

**ROYAL
PHARMACEUTICAL
SOCIETY**



**Qualified Person involved in the
manufacture of pharmaceuticals.**

QP Code of Practice

April 2024

QUALIFIED PERSON Code of Practice

1. INTRODUCTION

- 1.1. The concept of the Qualified Person (QP), first established in 1975, is a unique regulatory requirement that applies within the United Kingdom and the European Union (EU). The only comparable situation exists within Member States of the European Economic Area with whom the EU has reciprocal agreements. Other countries have since adopted similar roles (e.g. Switzerland). The term QP in this document is reserved to the UK and EU QP as they both stem from the same original EU Directive and the UK QP may rely on the EU QP's assessment based on a contractual agreement for products certified into the UK market.
- 1.2. Each holder of an Authorisation to manufacture products for use in a Clinical Trial or products subject to Marketing Authorisations, within the UK, must name a person or persons who are eligible to act in the capacity of QP. Since 31 January 2020 when the United Kingdom left the European Union, there have been some amendments to UK legislation. This Code of Practice applies to all QPs named on UK manufacturer and import authorisation.
- 1.3. The requirement for QPs covers both Human and Veterinary Medicinal Products including any product only intended for export.
- 1.4. Particular conditions for formal qualifications and practical experience for eligibility to act as a QP are specified in relevant UK and EU legislation. It is the legal duty of the Manufacturers Authorisation holder and the QP to ensure that the QP's practical experience acquired is appropriate to support the types of products the QP is certifying. Ensuring compliance with these conditions is the responsibility of the UK Licensing Authorities.
- 1.5. The QP has a legal duty to ensure that every batch has been manufactured and checked in compliance with National law, the requirements of the Marketing Authorisation (MA) and Good Manufacturing Practice (GMP). Each batch must be certified by the QP prior to release for sale or supply.

Although, the primary legal responsibility of the QP is to certify batches of Medicinal Product prior to use in a Clinical Trial (Human Medicinal Products only) or prior to release for sale and placing on the market (Human and Veterinary Medicinal Products), the wider technical, ethical and professional obligations in terms of patient safety, quality and efficacy must also be considered. Hence this professional Code of Practice is designed to take account of these requirements.

- 1.6. The QP Code of Practice is managed and maintained by the Joint Professional Bodies (JPB), which consists of the Royal Pharmaceutical Society (RPS), Royal Society of Biology (RSB) and the Royal Society of Chemistry (RSC).

2. PURPOSE OF THE CODE

- 2.1. It is a requirement that all QPs are subject to a professional code of conduct.
- 2.2. The purpose of this UK Code of Practice is to provide guidance to QPs, to support compliance with the professional code of conduct requirements.
- 2.3. It aims to provide guidance on how an individual QP can safeguard themselves, aspects a QP needs to be aware of when working with other QPs named on the same authorisation, and where a QP can obtain support in difficult situations.
- 2.4. This Code applies to all QPs involved in the manufacture of pharmaceuticals where the QP is:
 - employed or providing contract QP services;
 - involved in human or veterinary medicines; and
 - qualified under the permanent or transitional provisions.
- 2.5. It should be noted that the Licensing Authority may refer to this Code of Practice in connection with disciplinary proceedings against a QP under the current UK Medicines Regulations for human and veterinary products.

3. TERMINOLOGY

- 3.1. The terminology used in this Code of Practice corresponds with that used in the current versions of the UK legislation on Good Manufacturing Practice (GMP) and the Guide to Good Manufacturing Practice (MHRA Orange Guide).
- 3.2. The terms Marketing Authorisation, Manufacturer's Authorisation and Clinical Trial Authorisation are generally used and shall henceforth be referred to throughout this Code.

4. GENERAL PRINCIPLES

- 4.1. Pharmaceutical Manufacturers and the Regulatory Authorities must ensure that patients are protected and that all medicinal products, whether for sale or supply, meet the appropriate requirements for safety, quality and efficacy.
- 4.2. The QP performs a unique role on behalf of the patient and the Regulatory Authority when certifying that a batch complies with its pre-determined requirements and can be released for sale or supply.
- 4.3. The QP is responsible for ensuring that each individual batch has been manufactured and checked in compliance with laws in force where certification takes place.
- 4.4. The QP's legal roles and responsibilities apply regardless of where the final product will be sold and/or supplied.

- 4.5. The QP must understand the requirements of each Authorisation (Manufacturer's, Marketing or Clinical Trial) and ensure that the Pharmaceutical Quality System (PQS) in place is fit for purpose for the activities being performed and types of products involved.
- 4.6. The QP must use quality risk management principles, apply sound knowledge and have understanding of the relevant steps of manufacture before certifying any batch for release.
- 4.7. The QP needs to refer to all applicable UK legislation, and guidance (especially Annex 16 Part 1 of the MHRA Orange Guide). They also need to be fully conversant with the requirements stipulated within local regulations of the market the products are destined for.
- 4.8. All QPs should ensure adequate professional indemnity insurance arrangements are in place.
- 4.9. QPs have a professional duty to decline to certify any batches of product types for which they do not possess the relevant experience and/or knowledge.
- 4.10. QPs should ensure that this Code of Practice is brought to the attention of senior management and, where practical, the Chief Executive Officer/Site Head so they are aware of the requirements and expectations detailed within.

5. PRACTICAL DUTIES OF A QUALIFIED PERSON

- 5.1. QPs have duties, some of which may be delegated in line with the above general principles. Before certifying a batch prior to release, the QP should always ensure that all requirements have been met.

It is the QP's legal responsibility to ensure that local legislation is met when certifying and making a batch of product available to the public/market.

Annex 16 Part 1 of MHRA Orange Guide, for Rules and Guidance for Pharmaceutical Manufacturers and Distributors which provides the current guidance on these duties and should be consulted for the details.

- 5.2. The QP should also recognise the need to consult other experts to reinforce knowledge where required (for example but not limited to: stability, unusual analytical results, process or equipment changes, potential environmental or microbiological risks, re-labelling, abnormal yields, cross contamination risks, new technologies).
- 5.3. The QP should also take account of the nature and size of the operations being performed. It is good practice to manage such complex activities based on Quality Risk Management principles (ICH Q9). For example:

5.3.1. In a very small company with a limited range of products, it may be possible for the QP to take direct responsibility for some quality and non-quality related

roles, so long as there is no conflict of interest. In some cases, a QP may take on all of the duties as detailed in the current UK legislation.

5.3.2. In larger organisations, the QP will typically be dependent upon the knowledge and expertise of colleagues. It is of paramount importance that the QP is assured that the tasks allocated are being performed satisfactorily. Hence the duties of a QP depend upon a team effort.

5.3.3. In more complex organisations where multiple QPs from multiple organisations / entities are involved, QPs may clarify legal duties and responsibilities with a written contract / agreement between QPs (e.g. Quality or QP Agreements) to clarify division of legal responsibilities (also refer to Section 8 and 9).

6. PERFORMANCE OF DUTIES AND REGULATORY COMPLIANCE

6.1. Each QP has a personal and professional responsibility for being certain that the various checks and tests have been carried out. However, the certain aspects of this work can be delegated and be the responsibility of others.

Ultimately, the QP must be satisfied they have the appropriate oversight of the PQS and that it continues to be effective. In addition, the QP must ensure that the raw materials used, the manufacturing and packaging operations and the quality control testing comply with the relevant regulatory requirements (including but not limited to GMP, manufacturing authorisation, Product Specification File etc) and that any deviations and or changes are controlled and managed effectively. These requirements apply whether the work is carried out on the QP's site or at a different site.

Batch certification without such adequate oversight may be regarded as professional misconduct.

6.2. The QP depends upon many colleagues for the achievement of quality and regulatory compliance in the manufacture of medicinal products. It is therefore of paramount importance that the QP achieves good working relationships with others.

6.3. The QP should take the necessary steps to inform senior management and other functional groups of the legal role and responsibilities of a QP and help them to understand how they can provide effective support.

6.4. Manufacturer's Authorisations include the names of the persons responsible for Production, Quality Control and the name(s) of the QP(s). The duties of these members of staff must be clear in their respective job descriptions and they must have the authority required under the relevant UK legislation.

7. NUMBER AND LOCATION OF QUALIFIED PERSONS

- 7.1.** Safety of patients is of paramount importance, therefore it is vital that at each relevant site there are sufficient QPs available to cover all activities involved, including appropriate measures in place for any shift patterns. This may require a single QP, a team of QPs, a QP providing contract services or a combination thereof.
- 7.2.** The QP should be present at the manufacturing site for a sufficient proportion of the working time to discharge their legal and professional duties. The time spent on site should also allow the QP to both have effective oversight and to fulfil their other duties with respect to the PQS and delegated duties. See Section 7.6 for guidance on part-time or home working arrangements.
- 7.3.** Where there is more than one QP working on the same site, it is an expectation that each QP is sufficiently aware of the activities of the other QP(s). Where any significant discrepancies regarding decision-making are observed, these should be discussed between the QPs. Where significant differences cannot be resolved, these should be brought to the attention of senior management. It may be advisable for a concerned QP to contact their Professional Body for advice or the Licensing authority.
- 7.4.** It is expected that QPs will inform senior management if they believe there are insufficient QPs to perform all the required duties.
- 7.5.** QPs are typically part of the Quality organisation at site. Ideally, the QP or “lead” QP would also be a member of the senior management team.
- 7.6.** It is increasingly common to see flexible, part-time or home working arrangements. However, the QP’s responsibilities remain unchanged by different arrangements and QPs should ensure these do not impact the execution of their legal duties and responsibilities especially when travel is restricted, so to not adversely impact the supply of product to the market.

8. CONTRACTED QUALIFIED PERSONS

- 8.1.** In a number of cases, especially with smaller companies or where temporary / additional cover is required, a ‘Contract’ QP will be employed to provide the service. In such cases, the duties and responsibilities of a ‘Contract QP’ are the same as those for QPs who are permanently employed by their company. The Contract QP shall comply fully with this Code of Practice.

The term ‘Contract QP’ is not a formal title and is used only to describe a QP providing an independent service under contract to a company.

- 8.2.** In addition to compliance with the provisions applicable to all QPs including all the practical duties detailed within the legislation and GMP guidance, Contract QPs should observe the following:

- Have a clear written contract, which delineates the duties and responsibilities of the QP – as agreed between the company and the ‘Contracted QP.’ Both should sign and retain a copy of the contract;
 - Be on site for sufficient time to fulfil all legal and professional requirements and to maintain oversight and knowledge of site compliance;
 - Be readily available to the staff of the company for advice and discussion, be present during regulatory inspections and be involved in communications with the inspectors;
 - Ensure that the company to whom the services are provided will allow free access to any people, information, documentation, premises, systems, etc. which are relevant to the decision-making processes when certifying batches; and
 - The QP must be informed and aware of any issues arising relating to the PQS that are relevant to a QP, in particular, any events that occur when the QP is not on site.
- 8.3.** Particularly for smaller companies, a Contract QP may agree with the company to personally provide some additional services for example, staff training, internal audits and maintenance of authorisations, in addition to performing strictly batch related QP certification duties. All services provided should be reflected in the appropriate quality agreement(s).
- 8.4.** If any doubt exists between the QP and the company concerning the duties and responsibilities of the QP, it is recommended that the QP contact their Professional Body or Licensing Authority Inspector for advice.

9. OUTSOURCED ACTIVITIES

- 9.1.** Where products are manufactured and/or packed under contract, there should be a clearly written Quality/Technical Agreement between the contract giver and the contract acceptor; such an agreement should be reviewed by a QP.
- 9.2.** It may be necessary to consider a direct QP/QP agreement in addition to any Quality/Technical Agreement(s) where there is a requirement for clarity on division of responsibilities for QPs, or where there are a number of QPs in the supply chain.
- 9.3.** The provisions in 10.1 apply equally to QC testing of samples under contract. Refer to MHRA current guidance on the use of UK standalone contract laboratories for details.
- 9.4.** Where remote QP certification is employed, it must be described and controlled within the pharmaceutical quality system.

10. CONTINUING PROFESSIONAL DEVELOPMENT

- 10.1.** QPs have a personal, professional duty to ensure they keep their knowledge and experience up to date. Whilst the primary duties of the QP have remained principally unchanged, since inception in 1975, the practical situations and complexity of company operations and supply chains have increased significantly. In addition, the regulatory landscape is constantly evolving. It is therefore of paramount importance that the QP commits to and can demonstrate continued development and must adapt to new operational dynamics, evolving technologies, and regulatory changes to remain compliant with current legislation.
- 10.2.** This should include all relevant Regulatory aspects, changes to GxP guidelines, regional and international standards, and guidelines.
- 10.3.** In addition, it must also include any advances in manufacturing techniques or control technologies relevant to the dosage forms / types of products they work with.
- 10.4.** Each QP must also ensure he/she keeps up to date with all changes relating to the PQS, current expectations, recent issues and best working practices.
- 10.5.** Adequate records must be maintained to demonstrate that sufficient CPD is being performed, which also complies with any Professional Body requirements.
- 10.6.** Where appropriate, these records need to be submitted to the relevant Professional Body and to be available for review during any Regulatory inspection.
- 10.7.** In the event of a QP undergoing a significant change in job responsibilities in the same company, e.g. introduction of new dosage forms or technologies, it is a requirement that the QP undergoes formal training. There must be a plan prepared that details the gaps and training required with timelines, where possible and practical, this plan should be approved by senior management. Training must be satisfactorily completed and the QP must be named on the relevant company Authorisation prior to performing batch certification.
- 10.8.** In the event that a QP moves company, it is expected that the same approach is taken as 10.7 above and that the QP does not certify any batches until he/she is familiar with the new PQS, product range and associated technologies.
- 10.9.** If a QP has a break from work and/or temporarily moves away from the QP role, the QP must ensure he/she is fully up to date before returning to a QP role and certifying any batch.

11. PROFESSIONAL CONDUCT

- 11.1.** QPs are subject to the overall jurisdiction of the By-laws, Charters and Regulations, Codes of Conduct, Disciplinary Regulations and any general guidelines of their own Professional Body and should have access to them.
- 11.2.** QPs have duties not only to their employer but also to patients and the Licensing Authorities. They must ensure that appropriate senior company executives are made fully aware of any manufacturing and/or testing issues or regulatory concerns that may cast doubt on, or prevent the certification of batches, due to non-compliance to the Marketing or Clinical Trials Authorisation or may necessitate a product recall.
- 11.3.** If there is any aspect of the PQS that is not in accordance with the Legislation, Directives and Guidelines for GMP then the QP has a duty to bring this to the attention of senior management and ensure that appropriate corrective and preventative measures are taken.
- 11.4.** QPs should establish a good working relationship with Regulatory Inspectors and, as far as possible, provide information on request during site inspections.

NB. There may be situations outside of site inspections where the QP may wish to consult with the local Regulatory Inspector for advice.

- 11.5.** QPs may consult their Professional Body for confidential advice in cases where undue pressures to depart from professional obligations cannot be counterbalanced by reference to this and other relevant guidance, preferably having informed their employer first.
 - Management has a duty to provide appropriate resources, training and expertise within its organisation to ensure that QPs can operate effectively in discharging their responsibilities and to ensure that the PQS and communications are not compromised. Those resources may not necessarily reside in a Quality function.

12. PROFESSIONAL BODIES

Each Professional Body within the JPB has an “Officer” who is a point of contact for QPs. Each Professional Body has made arrangements so that any QP contacting their Professional Body can be directed to an experienced QP to discuss any difficult situations and obtain advice on possible courses of action.

13. DISCIPLINARY PROCEDURES

- 13.1.** UK legislation stipulates the QP's legal and routine duties. This legislation is to ensure that QP legal duties are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a Professional Code of Conduct.

The Licensing Authority may provide for the temporary suspension of such a person upon the commencement of administrative or disciplinary procedures against them for failure to fulfil their obligations.

If it were found that a QP had intentionally or unintentionally certified a batch as fit for sale or supply without ensuring that the relevant tests and checks had been performed or was otherwise not in compliance with either GMP or the Marketing Authorisation / PSF, this would be considered by both the appropriate Professional Body and the Licensing Authorities as a matter of professional misconduct.

- 13.2.** The Professional Bodies each have established disciplinary procedures to deal with cases of possible misconduct. One of the powers is to remove the name of an individual (or individuals) from the appropriate register or registers. Where required, the Professional Bodies will work together (e.g. if a person is a member of more than one). In all cases, the Professional Bodies will inform the Licensing Authorities of these situations.
- 13.3.** The Licensing Authorities has the power to delete the QP's name from any Manufacturer's Authorisation.