



The QP – Role & Responsibilities

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2 TYPES OF QPs in the EU

Regulation 726/2004 (Art. 19 (1) & 44 (1))

- **1. Manufacturing in / Import to EU/EEA; GMP-QP**

(ML: Directives 2001/83 (Art. 41 (c) + 2004/27 (Human) & 2001/82 (Art. 45 (c) + 2004/28 (Vet.))

(Importer: Directives 2001/83 (Art. 40(3) + 2004/27 (Human) & 2001/82 (Art. 44 (3) + 2004/28 (Vet.))

- **2. Marketing in EU/EEA; Pharmacovigilance-QP**

(PL: Directives 2001/83 (Art. 103) + 2004/27 (Human) & 2001/82 (Art. 74) + 2004/28 (Vet.))



GMP-QP ROLE & RESPONSIBILITIES

- **The GMP-QP Guarantees:**
 - **Import Compliance (E.g. IMPs Received)**
 - **Export Compliance (E.g. IMPs Exported)**
 - **Batch Compliance (GMP-Processes)**
 - **PSF Compliance (Clinical Testing)**
 - **PL Compliance (GMP-Processes)**
 - **Record Compliance (Traceability)**
- **Direct Report to the Authorities of Non-Compliance Issues?**
- **Personal Liability (Penal Sanctions / Authorisation Withdrawal)**



GMP Applies to IMPs (Directive 2003/94)

IMP DEFINITION (Directive 2001/20):

- **Pharmaceutical form of API (=FP) or Placebo**
- **Used for testing or as comparator where**
 - **Authorisation not obtained for indication and/or form tested or**
 - **Additional data sought for approved form (Phase IV)**



EU/EEA: GMP-QP IMP-Responsibilities

QP – Release Principles

1. EU / EEA: The QP issues BC & releases – Free circulation.
2. MRA country (E.g. CH): QP releases on basis of BC issued by "QP" in MRA country.
3. Non-MRA country (E.g. USA): QP-release only after full quality & quantity (API) control of ML compliance.



EU/EEA: GMP-QP IMP-Responsibilities

APIs / FPs / Placebo: Release Scenarios

- **API inventor has no GMP facility, and no QP**
- **Engages CMO to do scale up and API for IMP-production for clinical trials – GMP / QP release required?**
- **API sent to neighbouring CMO for formulation – GMP / QP release required?**
- **IMP sent back to inventor/sponsor who will send it to CRO for clinical testing – GMP / QP release required?**



EU/EEA: GMP-QP IMP-Responsibilities

APIs / FPs / Placebo: Case

- **API inventor in the USA (3rd country) has no GMP facility, and no QP**
- **Engages CMO in England (EU) to do scale up and API for IMP-production for clinical trials – GMP / QP release required?**
- **Exported to new CMO in Switzerland (MRA country) for formulation – GMP / QP release required?**
- **IMP exported to EU / EEA for clinical testing by CRO – GMP / QP release required?**



Conclusions

QP Responsibilities / Clinical Trials

IMP Compliance with:

- **GMP (or equivalent)**
- **Clinical Trial Application**
- **Product Specification File**

QP negligence may lead to loss of authorisation & penal sanctions



Matthew 6:24

No man can serve two masters: for either he will hate the one, and love the other; or else he will hold to the one, and despise the other. Ye cannot serve God and mammon.

A principle for legislators to consider?



List of Abbreviations

- API: Active Pharmaceutical Ingredient
- BC: Batch Certificate / Certification
- CMO: Contract Manufacturing Organisation
- CTA: Clinical Trial Application
- FP: Finished Product
- IMP: Investigational Medicinal Product
- ML: Manufacturer's License
- MRA-country: Mutual Recognition Agreement country
- PL: Product License (=Marketing Authorisation)
- PSF: Product Specification File