Charter for the European QP Association Engagement Board (Think Tank)

Purpose

- (Net)working group for active involvement by EQPA members
- Provide feedback to EQPA Board members on hot topics among fellow QPs
- Interested members will meet approx. every 1-2 months (usually online)

Targets and proposals will be endorsed by EQPA Board

- Provide comments to existing and upcoming regulations
- Contribute abstracts and publications in EQPA newsletter
- Identify evolving areas from EQPA members feedback including discussion forum, summarize, categorize
- Contribute to EQPA positions/position papers on selected topics
- Raise ideas for simplification or strengthening of GMP rules
- Suggest Q&As or positions in the name of EQPA to selected topics
- Suggest topics for surveys and contribute to the preparation, analysis and reporting of such surveys

Participation

- EQPA Board will endorse volunteers to become members of the Engagement Board (Think Tank)
- EQPA Board may limit the number of participants to the Engagement Board (Think Tank)

Potential topics for elaboration may be proposed by members of the group or EQPA board.

Approved by 02 November 2023 on behalf of the EQPA Board

Dr Ulrich Kissel
Chairman
European QP Association

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Annex 1 - First ideas for topics

- Best practice: How to work in organizations with more than one QP
- Position to Remote certification
- Best practice: how to perform imports from USA
- Position to certification as a process
- Job description QP (finalization of existing draft)
- One or more of the following topic list not yet covered by the Good Practice Guide for QPs:
  - Clarification on qualified electronic signature for register and certificate
  - Location requirements of server location for GMP relevant data
  - Chapter on quality of utilities (qualification, control, monitoring)
  - Chapter on single use systems (qualification, quality control, incoming goods control)
  - Chapter on MAH, sponsors, legal representative's GMP responsibilities, regulatory dossier, variations/change control to dossier/CTA and link to certification (in compliance to dossier)
  - A chapter on Marketing Authorization Dossier/IMPD, contents, use for certification, regular review by QP
  - New pharmaceutical legislation

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Annex2 - Endorsed (initial) Members of the EQPA Engagement Board (Think Tank)

1. Heike Meichsner
   QP at Dr. Falk Pharma GmbH, Freiburg, Germany
2. Dr Eva-Maria Kuhn
   QP (Global Quality) at MSD Anima) Health, Boxmeer, The Netherlands
3. Dr Nina Langoth-Fehringer
   Pharma Consultant, Vienna, Austria
4. Tushar Patel
   QP and QPPV, gxppharma, UK
5. Dr Sonja Puz
   QA at Globopharm Pharm. Prod.- und HandelsgmbH, Vienna, Austria
6. Ms Aoife Eyre
   IMP QP at Jazz Pharmaceuticals Ltd., Dublin, lreland

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