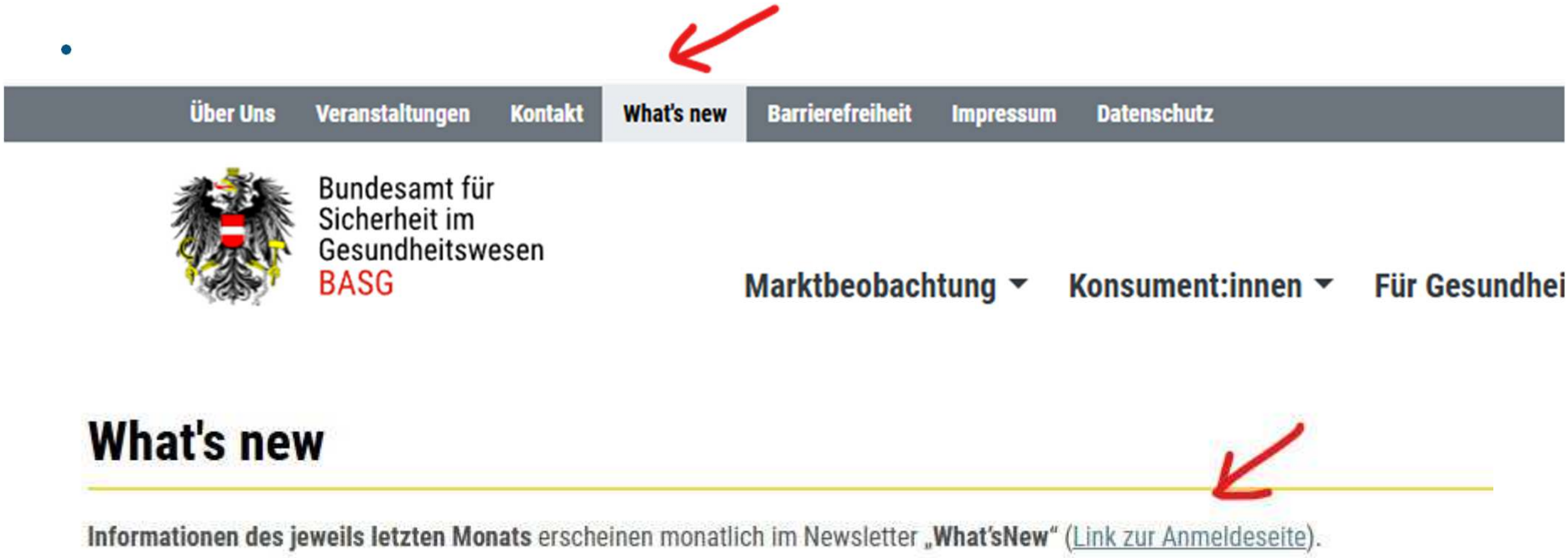
- FAQ – GMP/GDP:
https://www.basg.gv.at/fuer-unternehmen/bewilligung-und-zertifizierung/gute-herstellungs-/-vertriebspraxis-gmp/gdp/faq-gmp/gdp

-> Empfehlung BASG-Newsletter abonnieren!

Allfälliges

BASG Newsletter:

•Änderungen zu BASG FAQs über monatlichen Newsletter – Registrierung über Reiter „What‘s New“



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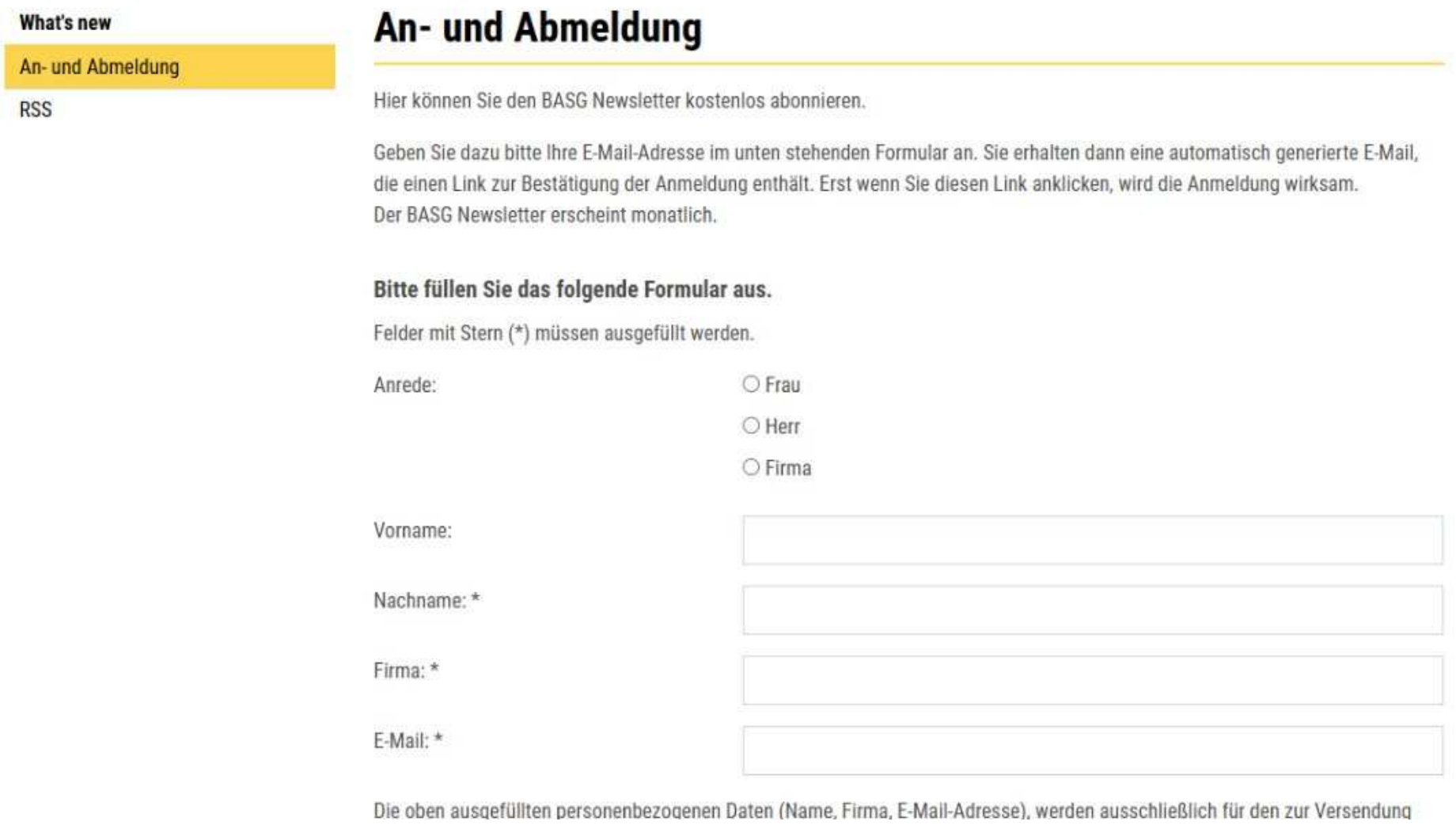

What's new

An- und Abmeldung

RSS

An- und Abmeldung

Hier können Sie den BASG Newsletter kostenlos abonnieren.

Geben Sie dazu bitte Ihre E-Mail-Adresse im unten stehenden Formular an. Sie erhalten dann eine automatisch generierte E-Mail, die einen Link zur Bestätigung der Anmeldung enthält. Erst wenn Sie diesen Link anklicken, wird die Anmeldung wirksam.
Der BASG Newsletter erscheint monatlich.

Bitte füllen Sie das folgende Formular aus.

Felder mit Stern (*) müssen ausgefüllt werden.

Anrede: ○ Frau ○ Herr ○ Firma

Vorname:

Nachname: *

Firma: *

E-Mail: *

Die oben ausgefüllten personenbezogenen Daten (Name, Firma, E-Mail-Adresse), werden ausschließlich für den zur Versendung

Allfälliges

EC Stakeholder Consultations:

- Revision of Chapter 4 – **Documentation** (from 9 to 17 pages)
- Revision of Annex 11 – **Computerised Systems** (from 5 to 19 pages)
- New Annex 22 – **Artificial Intelligence**
- Deadline for comments: 07 October 2025
- https://health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-4-annex_en

EU GMP Guide Chapter 1 Pharmaceutical Quality System:

- ✓ Stakeholder consultation by PIC/S & EMA
- ✓ Deadline 03 DEC 2025
- ✓ Establish effective framework based on good science and risk management
- ✓ Stressing importance of **proactive identification** of manufacturing risks to **prevent shortages** and mitigate **supply chain vulnerabilities**
- ✓ Clarifying requirements for **PQR**
- ✓ https://health.ec.europa.eu/consultations/stakeholders-consultation-eudralex-volume-4-good-manufacturing-practice-guidelines-chapter-1_en
- ✓ Zeitgleich auch Consultation des PIC/S GMP-Guide Kapitel 1
- ✓ Deadline 03 DEC 2025
- ✓ News

Allfälliges

EU Guidelines on categories of variations

- Examination of variations to the terms of the marketing authorisation
- Will become **mandatory from 15 JAN 2026**
- Revised and updated as part of update to the Variation Regulation (2024/1701 of 11 March 2024 (amending Regulation 1234/2008))
- Containing extensive list of type/scope of changes and related type/documentation/Conditions to be fulfilled
- 94 pages
- https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202505045

Allfälliges

EC decided not to ban titanium dioxide in medicines:

- Not banned in medicines despite its ban as food additive
- TiO_2 is used in about 91.000 human medicines and is critical for safety, quality, and efficacy, with no feasible alternatives
- EMA concluded carcinogenicity risk is negligible, given the small quantities in medicines
- Companies should monitor new developments for future products
- https://health.ec.europa.eu/latest-updates/commission-staff-working-document-use-titanium-dioxide-medicinal-products-2025-08-06_en
- On August 6, 2025, the EC published a staff working document confirming that TiO_2 will continue to be permitted in medicinal products within the EU. EFPIA has confirmed that the EC's decision is final and does not require any further legal action to maintain the use of TiO_2 in medicines.

EMA introduces a Limited Disclosure Notice process:

- ✓ Exchange of data relating to chemistry, manufacturing and controls (CMC) with **EMA's trusted partners**
- ✓ Will be disclosed to industry in advance, companies have opportunity to raise any objections within **48 hours**
- ✓ Trusted partners can be found at: https://www.ema.europa.eu/en/partners-networks/international-activities/international-agreements

Allfälliges

Keine neuen Q&A der EMA zu GMP und GDP seit Mai 2025:

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

EMA Q&A on impact of Mutual Recognition Agreement (MRA between EU and USA as of 01 OCT 2025:

- ✓ EMA/INS/GMP/369445/2024
- ✓ Human Vaccines and human-plasma-derived products: immer noch nicht im Scope! ☹
  - ✓ „A new date needs to be agreed“
  - ✓ Ursprünglich: “No later than **15 July 2022**, the Joint Sectoral Committee shall consider whether to include vaccines for human use and plasma derived pharmaceuticals within the product coverage of this Annex.”
  - ✓ „FDA has decided to consider the issue again in **July 2025** based on further assessment.”
  - ✓ Heute: 16. Oktober 2025 …
- ✓ IMPs and ATMPs excluded
- ✓ questions-and-answers-impact-mutual-recognition-agreement-between-european-union-and-united-states-7-August-2024_en (1)

Allfälliges

EMA/CMDh: Nitrosamine Q&A Document updated

- ✓ Revision 22

https://www.gmp-compliance.org/gmp-news/ema-cmdh-nitrosamine-q-a-document-updated?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW25-2025-MEU

EMA/HMA Nitrosamine Report:

- ✓ EMA/144509/2025
- ✓ Published 08 July 2025
- ✓ Nitrosamine impurities in human medicines – The response of the European Medicines Regulatory Network
- ✓ 18 pages
- ✓ Providing overview of the European Medicines Regulatory Networks response about nitrosamines
- ✓ https://www.gmp-compliance.org/gmp-news/ema-hma-nitrosamine-report-published?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW34-2025

Allfälliges

EMA's Clinical Trial Information system (CTIS):

- ✓ CTIS is mandatory since 31 JAN 2025
- ✓ EMA revised comprehensive **training materials** and **sponsor handbook**
- ✓ Version 6.0 published on 09 July 2025
- ✓ https://www.gmp-compliance.org/gmp-news/latest-information-on-the-emas-clinical-trials-information-system-ctis?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW35-2025-MEU

ECHA (European Chemicals Agency) updated PFAS restrictions

- ✓ PFAS (Per- and polyfluoroalkyl substances)
- ✓ Extensively revised document, now in Version 14
- ✓ https://www.gmp-compliance.org/gmp-news/echa-pfas-restrictions-updated?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW35-2025-MEU

Allfälliges

ICH Draft Q3E Guideline for Extractables and Leachables:

- ✓ Aligning with existing ICH impurity guidelines
- ✓ Requiring re-evaluation after product or process changes
- ✓ Date of Step 2b: 01 AUG 2025
- ✓ https://www.ich.org/page/quality-guidelines
- ✓ ICHQ3E as well as supporting documentation (class 3 leachable monographs) also published for public consultation by EMA:
- ✓ Deadline for comments: 18 DEC 2025
- ✓ ICH also published Training materials: “Q3E Step 2 Presentation”:
- ✓ https://www.ich.org/page/quality-guidelines#3-8
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q3e-guideline-extractables-leachables_en.pdf
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/ich-q3e-guideline-extractables-leachables-supporting-documentation-class-3-leachable-monographs_en.pdf

Allfälliges

ICH M4Q (R2) Guideline on CTD for registration of human pharmaceuticals:

- ✓ Published for comments
- ✓ Expanding scope to all pharmaceutical drug substances and products
- ✓ Enhancing Quality Module 2 to facilitate efficiency and effectiveness of submissions and assessments
- ✓ Deadline for comments: 24 OCT 2025
- ✓ https://www.ema.europa.eu/en/documents/scientific-guideline/ich-m4qr2-guideline-common-technical-document-registration-pharmaceuticals-human-use-quality-step-2b_en.pdf

ICH released training modules 1 to 7 on Q2/R2) "Validation of Analytical Procedures" and Q14 "Analytical Procedure Development"

- ✓ https://www.ich.org/news/ich-q2r2q14-iwg-training-materials-now-available-ich-website

Allfälliges

EDQM update Guideline “How to read a CEP”

- ✓ First revision published in May 2025
- ✓ Updates resulting from introduction of CEP 2.0 in 2023
- ✓ https://www.gmp-compliance.org/gmp-news/edqm-update-of-guideline-how-to-read-a-cep?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW23-2025-MEU

EDQM published 22nd version of its blood components guide:

- ✓ Donor selection
- ✓ Enhanced quality control measures
- ✓ https://www.edqm.eu/en/-/edqm-publishes-22nd-edition-of-the-blood-guide

EDQM new guidance document for QCABR:

- ✓ Points to consider for manufacturers/MAH for interaction with OMCLs during OCABR process
- ✓ PA/PH/OMCL (24) 105 R2

EDQM published revised texts on Pharmaceutical Water:

- ✓ WFI (0169), Purified Water (0008), TOC (2.2.44)
- ✓ Important steps towards further harmonization between Indian Pharmacopoeia, JP and USP
- ✓ TOC replacing test for oxidizable substances
- ✓ Revised text will be published in edition 12.3 of Ph. Eur. in January 2026 and will enter into force on 01 JUL 2026
- ✓ https://www.gmp-compliance.org/gmp-news/edqm-publishes-three-revised-texts-on-pharmaceutical-water?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW31-2025-MEU

Allfälliges

The European Pharmacopoeia Ph. Eur. 12.1 was published and will get effective on 01-Jan-2026:

Some chapters/monographs we want to highlight:

NEW General Chapters of this issue:

- 3.1.16. Cyclo-olefin polymers
- 3.1.17. Cyclo-olefin copolymers
- 3.1.18. Styrene block copolymers for containers and closures for parenteral preparations and ophthalmic preparations
- 5.36. mRNAvaccinesforhumanuse
- 5.39. mRNA substances for the production of mRNA vaccines for human use
- 5.40. DNA templates for the preparation of mRNA substances

NEW Monographs of this issue:

- Haemodialysis, concentrated solutions for (3206)
- Macrogol poly(vinyl acetate)-poly(vinylcaprolactam) grafted copolymer (3156)
- L-Malic acid (3143)
- Palonosetron hydrochloride (3041)
- Tazobactam (2210)
- Teriparatide injection (3130)

Revised General Monographs:

- 1. General Notices
- 2.2.39 Molecular mass distribution in dextrans
- 2.5.42 N-Nitrosamines in active substances and medicinal products
- 2.9.34 Bulk density of powders
- 4. Reagents
- 5.1.9 Guidelines for using the test for sterility
- 5.22. Names of herbal drugs used in traditional Chinese medicine

Revised General Chapters

- 2.4.20. Determination of elemental impurities
- 2.6.30. Monocyte-activation test
- 2.6.40. Monocyte-activation test for vaccines containing inherently pyrogenic components
- 2.7.24. Flow cytometry
- 3.1.3. Polyolefins
- 3.1.4. Polyethylene without additives for containers for parenteral preparations and for ophthalmic preparations
- 3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations
- 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations
- 3.1.7. Poly(ethylene-vinylacetate)forcontainersand tubing for total parenteral nutrition preparations
- 3.3.4. Sterile plastic containers for human blood and blood components
- 3.3.7. Sets for the transfusion of blood and blood components
- 5.1.10. Guidelines for using the test for bacterial endotoxins
- 5.2.11. Carrier proteins for the production of conjugated polysaccharide vaccines for human use
- 5.31. Phage therapy medicinal products
- 5.34. Additional information on gene therapy medicinal products for human use

Allfälliges

The European Pharmacopoeia Ph. Eur. 12.2 was published and will get effective on 01-Apr-2026:

Some chapters/monographs we want to highlight:

NEW General Chapters of this issue:

- 2.6.41. High-throughput sequencing for the detection of viral extraneous agents
- 5.32. Cell-based preparations for human use
- 5.37. Recombinant viral vectored vaccines for human use

NEW Monographs of this issue:

- 3002 Cedarwood oil
- 3187 Golimumab injection
- 3205 JK-PSMA-7 (18F) injection
- 2961 Ribwort plantain liquid extract

Revised General Monographs:

- 2.5.25. Carbon monoxide in gases
- 2.6.7. Mycoplasmas
- 2.9.50. Particle size analysis by dynamic light scattering
- 3.1.8. Silicone oil used as a lubricant
- 3.1.14. Materials based on plasticised poly(vinyl chloride) for containers for aqueous solutions for intravenous infusion
- 4.1.1. Reagents

Revised General & Individual Monographs:

- 0153 Vaccines for human use
- 0255 Human albumin solution
- 0430 Propylene glycol
- 0685 Povidone

Allfälliges

New Ph. Eur. Chapter on Phenolic antioxidants in Plastic Materials:

- 2.5.46
- Published in Pharmeuropa 37.3
- Deadline for comments: 30 SEP 2025
- https://www.gmp-compliance.org/gmp-news/phenolic-antioxidants-in-plastic-materials?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW28-2025

Ph. Eur. Chapter 3.2.1 Glass containers for pharmaceutical use revised:

- Published in Pharmeuropa 37.3
- Deadline for comments: 30 SEP 2025
- https://www.gmp-compliance.org/gmp-news/glass-containers-for-pharmaceutical-use?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW29-2025

Allfälliges

Ph. Eur. Update on Rubber Closures:

- Revised version of 3.2.9 published for comments
- Pharmeuropa 27.4
- Deadline 31 DEC 2025
- https://www.gmp-compliance.org/gmp-news/ph-eur-update-on-rubber-closures?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW38-2025

Pharmeuropa: Revision of Residual Solvents Chapter 2.4.24:

- Published in Pharmeuropa 37.4 for comments
- Fully revised draft
- Comments can be submitted until 31 DEC 2025
- Pharmeuropa: Revision of Residual Solvents Chapter 2.4.24 Published for Comments - ECA Academy

Allfälliges

Ph. Eur. New draft chapter 2.6.42 for procoagulant activity in immunoglobulin preparations:

- Public consultation in the current issue of *Pharmeuropa* (37.3).
- Stakeholders are invited to submit their comments by the end of September 2025.
- This new chapter has also been referenced in two revised monographs – *Human normal immunoglobulin for subcutaneous administration (2788)* and *Human normal immunoglobulin for intravenous administration (0918)* – which are likewise open for comment in *Pharmeuropa* 37.3.
- 3 methods described: chromogenic substrate assay (CSA) specific to FXIa, and two methods – the thrombin generation assay (TGA) and the non-activated partial thromboplastin time (NAPTT) assay
- https://www.edqm.eu/en/-/public-consultation-on-a-new-general-chapter-2.6.42.-test-for-procoagulant-activity-in-immunoglobulin-preparations-in-pharmeuropa-37.3

Allfälliges

Egypt joins EDQM's OMCL network as associated member:

- https://www.edqm.eu/en/-/egypt-joins-edqm-s-omcl-network-as-an-associated-member

PIC/S: Additional countries to become Pre-Applicants:

- Nigeria, Tanzania, Rwanda, and Senegal
- News

The EAEU Pharmacopoeia Volume 1 Part 3 is already effective with a transition period until 01-Jan-2026:

✓ There were several Texts added to the EAEU Pharmacopoeia

Allfälliges

Swissmedic updated QP Declaration for foreign manufacturers:

- clarify conditions for submitting risk assessments in Chapter 3.1 and update the contact phone number.
- https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl_hmv_iv/zl000_00_036d_wlgmp-konformitaetauslaendischerherstellervonwirks.pdf.download.pdf/zl000_00_036e_wlgmpcompliancebyforeignmanufacturersofactivepharm.pdf

Allfälliges

FDA draft guidance "Replacing Color Additives in Approved or Marketed Drug Products":

- ✓ Allow reformulation with ne color additives via CBE-30 supplement (not a prior-approval supplement)
- ✓ New color additive must conform to FDA's color additive regulations
- ✓ Updates required for labeling, composition statement, MBR, and specifications
- ✓ Documenting changes and maintaining records at manufacturing site is crucial

✓ https://www.fda.gov/media/186692/download

FDA issues FY 2024 report on the state of Pharmaceutical Quality

✓ https://www.fda.gov/media/188153/download?attachment

FDA releases White Paper on economics of quality management incentives:

- ✓ Comprehensive analysis demonstrating that strategic investments in quality management initiatives deliver measurable returns for both companies and public health
- ✓ Cost savings through reduced defects, decreased waste, improved operational efficiency
- ✓ https://www.fda.gov/drugs/pharmaceutical-quality-resources/cder-quality-management-maturity

Allfälliges

FDA Draft Guidance on Unique Device Identifier (UDI) Requirements for Combination Products:

- ✓ 26 Jun 2025
- ✓ US FDA published a draft guidance to help industry and FDA staff understand how UDI regulations apply to combination products with device constituent parts. Additionally, it clarifies how compliance with the Drug Supply Chain Security Act may exempt a product from UDI requirements. Finally, it includes best practices, recommendations, and illustrative examples to support compliance.
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/unique-device-identifier-requirements-combination-products

Allfälliges

FDA Final Guidance “Conducting Remote Regulatory Assessments”

- ✓ Final guidance for industry following reflected consideration of stakeholder comments
- ✓ Published 26 June 2025
- ✓ https://www.federalregister.gov/documents/2025/06/26/2025-11754/conducting-remote-regulatory-assessments-questions-and-answers-guidance-for-industry-availability

FDA thoughts on how AI-powered risk targeting with Elsa could change inspection readiness

- ✓ FDA’s new AI tool: Elsa
- ✓ FDA anticipates AI-assisted inspections
- ✓ Expect more potential variability in review timelines
- ✓ According to Ars Technica reporting: FDA staff encountered inaccurate and incomplete answers when querying Elsa about FDA-approved products during internal testing
- ✓ https://arstechnica.com/health/2025/06/fda-rushed-out-agency-wide-ai-tool-its-not-going-well/
- ✓ https://insider.thefdagroup.com/p/fda-elsa-ai-inspections

Allfälliges

FDA Final Guidance on Alternative Tools assessing Drug Manufacturing facilities identified in pending applications:

- ✓ September 2025
- ✓ Information on how FDA intends to use alternative tools to assess facilities during NDA, ANDA, BLA, or a supplement to those
- ✓ Tools may include:
  - ✓ Requesting records from manufacturers
  - ✓ Conducting remote interactive evaluations
  - ✓ Information from foreign regulatory partners
  - ✓ Collaborative inspections with FDA remote participants
  - ✓ Supporting PAI, PLI with FDA remote experts
- ✓ https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-tools-assessing-drug-manufacturing-facilities-identified-pending-applications?utm_medium=email&utm_source=govdelivery

Allfälliges

USP-NF 2025 Issue 3 published and will get effective on 01 DEC 2025:

- ✓ Some chapters highlighted:
- ✓ New General Chapters:
  - <1119> Bioburden Monitoring
  - <1119.1> Bioburden Test
  - <1245> Compaction Simulation
  - <1762> Solid State Nuclear Magnetic Resonance Spectroscopy - Theory and Practice
- ✓ Revised General Chapters:
  - <7> Labeling (eff. 01-Dec-2028)
  - <11> USP Reference Standards
  - <381> Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems
  - <761> Nuclear Magnetic Resonance Spectroscopy
  - <921> Water Determination
  - <1041> Biologics
  - <1047> Gene Therapy Products
  - <1265> Prescription Drug Infomration - Guidelines
  - <1761> Nuclear Magnetic Resonance Spectroscopy - Theory and Practice
- ✓ Revised Monograph:
  - Polyethylene Glycol

Allfälliges

USP-NF 2026 Issue 1 was published and will get effective on 01-Feb-2026:

Some chapters/monographs we want to highlight are added here:

- **NEW General Chapters / General Information Chapters**:
  - <317> ICP–OES Testing for Sodium Hydroxide and Potassium Hydroxids
  - <1040> Quality Considerations of Plasmid DNA as a Starting Material for Cell and Gene Therapies Including RNA Products
  - <1785> Osmolality and Osmolarity - Practical Considerations
- **Revised General Chapters / General Information Chapters**:
  - <41> Balances
  - <202> Identification of Fixed Oils By Thin-Layer Chromatography
  - <785> Osmolality and Osmolarity
  - <788> Particulate Matter in Injections (harmoized)
  - <797> Pharmaceutical Compounding—Sterile Preparations
  - <1085> Guidelines For Bacterial Endotoxins Testing
  - <1251> Weighing on an Analytical Balance
- **Revised Monograph:**
  - Lactose Monohydrate

Allfälliges

The **USP-NF 2026 Issue 2** was published and will get effective on **01-Apr-2026:**

- Some chapters/monographs we want to highlight are added here:
- **NEW General Chapters / General Information Chapters**:
  - ⟨315⟩ NMR Spectroscopy Number-Average Molecular Weight Determination for Lactide or Lactic Acid and Glycolide or Glycolic Acid Polymers
  - ⟨316⟩ Gel Permeation Chromatography Molecular Weight and Polydispersity Determination for Lactide or Lactic Acid and Glycolide or Glycolic Acid Polymers Using Universal Calibration
  - ⟨1154⟩ Liposome Drug Products
- **Revised General Chapters / General Information Chapters**:
  - ⟨651⟩ Congealing Temperature
  - ⟨701⟩ Disintegration
  - ⟨921⟩ Water Determination
  - ⟨1059⟩ Excipient Performance
- **Revised Monograph:**
  - White Petrolatum

Allfälliges

USP stimuli article proposes revision of USP Definition of Controlled Room Temperature:

- ✓ Discrepancy between USP (20-25°C) and JP, EP, WHO (15-25°C)
- ✓ Commenting until 31 JUL 2025
- ✓ https://www.gmp-compliance.org/gmp-news/stimuli-article-proposes-revision-of-usp-definition-of-controlled-room-temperature-crt?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW20-2025

New USP Chapter <1079.5> Transportation Lane Temperature Mapping and Qualification:

- ✓ Also a stimuli article "Transportation Lane Temperature Mapping and Qualification – Risk Identification and Evaluation" was published
- ✓ Published for comments until 30 NOV 2025
- ✓ Transportation modes, routes, and systems may need to be evaluated to identify risk areas and to assess the effectiveness of mitigation strategies
- ✓ It *"applies to every supply chain partner from the manufacturer through any entity that stores or holds a finished drug product, with the sole exception of the patient."*
- ✓ https://www.gmp-compliance.org/gmp-news/new-usp-chapter-1079-5-transportation-lane-temperature-mapping-and-qualification-published-for-comments?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW38-2025

Allfälliges

USP Draft Chapter on Extractables and Leachables in Parenteral Products:

- ✓ published in Pharmacopeial Forum (PF) 51(3)
- ✓ open for public comment until 31 July 2025
- ✓ https://www.gmp-compliance.org/gmp-news/usp-draft-chapter-for-e-ls-in-parenteral-drug-products?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW23-2025-MEU

USP: Process Analytical Technology

- ✓ New general chapter <1037> and 2 related stimuli articles
- ✓ Comments possible until 31 July 2025
- ✓ https://www.gmp-compliance.org/gmp-news/usp-comments-possible-on-the-topic-process-analytical-technology?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-KW25-2025-MEU

Allfälliges

USP update <1099> on Content Uniformity in Large Samples:

- ✓ Draft provides statistical method to assess large data sets using a zero-tolerance criterion
- ✓ Deadline for comments: 31 JUL 2025
- ✓ https://www.gmp-compliance.org/gmp-news/update-of-usp-chapter-1099-on-content-uniformity-in-large-samples?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW20-2025

USP proposal for Chapter <320> NMR-Based Determination of Degree of Hydrolysis and Monomer Ratio in Polyvinyl Alcohols

- ✓ The new draft can be viewed on the Pharmacopeial Forum website. Stakeholders are invited to review and comment on the draft chapter until 31 July 2025.

USP Drafts of new chapters <662> and <1662> on metal packaging materials:

- ✓ Re-published in the Pharmacopoeial Forum
- ✓ Deadline for comments: 30 NOV 2025
- ✓ https://www.gmp-compliance.org/gmp-news/usp-republishes-metal-packaging-drafts?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW39-2025

Allfälliges

USP new chapter <1049.1> Stability Studies for Biotechnological and Biological Products:

- ✓ To supplement chapter <1049>
- ✓ Detailed recommendations on design, conduct and adaptation of stability studies throughout the entire product life cycle
- ✓ To create a scientifically sound, regulatory accepted and risk based strategy for validating and controlling shelf life and storage conditions of such products
- ✓ For full context and regulatory compliance, refer to the complete draft available on the official USP website.
- ✓ Public comments are accepted until 30 September 2025
- ✓ https://www.gmp-compliance.org/gmp-news/usp-chapter-1049-1-stability-studies-for-biotechnological-and-biological-products?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW34-2025

Allfälliges

USP revising <1072> on Disinfectants and Antiseptics

- Proposal published more than 2 years ago (PF 46(5)) withdrawn and will be revised based on comments received
- Further details can be found, upon prior registration, in the chapter draft <1072> on the USP Webseite.
- https://www.gmp-compliance.org/gmp-news/usp-1072-revision-of-the-chapter-on-disinfection-and-antiseptics?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW34-2025

USP revising <111> Design and Analysis of Biological Assays

- https://www.gmp-compliance.org/gmp-news/usp-publishes-revision-of-chapter-111-design-and-analysis-of-biological-assays?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW36-2025
- Details can be found at USP website (following registration):
- https://login.usp.org/cas/login?service=https%3A%2F%2Fonline.uspnf.com%2Fcas%2Flogin

USP revised chapters Balances <41> and Weighing on an Analytical Balance <1251>

- Final chapters now available
- Will become official in February 2026

✓ https://www.gmp-compliance.org/gmp-news/usp-chapters-balances-41-and-weighing-on-an-analytical-balance-1251-final?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW36-2025

Allfälliges

USP draft Chapter <1029> Good Documentation Guidelines and Data Integrity:

- ✓ Published for comments
- ✓ Available on Pharmacopoeial Forum website (registration required)
- ✓ Deadline for comments: 30 SEP 2025
- ✓ https://www.gmp-compliance.org/gmp-news/usp-chapter-1029-good-documentation-guidelines-and-data-integrity-published-for-comment?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW28-2025

USP draft revised General Chapter <1231> on Pharmaceutical Water:

- ✓ Draft revision published in the Pharmacopoeial Forum PF 51(4)
- ✓ Available on Pharmacopoeial Forum website (registration required)
- ✓ Deadline for comments: 30 SEP 2025
- ✓ https://www.gmp-compliance.org/gmp-news/the-usp-has-revised-the-general-chapter-1231-on-pharmaceutical-water?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA-GMP-Newsletter-MEU-KW28-2025

Allfälliges

2 New EQPA Newsletter issues available:

- All EQPA Newsletters in the download section of the members' area.
  - Issue 21, July 2025
  - Special Issue, September 2025 "20 Years Anniversary EQPA, 50 Years Qualified Person"
- https://www.qp-association.eu/qpag_download.html#7

Website der AQPA im neuen Look

- Die Website der Austrian Qualified Person Association ist für Sie Ihre zentrale Anlaufstelle als Mitglied. Wir freuen uns, Ihnen mitteilen zu können, dass sie nun mit einem frischen, modernen Design neu gestartet wurde.
- Auf der neuen Website finden Sie weiterhin alles, was Sie von der bisherigen Seite gewohnt sind: Mitglieder-Infos, News, Events, wichtige Dokumente für Ihre tägliche Arbeit und vieles mehr. Machen Sie sich gleich selbst ein Bild vom Look & Feel der neuen aqpa Website.

Zur neuen Website

Danke an Concept Heidelberg für die Erstellung und Betreuung der AQPA Website!

Mitglieder-Umfrage

Carina Rappel

(Boehringer Ingelheim)

bzw. Link für die Teilnehmer:
https://www.menti.com/almei6wcyro7

Join at menti.com: access code

3608 6376

- Präsentationen werden wieder im Internet abrufbar sein: www.austria-qp.at
- **2 Rechnungsprüfer** -> *Markus Thiel*
- 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 2025 der EQPA:**

  26.-28. November 2025 in Barcelona, Barceló Sants Hotel

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

- **Austrian QP Forum 2026:**

  09.-10. Juni 2026, Austria Trend Parkhotel Schönbrunn

- **Nächstes Vereinstreffen der AQPA:**

  09. Juni 2026, Austria Trend Parkhotel Schönbrunn

Bye bye … ☺

- Vielen Dank für Ihr Vertrauen in die AQPA.
- Nehmen Sie bitte auch in Zukunft die Angebote der AQPA an!

Ich wünsche Ihnen Alles Gute für die Zukunft!

Georg Göstl
AQPA-Obmann 2012-2025
(Pensionist ab 1.2.2026)

Wir wünschen einen schönen Abend,
viel Spaß beim Netzwerken und die AQPA
hofft auf zahlreiches reales Wiedersehen beim
Vereinstreffen am
9. Juni 2026

Bleiben Sie gesund!

Der erweiterte AQPA-Vorstand:

Georg Göstl, Obmann außer Dienst
Stefan Schneider, Obmann
Gabriela Schallmeiner, Obmann-Stellvertreterin
Regine Tomasits, Schriftführerin
Markus Thiel, Kassier

Winfried Chang
Klaus Hofstädter
Carina Rappel
Richard Vasicek