# Vereinstreffen der AQPA

04. Mai 2022

**Der AQPA-Vorstand:**

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

# Agenda

- 18:00 Begrüßung
- Präsentationen:
  - Where no QP has gone before? *(Winfried Chang/Hookipa)*
    - Challenges for a QP working on the borderline between start up and early / mid clinical stage
  - Allfälliges:
    - 76 (!) Neuigkeiten von den Behörden *(Georg Göstl/Takeda)*
    - Stellenausschreibungen auf der AQPA-website *(Markus Thiel/Roche)*
- Teilnehmerliste *(Regine Tomasits/ViruSure GmbH)*
- Themenvorschläge für zukünftige Treffen oder AQPA-Forum
- Termine
- Gemütliches Beisammensein

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

# Allfälliges

## Annex 21 zum EU-GMP-Guide (NEU!)

- 16 February 2022
- Deadline for coming into operation: 21 August 2022
- Human, investigational and veterinary medicinal products
- Not for “import for export only”
- Only for “physical importation”, **not** for “**fiscal transactions**”
- Repeating some existing GMP-requirements
- QP certification only after physical importation and **custom clearance**
- Specific new requirements related to **PQRs** (site of QP-certification, written agreements to compile PQR, sampling in third countries, analytical results from importation testing, transportation deviations)
- Specific requirement for **availability of full batch documentation** (access at site of QP-certification, justified frequency of BRR defined in the PQS, relevant ordering/delivery documentation at site of QP-certification available for inspection, batch documentation in a format/language understood by the importer)
- Any discrepancy during reconciliation of subdivided batches investigated **under responsibility of the certifying QP**
- QP is mentioned 23 times in this new guidance, mainly “**site of QP certification**”!
  https://ec.europa.eu/health/system/files/2022-03/vol4_annex21_en.pdf

## EMA updates Q&A on GMP and GDP

- The new chapter deals with requirements for active substances that are used as starting materials for the manufacture of veterinary medicinal products.

https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice/guidance-good-manufacturing-practice-good-distribution-practice-questions-answers#requirements-for-active-substances-used-as-starting-materials-in-ve

# Allfälliges

## European Commission: Q&A on list of 10 candidate COVID-19 therapeutics

- Objective and science-based criteria for selecting promising COVID-19 therapeutics
- Candidates benefit from regulatory flexibility, scientific support by EMA or matchmaking activities under EU therapeutics strategy
- Top 10 include:
  - 3 Antiviral monoclonal antibodies
  - 3 Oral antivirals
  - 4 Immunomodulators

https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_5367

## EC Draft Q&A to Clinical Trials Regulation (EU) No 536/2014

- Version 5
- January 2022
- 132 pages
- Submitted for discussion to the Expert Group on Clinical Trials

https://ec.europa.eu/health/system/files/2022-02/regulation5362014_qa_en_1.pdf

## EC – MDCG (Medical Device Coordination Group) Q&A "Repackaging & relabelling activities under Article 16 of Regulation (EU) 2017/745 and 2017/746"

- October 2021
- Q&A about obligations on medical devices and in-vitro diagnostics

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2021_26_en.pdf

# Allfälliges

## Amendment re the ban of TiO2 in foods went into force without any further changes:

- The ban for foods will be effective by 14-JUL 2022
- The use as excipient will remain to be accepted PROVISIONALLY and EMA is requested by EC to perform a review within 3 years from now
- Industry is strongly encouraged to work towards replacement

https://ec.europa.eu/commission/presscorner/detail/en/mex_22_361

## EU strengthening the EMA:

- Regulation (EU) 2022/123 "on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices"
- regulation applies from 1 March 2022 (with the exception of the provisions on shortages of critical medical devices, which will apply from 2 February 2023)
- The document also assigns several new tasks to the EMA. For example, as part of its extended mandate, EMA will be entrusted with monitoring potential crisis situations. These include, for example drug shortages and shortages of critical medicines. To this end, the EMA is to establish, maintain and manage a European medicines shortage surveillance platform by early 2025.
- 38 pages

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2022:020:FULL&from=EN

- EMA has informed EFPIA on 07. Feb 2022: '*I can confirm that the Agency has developed a dedicated external communication and stakeholder engagement plan on the implementation of the extended mandate, and industry will be made aware of the next steps in due course.*'

# Allfälliges

## EMA Draft Reflection Paper "Environmental safety documentation and environmental risk assessment of certain veterinary medicinal products"

- Interpretation of Article 72 of Regulation (EU) 2019/6
- EMA/CVMP/ERA/245311/2021
- Public consultation: deadline for comments: 31 January 2022

https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-interpretation-article-72-regulation-eu-2019/6-environmental-safety-documentation-environmental-risk-assessment-certain-veterinary-medicinal_en.pdf

## EU: Delegated Regulation (EU) 2021/1760 supplementing Regulation (EU) 2019/6

- 26 MAY 2021
- Criteria for designation of antimicrobials to be reserved for treatment of certain infections in human
- Shall apply from 28 January 2022

https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R1760&from=DE

## At the HMPC meeting, held from 20-22 September 2021, the herbal medicinal products committee (HMPC) of the EMA adopted the following revised guidance documents:

- Guideline on quality of herbal medicinal products / traditional herbal medicinal products (EMA/HMPC/201116/2005 Rev. 3)
- Guideline on Specifications: test procedures and acceptance criteria for herbal substances, herbal preparations and herbal medicinal products/traditional herbal medicinal products (EMA/HMPC/162241/2005 Rev. 3)
- In addition, the HMPC recently announced to revise the Guideline on Good Agricultural and Collection Practice (GACP) in order to address stakeholder requests on required clarifications, e.g. overlap GMP vs. GACP.
    - Concept paper on revision of GACP for starting materials of herbal origin:
    - Deadline for comments: 01 June 2022
    - https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-guideline-good-agricultural-collection-practice-starting-materials-herbal_en.pdf

https://www.gmp-compliance.org/gmp-news/hmpc-adopts-revised-quality-guidelines-for-herbal-medicinal-products?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW47+-+MEU

# Allfälliges

## EC published revision of "Compilation of Union Procedures on Inspections and Exchange of Information"

- 18th revision (21 September 2021)
- EMA/INS/428126/2021 Rev 18
- 295 pages
- Revised parts include:
  - Suspected quality defects and risk-based decision making
  - Rapid alerts
  - Verification of GMP status of manufacturers in Third Countries
  - Issue and update of GMP certificates
  - Risk based planning for inspections
  - Dealing with serious GMP non-compliance
  - New procedure for compliance management

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/compilation-union-procedures-inspections-exchange-information_en.pdf

## EMA: ICH guideline Q9 (R1) on quality risk management

- Draft version as endorsed by ICH on 18 NOV 2021
- Step 2 b
- Deadline for comments: 15 MAR 2022

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-international-conference-harmonisation-technical-requirements-registration-pharmaceuticals_en-1.pdf

## EMA: Draft "Guideline on the acceptability of names for human medicinal products processed through the centralised procedure":

- Open for comments until 16 March 2022
- EMA/CHMP/287710/2014, Revision 7

https://www.ema.europa.eu/en/documents/scientific-guideline/draft-guideline-acceptability-names-human-medicinal-products-processed-through-centralised-procedure_en.pdf

# Allfälliges

## EMA Q&A "Safety Features for medicinal products for human use":

- Version 19
- Ref. Ares(2021)7781918 – 16/12/2021
- New Q&A: 1.29 (decommissioning of reference and retention samples)
- Revised Q&As: 1.22 (covering or removing safety features by parallel traders), 5.8 (Authentication and decommissioning by wholesalers), 7.19 (Delegation of uploading data by the MAH; "**Data uploading** performed by means of infrastructure, hardware and software that are **physically located outside the EEA** is **strongly discouraged**.")

https://ec.europa.eu/health/sites/default/files/files/falsified_medicines/qa_safetyfeature_en.pdf

## EU Commission amends Delegated Regulation on Safety Features again

- Derogation from requirement to decommission unique identifiers of products exported to the UK until 31 DEC 2024
- 17 DEC 2021

https://ec.europa.eu/info/sites/default/files/c_2021_9700_1_en_act_part1_v2.pdf

## EMA Q&As Webinar for MAHs on Integration of EudraGMDP and OMS:

- EMA/587537/2021 (11 NOV 2021)

https://www.ema.europa.eu/en/documents/other/questions-answers-webinar-industry-integration-eudragmdp-oms_en.pdf

## EMA: Update of the "IRIS Guidance Documents"

- IRIS guide to registration and RPIs (Research Product Identifier)
  - Version 2.8
  - Published 14 FEB 2022
  - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-registration-rpis_en.pdf
- IRIS guide for applicants
  - Version 2.8
  - Published 08 APR 2022
  - https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/iris-guide-applicants_en.pdf

# Allfälliges

## The CMDh Rev. 7 of the Q&A on the QP Declaration

- Mainly adjustments were made due to the new Veterinary Medicinal Products Regulation (EU) 2019/6. Also, in several answers a differentiation was made between human and veterinary medicinal products.

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_340_2015_Rev.7_2021_12_clean_-_QA_on_QP_Declaration.pdf

## EMA "Reflection paper on Good Manufacturing Practice and Marketing Authorisation Holders"

- Version 2
- 10 January 2022
- It seems only editorial changes were made. However, the following sentence was **deleted**: "In relation to Contract Manufacturing Organisations (CMOs), these will not be permitted to on-board to the EU-Hub, and it is considered that the relevant MAH needs to ensure that appropriate arrangements are put in place in this regard, in order to ensure the secure upload of the serialisation data."

https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-good-manufacturing-practice-marketing-authorisation-holders_en.pdf

## CMDh updated Q&A on Nitrosamine Impurities:

- updated last in December 2021 (CMDh/400/2019, Rev.5)
- addresses the response to question 7, which explains and defines change notifications and their classification - "**Which variations are necessary to lift the conditions on the MA?**"
- Specifically, it addresses updates related to "**Condition B**" and "**Condition D**".

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Advice_from_CMDh/CMDh_400_2019_Rev.5_12_2021_TC_-_QA_sartans.pdf

## CMDh/HMA: Update of Q&A List for submission of Variations

- CMDh/CMDv/132/2009, Rev.57
- December 2021
- Version with track changes under following link:

https://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/Questions_Answers/CMDh_132_2009_Rev57_12_2021_TC_-_QA_on_Variations.pdf

# Allfälliges

## EMA Renewed Update of the Q&A Documents on “Centralised Procedures”

- Pre-authorisation procedural advice (February 2022): https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-pre-authorisation-procedural-advice-users-centralised-procedure-document_en.pdf
- Post-authorisation procedural advice (February 2022): https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-post-authorisation-procedural-advice-users-centralised-procedure-document_en-0.pdf
- The updated passages are listed below:
  - Paragraph 4 Extension of marketing authorisation
    - 4.5. How shall I present my Extension Application?

    Paragraph 7 Classification of changes
    - 7.2.4. How should I submit a revised updated Certificate of Suitability (CEP)?

    Paragraph 23 Marketing status updates
    - 23.4. What information should be reported to the Agency on the marketing status of CAPs?
    - 23.6. How to report marketing status updates to the Agency for CAPs?
    - 23.10. When and how to report to the Agency actions taken in 3rd countries?
    - 23.11. What information does the Agency publish about the marketing status of EU medicinal products?
  - Question 23.10. is new and explains the procedure for marketing authorisation holders who hold marketing authorisations outside the European Economic Area (EEA) and wish to withdraw, suspend or not renew them.

## EMA Q&A on Labelling Flexibilities for COVID-19 Vaccines

- EMA/747041/2021 rev 3 (10 DEC 2021)
- Any exemptions only of temporary nature
- Questions regarding packaging leaflet and printed expiry date (e.g. access via QR Codes)
- Different requirements by several member states

https://www.ema.europa.eu/en/documents/other/questions-answers-labelling-flexibilities-covid-19-vaccines_en.pdf

# Allfälliges

**EMA communication: Launch of the establishment phase of DARWIN EU® and the initiation of the Coordination Centre:**

- EMA is initiating the establishment of the Coordination Centre for the Data Analysis and Real World Interrogation Network (DARWIN EU®) – see EMA press release:
- Initiation of DARWIN EU® Coordination Centre advances integration of real-world evidence into assessment of medicines in the EU | European Medicines Agency (europa.eu)
- Vision: support EU regulatory decision-making on development, authorisation and surveillance of medicines by giving regulators access to valid and trustworthy real-world evidence throughout the lifecycle of a medicinal product.
- First pilot studies in 2022
- DARWIN EU® will also act as pathfinder for EHDS (European health data space) and will ultimately connect to the EHDS services, enabling the use of EHDS in the context of medicines regulation in Europe.

# Allfälliges

**EMA und PIC/S:**

**Concept Paper on revision of Annex 4 „Manufacture of veterinary medicinal products other than immunologicals“**

- Public consultation: 09 NOV 2021 – 09 JAN 2022
- Proposed date for release of draft guideline for comments: March 2023
- https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-annex-4-guidelines-good-manufacturing-practice-manufacture-veterinary_en.pdf

**Concept Paper on revision of Annex 5 „Manufacture of immunological veterinary medicinal products“**

- Public consultation: 09 NOV 2021 – 09 JAN 2022
- Proposed date for release of draft guideline for comments: March 2023
- https://www.ema.europa.eu/en/documents/scientific-guideline/concept-paper-revision-annex-5-guidelines-good-manufacturing-practice-medicinal-products-manufacture_en.pdf

# Allfälliges

## New PIC/S Executive Bureau for period 2022-2023:

- Mr Paul Gustafson (Canada / ROEB), PIC/S Chairperson;
- Ms Susan Laska (US FDA), PIC/S Deputy Chairperson and Chair of the Sub-Committee on Strategic Development (SCSD).
- Ms Anne Hayes (Ireland / HPRA), immediate past PIC/S Chairperson;
- Mr Jacques Morénas (France / ANSM), Chair of the Sub-Committee on Training (SCT);
- Dr Andreas Krassnigg (Austria / AGES), Chair of the Sub-Committee on Expert Circles (SCEC);
- Mr Ger Jan van Ringen (Netherlands / IGJ), Chair of the Sub-Committee on Budget, Risk and Audit (SCB);
- Mr Ian Jackson (UK / MHRA), Chair of the Sub-Committee on GM(D)P Harmonisation (SCH);
- Dr Kentaro Hara (Japan / PMDA), Chair of the Sub-Committee on Communication (SC COM); and
- Mr Henning Willads Petersen (Denmark / DKMA), Chair of the Sub-Committee on Compliance (SCC).

https://picscheme.org/en/news/new-pics-executive-bureau

## PIC/S revised GMP guide to reflect EU Clinical Trials Regulation:

- Revised Annex 13 based on EU GMP Annex 13, in line with the Cooperation Agreement between EMA and PIC/S

https://picscheme.org/en/news

## PIC/S has adopted EU GMP Annex 16:

- “Authorised Person” instead of QP
- PIC/S currently comprises 54 participating authorities
- Revised Annex 13 and new Annex 16 entered into force on 01 February 2022
- Please note: any non-EU/non-EEA member countries may have nationally QPs, but this may only be accepted for reducing/eliminating import testing and QP certification under an MRA (with related product in scope)

https://picscheme.org/docview/4590

# Allfälliges

**EMA und ICH:**

**EMA published two ICH guidelines for public consultation (31 MAR 2022):**

- ICH Q2(R2) on validation of analytical procedures:
  - 39 Seiten
  - https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-q2r2-validation-analytical-procedures-step-2b_en.pdf

- ICH Q14 on analytical procedure development:
  - 65 Seiten
  - https://www.ema.europa.eu/en/documents/scientific-guideline/ich-guideline-q14-analytical-procedure-development-step-2b_en.pdf

- Comments by 31 JUL 2022

# Allfälliges

## EU and UK: Annex 13 and Commission Guidelines on GMP for IMP:

- 31 JAN 2022: CTR (Clinical Trial Regulation) came into force in the EU
- Commission guidelines on GMP for IMP for human use came into force (= “new Annex 13)
- EU CTR will not be applicable to the UK, UK will continue to apply the January 2010 version of Annex 13
- UK requirements will remain unchanged pending completion of the consultation on new proposals for the future of UK clinical trial legislation
- UK will remain aligned with internationally harmonized standards of PIC/S and the EU, including requirements for the QP

https://mhrainspectorate.blog.gov.uk/2022/02/10/new-year-new-standards-for-investigational-medicines/

## ECA published Contamination Control Strategy Guideline:

- https://www.gmp-compliance.org/gmp-news/eca-publishes-contamination-control-strategy-guideline?utm_source=Newsletter&utm_medium=email&utm_campaign=Sonder+KW06+-+2022+-+EN+-+Sondernewsletter+Contamination+Control+Strategy+Guideline

# Allfälliges

## EDQM: harmonized general chapter Chromatography:

- Bringing together EP, JP and USP
- Particular attention:
  - Terminology, definitions and interpretation of chromatograms
  - System suitability
  - Adjustment of chromatographic conditions
  - Quantitation procedures
- Publication scheduled for:
  - Ph. Eur.: July 2022
  - JP: December 2022
  - USP: December 2022

https://www.edqm.eu/sites/default/files/press-release-pheur-pdg-revised-chapter-chromatography-november-2021.pdf

## EDQM: Notification for CEP holders – Implementation of Ph. Eur. Supplement 10.7

- Revised monographs implemented on 1 April 2022
- **"it remains the responsibility of the CEP holder to comply with the requirements of the monograph"**
- List of substances under the link:

https://www.edqm.eu/en/news/implementation-european-pharmacopoeia-supplement-107-notification-cep-holders

## EDQM: CEP holders invited to comment on draft monographs published in Pharmeuropa 33.4

- Deadline: 31 DEC 2021
- Users are encouraged to register for free, giving them access to *Pharmeuropa* on the European Directorate for the Quality of Medicines & HealthCare (EDQM) website *Pharmeuropa, Pharmeuropa Bio & Scientific Notes*.
- List of substances available at the link:

https://www.edqm.eu/en/news/cep-holders-invited-comment-draft-monographs-published-pharmeuropa-334

# Allfälliges

## EDQM introduced new IT application for CEP:

- Published November 2021
- PA/PH/CEP (13) 110, 3R
- Some innovations and changes, especially in communication between applicant and EDQM

https://www.edqm.eu/sites/default/files/medias/images/European_Pharmacopoeia/News/management_of_applications_for_new_certificates_of_suitability_requests_for_revision_or_renewal_of_certificates_of_suitability_and_applications_using_the_sister_files_procedure.pdf

## Council of Europe: "All you ever wanted to know about Ph. Eur. Procedure 4 but never dared to ask!"

- Advantages of applying for a monograph elaboration via Ph.Eur. procedure 4

https://www.edqm.eu/en/news/all-you-ever-wanted-know-about-ph-eur-procedure-4-never-dared-ask

## EDQM: Revised chapter on Osmolality (2.2.35)

https://www.edqm.eu/en/news/revised-osmolality-chapter-public-comment-pharmeuropa

## New Ph. Eur. Draft for Cyclo Olefin Copolymers:

- 3.1.17
- Public comments until 31 MAR 2022

https://www.gmp-compliance.org/gmp-news/new-ph-eur-draft-for-coc?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW02+-+MEU

# Allfälliges

**EDQM: new public document on Information Duties and Responsibilities of CEP Holders**

- MAH and applicants depend on good cooperation with suppliers of APIs
- Nitrosamine scandal revealed deficits in information flow between CEP holders and MAHs
- EDQM document published in January 2022 clarifying points on which a CEP holder has a duty towards its customers
- https://www.edqm.eu/en/news/edqm-reminds-cep-holders-their-responsibilities-towards-their-customers

**EDQM: CEP Application Templates redesigned**

- Implementation date for updated forms is 01 APR 2022
- https://www.edqm.eu/en/news/update-application-forms-certificate-suitability-applications

**EDQM survey for the use of total organic carbon (TOC) test as a replacement of oxidisable substances test in Water for injections**

- https://www.edqm.eu/en/-/ph.-eur.-to-launch-survey-for-the-use-of-total-organic-carbon-toc-test-as-a-replacement-of-oxidisable-substances-test-in-water-for-injections

# Allfälliges

## Implementation of Ph. Eur. Supplement 10.8 – Notification for CEP holders

- Supplement 10.8
- CEP holders are invited to update applications according to revised monographs
- Implementation on 01 July 2022
- Acc. Dir. 2001/83/EC it is responsibility of the manufacturer to comply, and therefore update specifications when a revised monograph is issued
- List of substances under following link:

https://www.edqm.eu/en/news/implementation-european-pharmacopoeia-supplement-108-notification-cep-holders

## CEP holders invited to comment on draft monographs published in Pharmeuropa 34.1

- Deadline: 31 March 2022

## CEP holders invited to comment on draft monographs published in Pharmeuropa 34.2

- Deadline: 30 June 2022
- For companies in a Ph. Eur. Member state: comments to be sent to National Pharmacopoeial Authority

https://www.edqm.eu/en/-/cep-holders-invited-to-comment-on-draft-monographs-published-in-pharmeuropa-34.2

## "CEP of the future"

- Project update published by EDQM

https://www.edqm.eu/en/news/cep-future-project-update

# Allfälliges

**Revision of Chapter 2.6.7 of Ph.Eur. on mycoplasma testing**

- Published for comments
- The draft revision can be viewed, after registration, on the EDQM/Pharmeuropa website.

**New Ph.Eur. Chapter 3.1.18 on Styrene block copolymers for containers and closures for parenteral preparations and ophthalmic preparations**

**Ph. Eur. Draft general chapter 2.4.35 „Extractable elements in plastic materials for pharmaceutical use”**

- Pharmeuropa 34.2
- Comment deadline 30 June 2022
- More information can be found after registration on the Pharmeuropa website.

# Allfälliges

## New FDA Commissioner: Dr. Robert Califf

- 12 November 2021
- President Biden has nominated Dr. Robert Califf, an expert in clinical trials (Dr Califf is founding director of the Duke Clinical Research Institute and currently a professor of medicine at Duke University School of Medicine). He brings nearly four decades of experience as a physician, researcher, executive, and public servant, and has previously served as an FDA Commissioner (2016-2017).

https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/12/statement-from-president-joe-biden-announcing-his-intention-to-nominate-dr-robert-califf-for-commissioner-of-food-and-drugs/

## US-FDA: increasing number of Warning Letters to manufacturers of hand disinfectants

- Interesting reading:
  - adulterated product in which ingredients were substituted,
  - ingredients replaced with other substances,
  - claimed it is a drug product but without approval,
  - wrong composition, lower concentration as labeled, methanol instead of ethanol
  - containers resembling beverage containers, containers looking like drinking water bottles (misbranding)
  - labelling violations,
  - discrepancies in hygiene standards
  - …
  - Assumed that more cases will follow and US controls will end in import bans and more Warning Letters

https://www.gmp-compliance.org/gmp-news/increasing-number-of-fda-warning-letters-in-the-area-of-hand-disinfection?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2021+-+KW48+-+MEU

# Allfälliges

## FDA Draft Guidance on Visual Inspection of Parenterals

- Visual inspection, particle identification and measures to be taken if particles are found
- Subvisible particles not included
- FDA distinguishes three types: inherent, intrinsic, and extrinsic particles
- 100 % inspection and in additional statistical sampling and testing shall be performed by the Quality Unit
- Procedures in case of deviations, including statements regarding re-inspection (per approved SOP with tightened criteria)
- Published for comments (until 15 FEB 2022)

https://www.fda.gov/media/154868/download

## FDA "Updates on possible mitigation strategies to reduce the risk of nitrosamine drug substance-related impurities in drug products"

- Published 18 NOV 2021
- Suppression of nitrosamine formation by antioxidants (e.g. ascorbic acid or alpha-tocopherol)
- FDA recommends examining addition of these substances to the formulation, when risk assessment does not exclude a possible formation of nitrosamines

https://www.fda.gov/drugs/drug-safety-and-availability/updates-possible-mitigation-strategies-reduce-risk-nitrosamine-drug-substance-related-impurities

## FDA Guidance for Industry "CMC Postapproval Manufacturing Changes for Specified Biological Products To Be Documented in Annual Reports":

- Published December 2021

https://www.fda.gov/media/106935/download

# Allfälliges

**FDA draft Guidance for Industry: "Human Gene Therapy Products Incorporating Human Genome Editing":**

- Published for comments in March 2022
- Recommendations to sponsors
- Information that should be provided in an IND application
- https://www.fda.gov/media/156894/download

**FDA Draft Guidance for Industry: "Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products"**

- Published for comments in March 2022
- https://www.fda.gov/media/156896/download

**FDA Guidance for Industry: "Initiation of Voluntary Recalls Under 21 CFR Part 7, Subpart C"**

- 04 March 2022
- Issued by ORA, CBER, CDER, and CDRH
- Finalizing the draft guidance from April 2019
- https://www.fda.gov/regulatory-information/search-fda-guidance-documents/initiation-voluntary-recalls-under-21-cfr-part-7-subpart-c

# Allfälliges

**FDA Q&A document "Drug Product Tracing"**

- February 2022
- Product Identifiers under the DSCSA (Drug Supply Chain Security Act)
- https://www.fda.gov/media/89954/download

**FDA moves on with Quality Metrics Reporting Program**

- FDA trying to revive program
- Aim: improve quality management, but also reduce supply chain disruptions
- Original draft 2015, revised in 2016; voluntary phase and asked for feedback
- Now FDA is asking for specific feedback on three areas:
  - Reporting Levels
  - Practice Areas and Quality Metrics
  - Other considerations
- Deadline for submitting comments: 09 June 2022
- https://public-inspection.federalregister.gov/2022-04972.pdf

**FDA: final guidance for industry "R8(R1) General Consideration for Clinical Studies"**

- Published in the Federal Register on April 11, 2022
- https://d31hzlhk6di2h5.cloudfront.net/20220414/ee/83/93/f8/850bf2bc57a8cb8d93ed6116/2022-07690.pdf

# Allfälliges

## USP: Notice of Intent to Revise General Chapter <711> Dissolution

- Anticipated publication as “Interim Revision Announcement” in Pharmacopoeial Forum 48(2) in March 2022
- Commenting period until 31 May 2022
- May become official on 01 September 2022

https://www.uspnf.com/notices/gc-711-nitr-20211029

## Proposal for new general USP Chapter on Quality Attributes of Starting Materials for the Chemical Synthesis of Therapeutic Peptides

- <1504>
- Published in the Pharmacopoeial Forum, PF 48(1)
- Available on PF Online (one time registration is required to access)
- Deadline for submitting comments: 31 MAR 2022

https://www.gmp-compliance.org/gmp-news/proposal-for-new-general-usp-chapter-on-quality-attributes-of-starting-materials-for-the-chemical-synthesis-of-therapeutic-pepti?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW02+-+MEU

## USP proposal for Contaminant Pyrrolizidine Alkaloids

- New chapter <1567> is being proposed
- Deadline for comment: 31 March 2022
- draft chapter <1567> *Pyrrolizidine Alkaloids as Contaminants* is available after registration for the Pharmacopeial Forum.

# Allfälliges

## Approved USP chapters on Plastic Components used in Manufacturing:

- New USP chapters <665> and <1665> finally approved
- Baseline for qualification of plastic components used in the manufacturing of pharmaceutical and / or biopharmaceutical drugs
- For more information about the two new USP general chapters <665> and <1665> access to USP online is required.

## New USP Draft monograph for Cannabidiol (CBD)

- The proposed monograph has been published in the current issue of Pharmacopeial Forum (PF) 48(1), January 2022
- The deadline for comments is 31 March 2022
- Proposed draft is available after registration for the Pharmacopeial Forum.

## USP proposed addition to chapter <1236> "Solubility Measurements":

- Published in Pharmacopoeial Forum, PF 48(2) for public comments
- The proposal can be consulted after registration on the Pharmacopeial Forum website.
- Comments can be submitted until May 31, 2022.

# Allfälliges

**Australian TGA: on-going use of Remote Inspections:**

- Overseas GMP inspections suspended by TGA
- As travel restrictions remain in place, remote GMP inspection program will continue
- Prioritization of remote GMP-inspections based on:
  - the ability to use the alternative GMP Clearance processes
  - current compliance information
  - applications for marketing authorisation

https://www.tga.gov.au/gmp-approach-overseas-manufacturers-medicines-and-biologicals-during-covid-19-pandemic

**Brazilian Pharmacopoeia 6th Edition:**

- Officially available in English
- ANVISA-homepage
- 6th edition released in 2019, official as of 12 FEB 2020

https://www.gov.br/anvisa/pt-br/assuntos/farmacopeia/farmacopeia-brasileira/brasileira

# Allfälliges

**Japan: Revised Inspection Guideline**

- Compliance and Narcotics Division of MHLW
- Applicable from 01 April 2022
- “in principle, no prior notice” for on-site inspections
- “in principle, at least one unannounced inspection per year” (manufacturing sites with a high risk of violations)
- Risk assessment takes into account: status of changes to the MA, results of previous investigations, product recalls, complexity of manufacturing process

**Japanese Pharmacopoeia 18th Edition – English Version now available:**

- Available for download free of charge
- https://www.gmp-compliance.org/gmp-news/japanese-pharmacopoeia-18th-edition-english-version-now-available?utm_source=Newsletter&utm_medium=email&utm_campaign=ECA+GMP+Newsletter+-+2022+-+KW15+-+MEU

# Allfälliges

## WHO publishes Draft Working Document on Chromatography

- Draft proposal for inclusion in *The International Pharmacopoeia*
- New chapter 1.14.1 Chromatography
- The draft working document (QAS/21.905) is available as a PDF file on the WHO homepage.
- Comments until 25 March 2022.

## WHO-draft guideline: safe production and quality control of monoclonal antibodies for use in humans

- Published 12 October 2021 (for comments until 30 NOV 2021)
- Continuation of WHO-guidance already existing sine 1991

https://cdn.who.int/media/docs/default-source/biologicals/mabs-manufacture-guideline-draft-for-1st-public-comment.pdf?sfvrsn=348325c2_5

## ICMRA (International Coalition of Medicines Regulatory Authorities, a voluntary association of 37 drug regulatory authorities from around the world) Reflection Paper

- Reflection on the regulatory experience of remote approaches to GCP and GMP regulatory oversight during the COVID-19 pandemic
- Remote inspections do not replace regular on-site inspections, but have enabled many regulators to continue surveillance programs

https://www.icmra.info/drupal/sites/default/files/2021-12/remote_inspections_reflection_paper.pdf%20

# Allfälliges

## Stellenanzeigen auf der aqpa-Webseite

- Via Hauptseite „https://www.austria-qp.at/“ und dann auf der Liste „Stellenanzeigen“ anklicken oder direkt „https://www.austria-qp.at/qpaus_stellenangebote.html“

# Allfälliges

**Stellenanzeigen auf der aqpa-Webseite**

- Allgemeine Informationen
  - Eine der Haupteinnahme-Quellen der aqpa
  - Einnahmen: 120 Euro pro Monat, meist für 3 Monate
  - Pro Jahr: Ca. 1 bis 4 Stellenanzeigen

- Derzeitige Stellenanzeigen
  - 3 Stellenanzeigen von 2 Firmen veröffentlicht

- Bitte um Bewerbung der aqpa-Stellenanzeige

  -> Der Firma mitteilen, dass man sich aufgrund der aqpa-Stellenanzeige bewirbt

  -> Rückmeldung an die aqpa, bei erfolgreicher Bewerbung (info@austria-qp.at)

- Präsentationen werden wieder im Internet abrufbar sein:
  www.austria-qp.at
- 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
- Nächstes **Vereinstreffen** der AQPA: **20. Okt 2022**
  - Radisson Blu Park Royal Palace Hotel, Vienna
- **Austrian QP Forum 2023**: **24.-25. Mai 2023**
- **Qualified Person Forum 2022 der EQPA:**
  **30 November - 02 December in Berlin**

**Wir wünschen einen schönen Abend und hoffen auf zahlreiches reales Wiedersehen am 20. Oktober 2022**

**Bleiben Sie gesund!**

**Der AQPA-Vorstand!**

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