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How the Qualified Person relies on the analyst

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In order to understand the reliance that the Qualified Person (QP) has on the analyst we need to examine the role the Qualified Person within a manufacturing pharmaceutical operation. The pharmaceutical QP role was established in 1975 through European Directive 75/319. The Directive defined the key responsibility of the QP as ensuring that each batch of medicinal product meets the requirements of the its Marketing Authorisation (Product Licence) as well as having been manufactured in accordance with pharmaceutical Good Manufacturing Practices.

In establishing the QP in the UK a code of practice was drawn up by the professional bodies responsible for maintaining the register of QPs within the UK. This code is now included as a section in the Medicines Control Agency's Rules and Guidance to Pharmaceutical Manufacturers and Distributors. The code of practice identified 10 elements in the QP's duties. It also indicated that, given the broad scope expected in these 10 elements, that the QP would be reliant on delegating some of the duties to working colleagues to ensure that all the duties were professionally discharged. Review of these elements of the QP's duties reveals three main areas in which the QP is reliant on the analyst; namely in establishing product quality on a batch by batch basis, establishing process assurance through validation and investigating failures in the product or process.

The first of these three areas covers the majority of the routine support given by the analyst to the QP. Included in each Marketing Authorisation will be tests to be carried out, either in-process or on the finished product, which confirm product quality. Whilst some of these tests may be relatively simple physical characterisations of the product the majority will be complex qualitative and quantitative analytical tests designed to confirm that the particular batch has been manufactured to the required quality and formula. The data generated in routine product testing is a keystone of the QP's decision to release a batch of product to the market.

The second area of the areas in which the analyst provides support is in process assurance. This includes validation of the test methodology used in routine product testing. Here the analyst will be generating the data to show that the test methodology employed is precise, accurate and robust. In addition the analyst will also be involved in the validation of the manufacturing process, taking samples taken from various stages of the process and testing to ensure that the process consistently produces product of the required quality.

The final area, and the most demanding for the analyst, is in failure investigation. This may come about from problems with the manufacturing process or from customer complaints returned from the marketplace. Here the analyst may well have to resort to non-routine methodology to help the QP to establish both the cause of failure and its effect on the product.

In all three of these areas the QP is relying on the analyst to provide accurate data from testing to underpin decisions that the QP is called on to make. The QP is also relying on the analyst's expertise to evaluate test results against knowledge of the test methodology's performance and limitations.

In supporting the decisions that the Qualified Person has to take the analyst is playing a vital part in ensuring that the patient receives a medicinal product of adequate quality, safety and efficacy.

European Directive 75/319 (1975). Office for Official Publications of the European Communities. Chapter IV

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (1997) Code of Practice for Qualified Persons. The Stationary Office. Part two: 17–28