Qualified Person involved in the manufacture of pharmaceuticals.

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 Eoi(a)10.5 ta(n)10.5 (AE)1.9 (n)-5.9 (eoe)10.5 (r)-5.9 (i)2.6 (s)-2 a(t)-676 and the UKand o

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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

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- 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

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. [illegible]