ROYAL PHARMACEUTICAL SOCIETY

Royal Society of Biology

ROYAL SOCIETY OF CHEMISTRY

## Qualified Persons involved in the manufacture of pharmaceuticals

# Study Guide

**The knowledge and practical experience required by Qualified Persons involved in the manufacture of pharmaceuticals in the UK.**

**January 2022**

**Contents**


Preface

Purpose

1.0 The Qualified Person involved in the manufacture of pharmaceuticals: background.

2.0 The three foundation knowledge elements

a. Pharmaceutical law and administration

b. The role and professional duties of the Qualified Person

c. Pharmaceutical Quality Systems

3.0 Additional knowledge requirements for the Qualified Person

d. Mathematics and statistics

e. Medicinal chemistry and therapeutics

f. Pharmaceutical formulation and processing

g. Pharmaceutical microbiology

h. Analysis and testing

i. Pharmaceutical packaging

j. Active Substances and excipients

k. Investigational medicinal products

4.0 The Qualified Person Practical experience requirements

4.1 Illustration of requirements

5.0 Role of the Qualified Person

5.1 Human & Veterinary Products

5.2 Clinical Trials

5.3 Qualified Person suitability

6.0 Other Countries

7.0 Summary


| | |
|---|---|
| Reason for issue: | Wrong month stated in the preface section. This has been corrected. Title slide has also been updated to match the guidance notes. |
| Issue date: | January 2022 |

**Preface**

The three UK professional bodies, also known as the Joint Professional Bodies (JPB), administering the Qualified Persons scheme, the Royal Pharmaceutical Society, the Royal Society of Biology, and the Royal Society of Chemistry, first introduced a Study Guide for Qualified Persons in 1978 based on EC Directive Article 23 of 75/319/EEC. Further revisions were completed in 2000, 2004, 2006, 2008, 2013 and 2017. This revision was made effective from September 2021.

**The three professional bodies require an applicant for certification of eligibility for nomination as a Qualified Person to demonstrate a thorough understanding of the foundation knowledge elements, to apply their knowledge of Pharmaceutical Quality System (PQS) principles, and to demonstrate understanding of the additional knowledge requirements. The applicant will be required to demonstrate this by reference to the products and processes for which they are claiming qualifying experience, which will apply wholly or in part to the Manufacture & Importation Authorisation (known as a Licence herein) detailed on the application. The applicant will also be expected to demonstrate an ability to translate those principles and requirements to other dosage forms or scenarios currently outside their direct experience.**

The three professional bodies have determined that the foundation knowledge elements are:

- Pharmaceutical law and administration;
- The role and professional duties of the Qualified Person; and
- Pharmaceutical Quality Systems (PQS) i.e. the basic philosophy and principles of Quality Assurance, which applies to all sections of this guide.

Certification of eligibility for nomination as a Qualified Person on a Licence is dependent upon the demonstration of both an appropriate knowledge of those activities and disciplines relevant to pharmaceutical manufacturing and QA, and appropriate practical experience (see section 4.0). The education requirements for candidates are described in the Guidance Notes for Candidates and Sponsors.

**Purpose**

The purpose of this guide is to describe the areas of knowledge and experience to be met by Qualified Persons. It can be used as a reference by applicants wishing to attain QP eligibility to ensure they have relevant practical and theoretical skills. It may also be used to assist with both gap analysis for training/development and in the preparation of QP application forms. The QP applicant should also ensure that in addition to the content in this guide, their knowledge is aligned with the current standards, technology and methods being applied to pharmaceuticals.

## 1.0 The Qualified Person involved in the manufacture of pharmaceuticals: background.

The Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom Department of Health, and the Veterinary Medicines Directorate (VMD), have interpreted the requirements of the UK Statutory Instruments and European Union (EU) Pharmaceutical Directives, relevant to the Qualified Person, through a “Study Guide”, drawn up by a JPB panel of experts.

The role of the professional bodies is to assess the suitability of the applicant against the requirements in this study guide and the educational requirements for candidates as described in the Guidance Notes for Candidates and Sponsors and, if successful, certify their eligibility for nomination as a Qualified Person on a Licence.

The assessment process includes submission of a completed application form, the sponsorship of an applicant by suitable persons, must include a Qualified Person who is also a member of one of the joint professional bodies, (see Guidance notes for applicants and Sponsors), the payment of an application fee, and an oral assessment of the applicant's knowledge and experience. Acceptance of a person, certified as eligible for nomination, on a Licence is a matter for the Licensing Authority.

The Licencing Authorities have the capacity to appoint QPs independently of being certified as eligible by the professional bodies.

Assessments are conducted by a panel of assessors typically drawn from all three professional bodies, who are themselves well acquainted with the role of the Qualified Person. The professional bodies have agreed with the MHRA and VMD that, in principle, an individual who has been certified as eligible for nomination as a Qualified Person is also potentially eligible for transfer from one Licence to another, although the final decision for accepting a person as a Qualified Person on a Licence rests with the Licensing Authority in the UK. In consequence the assessors must be satisfied that an applicant, after a suitable induction period, will be able to function as a Qualified Person in any licensed undertaking and for this reason the QP applicant should expect questions outside of their chosen dosage form and/or experience.

## 2.0 The three foundation knowledge elements

### a. Pharmaceutical law and administration

To assure patient safety, the manufacture and distribution of pharmaceutical products is highly regulated within the UK. The Qualified Person must ensure that all legislative obligations are fully satisfied before any product is certified and released for sale or supply in countries where manufacturing has occurred or where the product will be distributed.

A Qualified Person must have a comprehensive knowledge of all current and forthcoming UK and European legislation relating to the manufacture, storage and supply of licensed medicinal products (human and veterinary), Investigational Medicinal Products and the interpretation of the law and guidance. Legislation is subject to regular update and details of major changes can be found in FAQs published on the individual Professional Body websites.

Statutory Instruments (SI) set out a comprehensive regime for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale, and supply of those products; for their labelling and advertising; and for pharmacovigilance: including provision for the role of the Qualified Person. The withdrawal agreement also established the “Northern Ireland Protocol”, under which the province of Northern Ireland will remain within the EU regulatory system and must comply

with relevant EU requirements. Qualified Person applicants should be able to demonstrate an awareness of both the UK SI and EU Directives applicable to the Qualified Person operating under the “Northern Ireland Protocol”.

Applicants will be expected to **demonstrate a thorough understanding through application** of the following:

- Human Medicines Regulations 2012 and other UK national medicines legislation e.g. SI, and the Veterinary Medicines Regulations, including amendments;
- European Pharmaceutical Directives
- Marketing, Manufacturing and Wholesaler Authorisation structure, content, application and approval procedures, and responsibilities;
- the role, legal status, and structure of both the British and European Pharmacopoeias, including the certification procedure of the EDQM;
- the organisation of the UK MHRA, the role of the European Medicines Agency (EMA) and the role of the Veterinary Medicines Directorate (VMD);
- procedures for dealing with complaints and product recalls, the role of the MHRA’s Defective Medicines Report Centre, VMD’s defect reporting process and the EMA’s CHMP/CVMP guidelines on Quality;
- pharmacovigilance regulations and requirements;
- the application and scope of Mutual Recognition Agreements (MRAs) between GB and other countries, and between EU and other countries, for Northern Ireland;
- how to interpret and apply the regulations concerning importation of pharmaceutical medicinal products from outside of GB and Northern Ireland; and
- Pharmaceutical Inspection Co-operation Scheme (PIC/S) and International Council for Harmonisation (ICH).

### b. The role and professional duties of a Qualified Person

It is incumbent upon all Qualified Persons, whether or not members of one of the three UK professional bodies, that they discharge their professional duties in accordance with the **Code of Practice for Qualified Persons. The Code of Practice was produced by MHRA, VMD and the three UK ‘professional bodies’ and defines the standards of conduct and good practice for the Qualified Person.**

It is the responsibility of the Qualified Person to certify that a product has been manufactured in accordance with its Marketing Authorisation or Clinical Trial Authorisation (where appropriate) and with Good Manufacturing Practice (GMP).

The Qualified Person might not have direct line responsibility for many of the activities which could affect compliance with GMP or the relevant Marketing Authorisation, however, they must be aware of any information, incidents or deviations which may influence their decision to certify whether a batch is compliant and subsequently suitable for release.

Applicants will be expected to **demonstrate a thorough understanding through application** of the following:

- the Legal and Routine duties of a Qualified Person as described in Annex 16, the level of oversight required; including detailed knowledge on the principles and application of 'risk management' within the pharmaceutical industry;
- how to interpret and apply the various International Conference on Harmonisation (ICH and VICH) guidelines;
- the key factors, product or process information or metrics that confirm that a batch of pharmaceutical product is suitable for certification and has been made to GMP;
- the principles and practice of current GMP as described within the GMP guidance including the Regulations made under the Human Medicines Regulations 2012 and MHRA guidance issued via their website, and within in European Directives/Regulations and EudraLex;
- the conduct and obligations of Marketing Authorisation (MA) and Manufacturer's / Importer's Authorisation (MIA) holders (and the equivalent for Veterinary Medicines);
- the GMP requirements for Import and Export of medicinal products to GB and Northern Ireland;
- the conduct and obligation of Clinical Trial Sponsors and Investigational Medicinal Product providers;
- the role of the QPPV and the interactions between the QP and QPPV;
- the preparation and management of Regulatory Inspections;
- the requirements and responsibilities of the QP regarding Active Substances or Investigational Medicinal Product declarations; and
- the requirements for QPs when acting as independent contractors or on behalf of third parties.

### c. Pharmaceutical Quality Systems

The manufacture of pharmaceutical products requires the establishment and implementation of an effective 'Pharmaceutical Quality System' (PQS). The concepts of Quality Assurance, GMP and Quality Control (QC), which are interrelated, form the basis of such a system for the manufacture of pharmaceutical products from initial development, through clinical phases to commercial supply and discontinuation.

Applicants will be expected to **demonstrate a thorough understanding through application** of the following:

- the philosophy and basic principles of Quality Assurance, and roles of other functions throughout the product lifecycle;
- the design criteria for an effective PQS including but not limited to;
    - auditing and self-inspections;
    - management of quality and GMP at approved vendors and contractors;
    - deviations, root cause analysis, corrective and preventive actions;
    - process and product understanding;
    - validation life cycle including computer systems;
    - change and knowledge management;

- documentation, record management and data integrity;
- complaints and recalls;
- management review;
- training and competency assessment

- the principles of Quality Risk Management for the assessment, control, communication, and review of risks to the quality of the medicinal product;
- the interpersonal skills (leadership, delegation, communication, teamwork etc.) necessary to implement an effective PQS;
- the principles of design, selection, introduction and maintenance of premises, equipment, utilities, and services to maintain the validated state;
- calibration and preventative maintenance;
- the principles of purchasing and supplier certification, knowledge of supply chains and material control including but not limited to:
  - the roles of brokers, distributors and repackagers;
  - prevention of counterfeiting and illegal activities;
  - processes to support and verify the supply chain pedigree;
  - monitoring and control of both product and raw material transport and distribution processes;
- production planning, scheduling, and inventory control and principles of GDP;
- product quality reviews;
- organisational structures and reporting relationships; and
- technical agreements in contract giving and acceptance.

## 3.0 Additional knowledge requirements for the Qualified Person

### d. Mathematics and statistics

The practical application of basic statistical tools in pharmaceutical production and QA is essential in demonstrating the capability of processes or the acceptability of materials.

Applicants will be expected to **demonstrate understanding through application** of the following:

- the underlying principles and application of Statistical Process Control to pharmaceutical manufacturing, testing, control processes and use in product quality reviews;
- the underlying principles and application of ISO2859 “Sampling by Attributes” and ISO3951 “Sampling by Variables”, including the use of sampling plans and Acceptable Quality Levels (AQLs);
- the interpretation of stability data for modelling product performance and quality;
- appropriate data monitoring tools used to verify that appropriate storage and distribution conditions have been maintained;
- simple and statistical trending methods including but not limited to the underlying principles and application of Process Control Charts, Shewhart Charts, CUSUM Charts, Pareto Analysis, process capability (Cp/CpK) and process performance (Pp/PpK);

- statistics used in the planning and interpretation of process, facilities, utilities, and equipment validation;
- statistics applied during analytical method validation including, precision, accuracy, linearity and range, specificity / selectivity, LOD / LOQ, ruggedness, solution stability, robustness; and
- statistical tools for comparing data sets, e.g. analytical test results.

### e. Medicinal chemistry and therapeutics

The Qualified Person must understand the mode of action and uses of medicines in clinical practice to judge their significance for commercial or clinical trial supplies.

Applicants will be expected to **demonstrate understanding through application** of the following:

- basic physiology;
- outline knowledge of the autonomic nervous system and some general aspects of chemical structure/pharmacological action relationships;
- summary of key therapeutic drug classifications with examples;
- examples of disease states and their treatment with medicinal products;
- general absorption, distribution, metabolism, and excretion of drugs;
- principal routes of drug administration;
- principles of Good Pharmacovigilance Practice;
- general implications of clinical knowledge of drugs upon facility design (cross contamination control strategies, Health Based Exposure Limits (HBEL)), plant segregation/isolation, cleaning verification and production scheduling; and
- general implications of clinical knowledge of drugs in relation to complaint investigation, incidents, and deviations.

### f. Pharmaceutical formulation and processing

The formulation and processing conditions employed in the manufacture of medicinal and combination product dosage forms have a significant effect upon their safety, quality, and efficacy. Even subtle changes to the input materials and/or processing conditions can have a profound adverse effect on content uniformity, stability, bioavailability, and other attributes which are not detectable by routine QC testing.

It is vitally important that the Qualified Person understands the principles of formulation and pharmaceutical processing to ensure that informed certification and release decisions are made.

Applicants will be expected to **demonstrate understanding through application** of the following:

- the major processing techniques (chemical, biological, biotech and ATMP), their limitations, critical quality attributes and critical control parameters;
- the factors that could potentially affect purity, content uniformity, stability (chemical, physical, and microbiological) and bioavailability in manufacture;
- the principles of process validation and control;
- the principles of technology transfer and production scale-up;

- the principles of new manufacturing technologies;
- the principles of continuous manufacturing;
- quality critical attributes and in-process tests;
- pre-formulation studies and product development; and
- the storage and distribution of materials and finished products.

### g. Pharmaceutical microbiology

The Qualified Person must understand the significance of the presence of bacteria, yeasts, moulds, viruses, mycoplasmas and toxins in pharmaceutical raw materials, products, and production environments. In addition, they must understand how to prevent contamination by good product and facility design, GMP and control over starting materials, intermediates, finished products, production plant, utilities, processes, people, and the environment.

Applicants will be expected to **demonstrate understanding through application** of the following:

- sources and types of micro-organisms as related to pharmaceutical production and distribution;
- production of sterile and non-sterile products (small and large molecule) and associated environmental controls;
- bacterial endotoxins and pyrogens, their sources, removal, and testing;
- microbiology of water, its production and distribution systems; including different grades of water, their use, manufacture, and control;
- sterilisation and disinfection methods;
- interpretation of microbiological data;
- validation of microbiological test methods;
- microbiological specifications;
- selection and use of preservatives;
- microbiological test methods used in routine manufacture and product development, including for small and large molecule pharmaceutical production; and
- advances in rapid and automated methods of microbiological testing.

### h. Analysis and testing

The sampling and testing of materials do not themselves assure product quality, but are part of a comprehensive Pharmaceutical Quality System, which must be correctly implemented and controlled.

The data generated by laboratory testing of samples must be valid, representative, and evaluated before materials are certified and released for sale.

Applicants will be expected to **demonstrate understanding through application** of the following:

- Quality Control (QC) and Good Laboratory Practice (GLP);
- specification development and lifecycle management to support product quality;

- structured investigation of out of specification (OOS) and out of trend (OOT) results;
- the underlying principles, application and design of sampling regimes and their importance to achieving meaningful and accurate results;
- sample retention and retesting;
- pharmacopoeial monographs, test methods and general chapters;
- the principles of and interpretation of qualitative and quantitative analytical methods in common use for the analysis of medicinal products;
- the principles, methods and types, purpose, significance, and management of systems of in-process control;
- the principles, application and interpretation of biological analytical test methods and validation;
- the significance of degradation, contamination, and adulteration of pharmaceutical materials;
- the application of analytical techniques and sampling to cleaning verification and validation;
- the ICH guidelines for method validation, impurities, and stability testing;
- the principles, application, and interpretation of stability testing (protocols and methods), used during development to determine product shelf life and support ongoing marketing of the product; and
- the principles, application, and design of analytical method transfers.

### i. Pharmaceutical packaging

It is a requirement of GMP that holders of a Licences establish procedures for their packaging operations to minimise the risk of cross-contamination, mix-up, or substitutions. The Qualified Person must understand the importance of controlling packaging components (both primary and secondary, including printed materials) throughout the supply chain to assure the quality of finished products.

Applicants will be expected to **demonstrate understanding through application** of the following:

- control of packaging components by suppliers and throughout production;
- the chain of systems which ensure the integrity and accuracy of textual information from originator to routine production, including artwork generation, text approvals and regulatory submission / implementation requirements;
- the testing of packaging materials as part of incoming goods checks, including the application of sampling regimes and assurance of outsourced activities;
- the potential root causes of label and other printed component mix-ups and how they can be identified and eliminated;
- the optimum layout, organisation and control of packaging operations, different types of packaging and labelling processes and equipment, including the consideration of the type of equipment required for high volume / high speed operations and smaller / manual operations;
- the underlying principles and application of in-process controls conducted during packaging operations, including line clearance, pack integrity testing, challenge testing, reconciliation, bar coding and optical systems;

- the design and completion of packaging batch records, including full traceability of all product and materials for investigation and recall purposes;
- effects of packaging materials on product stability; and
- the requirements and desirability of tamper-evidence, anti-counterfeiting measures and general supply chain security.

### j. Active Substances and Excipients

The Qualified Person must understand the influence of manufacturing pathways and associated physical and physico-chemical attributes, of both active substances and major excipients on the quality of the finished dosage form.

Applicants will be expected to **demonstrate understanding through application** of the following:

- the steps commonly taken in the manufacture of small molecule Active Substances (AS) and excipients made by chemical synthesis, including their purpose and limitations;
- the steps commonly taken in the manufacture of large/ biological molecule and ATMP AS made by different pathways, including their purpose and limitations;
- the requirements of Good Manufacturing Practice as applied to the production of AS;
- the underlying principles, objectives, and limitations of the EDQM certificate of suitability;
- the pathways responsible for the generation of impurities or degradation products, and strategies for elimination, control, or removal of such impurities;
- impact and control of solvents, catalysts, and process aids;
- the potential and avoidance of contamination and adulteration of AS and verification of the supply chain pedigree;
- the physico-chemical and biological properties of AS and excipients, and their effect on the attributes of the final dosage form;
- the principles of process validation applied to AS;
- the requirements for AS intended for use in sterile products;
- the requirements for control and declarations regarding adventitious infectious agents e.g. TSE; and
- AS audit and QP declaration requirements.

### k. Investigational medicinal products

The manufacture, packaging, and distribution of Investigational Medicinal Products (IMP) must comply with GMP. There are significant differences between the manufacture and packaging of IMPs and licensed dosage forms which provide challenges. The Qualified Person must understand these differences together with the safeguards required to assure the quality of IMP supply.

Applicants will be expected to **demonstrate understanding through application** of the following:

- the functions of a Qualified Person as set out in the UK SI and EU Clinical Trials Directive 2001/20/EC, as described in section 5.2;

- the structure, contents, control and application of the Clinical Trial Application (CTA) and Product Specification File (PSF);
- ethical considerations in the design & lifecycle management of the Clinical Trial to protect the safety of clinical subjects including pharmacovigilance and reporting requirements to meet the desired outcome and the role of the sponsor and ethics committee;
- an understanding of clinical trial design at all phases (I, II, III and IV);
- controls surrounding the procurement, storage, distribution and control of IMP, Non-IMPs, placebo, licensed / un-licensed comparators, and rescue products;
- the underlying principles for the development, justification and application of the manufacture and control parameters for each phase of clinical trial, applying risk management principles to assure the safety and quality of the product, and additional requirements for sterile and biological products;
- what aspects of validation and qualification need to be completed prior to investigational medicinal product administration to a human subject. In addition, applicants must also be able to demonstrate risk-based approach to establish expectations of the level of validation/qualification required for equipment, cleaning, process, and test methods;
- the underlying principles and application of the control of packaging of investigational medicinal products in the conduct of Clinical Trials including labelling and blinding;
- awareness of interpretation and application of Good Clinical Practice (GCP) and reporting of safety information; and

the requirements for effective batch documentation, control, sampling, testing and batch certification / release, including the control, certification and release of imported IMPs and comparators.

### 4.0 The Qualified Person: practical experience requirements

The precise wording used in the UK Statutory Instruments, “The Human Medicines Regulations 2012”, No. 1916, Schedule 7, Part 1 Paragraph 8 (qualified persons) as follows:

“The person must have at least two years’ practical experience in an undertaking authorised to manufacture medicinal products of qualitative analysis of medicinal products, quantitative analysis of active substances; and the testing and checking necessary to ensure the quality of medicinal products.”

This legal obligation has been interpreted in the UK as requiring the applicant to have had at least one/two[#] years of relevant practical, “hands on”, day to day practical experience in assuring the quality of medicinal products during their manufacture, including Good Manufacturing Practice, as defined in the current edition of the GMP guidance.

([#]In the UK, the MHRA and VMD have approved one year of practical experience for pharmacists.)

### 4.1 Illustration of requirements

Applicants may find the following information helpful in further understanding the expectations of the professional bodies and of the knowledge and practical experience requirements which need to be satisfied.

The professional bodies will seek demonstration of the following:

i. The applicant must have had at least one/two[#] years relevant practical experience in one or more Quality Assurance activities gained in premises Licensed for the manufacture of medicinal products. (The MHRA advises that experience obtained in an establishment that has only a Specials Licence (MS) cannot contribute to the practical experience requirement as described in part 5.0 above. Experience in manufacture of Active Substances (AS) only contributes if the AS is made under the provisions of a MIA or MIA(IMP). The applicant must demonstrate a thorough core competence in the manufacturing processes and the Pharmaceutical Quality Systems involved in the production, testing, batch certification and approval for sale of the products made under the Licence (s) under which they are claiming qualifying experience. All candidates should show in their application that experience has been actively gained, for example through participation in Audits, leading or participating in investigations, rather than passive experience gained from visiting a facility or reading and reviewing PQS documentation.

ii. In addition, it is important that the applicant can demonstrate an ability to translate and extrapolate the working knowledge and understanding gained from their qualifying experience. Scenario questions may be used to determine whether an applicant is able to articulate a logical approach to a practical situation with which they may be unfamiliar, thereby demonstrating their ability to apply knowledge and experience.

iii. The applicant can expect detailed questioning on their knowledge of PQS principles and will be required to demonstrate this by reference to the products or processes operating under the Licence(s) under which they are claiming qualifying experience. The assessors may ask questions pertinent to other products, processes, activities, or functions which they consider relevant. The applicant must satisfy the assessors that after a suitable induction period, they will be able to function as a Qualified Person in any licensed undertaking.

(#In the UK, the MHRA and VMD have approved one year of practical experience for pharmacists.)

## 5.0 Role of the Qualified Person

### 5.1 Human and Veterinary Medicinal Products

The functions of a Qualified Person are set out in the relevant UK SI (for Great Britain) and EU Directives (for Northern Ireland) as follows:

- to ensure that each batch of the medicinal product to which the Licence relates has been manufactured or assembled and checked in compliance with the provisions of the Licence and Product Licence/Marketing Authorisation which relates to the product;
- to certify in a register, or other record appropriate for the purpose, whether each production batch of the medicinal product to which the licence or authorisation relates satisfies the requirements set out above and to ensure that such register or other record is regularly maintained, and that the appropriate entries in such register or other record are made as soon as practicable after each such batch has been manufactured;
- for medicinal products manufactured outside GB or EU, the Qualified Person must ensure that each imported batch has undergone a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the Marketing Authorisation;
- in the case of medicinal products imported from outside GB or EU, where appropriate arrangements have been made with the exporting country to ensure that the manufacturer of the medicinal product applies standards of GMP at least equivalent to those laid down by the

UK and to ensure that the controls referred to above have been carried out in the exporting country, the Qualified Person may be relieved of responsibility for carrying out those controls.

- For supply into NI the QP must also ensure that the requirements in 2016/161/EU (delegated regulation for safety features) are met.

### 5.2 Clinical Trials

The functions of a Qualified Person as set out in the relevant UK SI and EU Directives (for Northern Ireland) in particular regulations 13 and 17 of The Medicines for Human Use (Clinical Trials) Regulations 2004, No. 1031 which require that each batch of IMP has:

- been manufactured and checked in compliance with the UK SI or EU Directive laying down the principles of good manufacturing practice for medicinal products for human use and investigational medicinal products for human use, the product specification file and current UK and EU clinical trials legislation
- in the case of an investigational medicinal product manufactured outside of the UK or EU, that each production batch of product has been manufactured and checked in accordance with standards of Good Manufacturing Practice at least equivalent to those laid down in UK SI and EU directives, in accordance with the product specification file and current UK and EU clinical trials legislation;
- in the case of an investigational medicinal product which is a comparator product manufactured outside of UK or EU and which has a Marketing Authorisation, where the documentation certifying that each production batch has been manufactured in conditions at least equivalent to those laid down in UK SI and EU directives cannot be obtained, that each production batch has undergone all relevant analyses, test or checks necessary to confirm its quality in accordance with current UK and EU clinical trials legislation.

### 5.3 Qualified Person Suitability

The role of the Qualified Person is thus of considerable importance within the industry and this should be reflected in the calibre of applicant appointed to such a position. Although every person included in the Register meets, in the opinion of the professional body concerned, the statutory requirements to be considered eligible to be a Qualified Person, it is up to individual companies to satisfy themselves of the suitability of any individual applicant for a particular post.

The Licensing Authority makes the final decision of who can be named as a Qualified Person on a Licence.

## 6.0 Other Countries

Applicants from outside the UK, who are not members of any of the three professional bodies, but who hold an appropriate qualification as defined in the UK SI, will be considered by the Licensing Authority, on nomination by a company, as a QP for a Licence.

## 7.0 Summary

**In summary,** the applicant must demonstrate:

- the relevant practical experience in one or more Licensed facilities;
- an in-depth working knowledge of the foundation elements and understanding of all the requirements described in this Study Guide;
- a thorough understanding of the PQS principles and requirements laid out in the GMP guidance and other documents issued by the Health Authorities and relevant organisations (e.g. PICS, WHO, ICH, EU);
- an ability to translate those principles and requirements to other dosage forms or scenarios currently outside their direct experience;
- an endorsement of their credentials, including qualifications and experience, from a Sponsor (or if necessary, more than one sponsor) who meets the requirements described in the Guidance Notes for Applicants and Sponsors issued by the three professional bodies.