



Ethics for the QP

A Professional Code of Conduct

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Background

- In addition to QP's educational and practical experience, Article 52 of Directive 2001/83/EC:
 - *“Member States shall ensure that the duties of qualified persons referred to in Article 48 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.”*
 - *Member States may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary procedures against him for failure to fulfil his obligations.”*
- EQPA is unaware of a Code of Conduct published by any EU/EEA authority that applies specifically to QPs (exception in UK)
- Code of Conduct to define and ensure the ethical dimension for QPs
- Board of EQPA decided to develop Code of Conduct
- Until EU-regulators or NCAs might publish one

Purpose

- Provide guidance to EQPA-member QPs
- Define what constitutes professional conduct with QP-role
- May serve as reference and standard
- Ethical training of QPs
- Underpin decision making by QPs

Ethical Duties of the QP

- Ensuring patients are protected
- All medicinal products meet requirements of compliance, safety, quality, and efficacy
- QPs have professional duty to decline certifying any batch for which they have ethical concerns

Ethical Duties

- Selflessness
- Integrity
- Objectivity
- Reponsibility
- Transparency
- Honesty
- Leadership
- Knowledge
- Prevent Professional Misconduct
- Rigour and Robustness

General Duties

- Follow up in case of any indication of fraud or negligent violation of rules by others
- QPs should ensure senior management is sufficiently aware of QP-R&R including matters of ethics (this code is recommended for use)
- QP has to achieve good working relationship with others
- QP should inform other groups of R&R of the QP
- QP should consult other experts to reinforce knowledge
- QP must be satisfied by proper operation of the PQS
- Batch certification without such adequate step may be regarded as professional misconduct

Professional and Ethical Conduct

- QP duties to employer, but also to NCA and specifically the patient
- When any aspect of PQS is not in accordance with ethical norms, the QP has the duty to bring to attention of senior management to ensure appropriate measures are taken
- QP might have to consider refusing batch certification until corrections are effective
- QPs should establish good working relationship with Regulatory Inspectors
- When undue pressure to depart from these standards cannot be counterbalanced, QPs should contact appropriate authority, preferably having informed the employer first

Disciplinary Procedures

- QP has a personal responsibility
- In certifying a batch, the QP is indicating having been satisfied that the batch complies with all requirements and to the benefit of the patient
- If risks to the patient have not been excluded a legal investigation against the QP on negligence, gross negligence or fraud may be initiated.
- Disciplinary measures against the QP may be enforced
- This Code intends to become a reference to QPs and NCAs to assess professional and ethical conduct

Availability/Publication

- Version 1 of this „Code of Conduct“ is included as a new Chapter 3 in the revision of the existing Good Practice Guide „EQPA Code of Practice for QPs“ (version 9.0; January 2023):

https://www.qp-association.eu/qpag_good_practice_guide.html

- Mittlerweile bereits Version 10.0 (March 2023) im Mitgliederbereich der EQPA

- Video unter:

<https://www.qp-association.eu/code-of-conduct-good-practice-guide.html>

Thank You!