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PROPOSAL FOR A QUALIFIED PERSON IN THE NEW EUROPEAN REGULATION FOR MEDICAL DEVICES

JOHN WORROLL | 2013

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INTRODUCTION

This Article describes the requirement for a "Qualified Person" (QP) contained in the EU Commission Proposal for a new Regulation to cover medical devices and active implantable medical devices.

The Proposal is the result of long discussions between the Commission and stakeholders in the 27 Member States and aims to address the perceived weaknesses of the current Directives 93/42/EEC and 90/385/EEC.

The Proposal says that the QP should be responsible for regulatory compliance within a manufacturer's organisation and points out that a similar requirement exists within the EU legislation for medicinal products.

Some Member States (eg Germany) have a similar requirement in their local laws for medical devices.

REQUIREMENTS FOR A QP

Article 13.1 of the Proposal says that:

"Manufacturers shall have available within their organisation at least one qualified person who possesses expert knowledge in the field of medical devices."

It goes on to say that the expertise of the QP shall be demonstrated in one of two ways:

Either: "a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices;"

Or: "five years of professional experience in regulatory affairs or in quality management systems relating to medical devices."

In other words, extra professional experience can take the place of academic qualifications.

Another point to note is that the Proposal is quite explicit about the QP being "within the manufacturer's organisation" which appears to preclude the use of an external consultant. On the other hand, most manufacturers who are complying with the medical devices directives will already have, de facto, such a person within their organisation. Therefore, providing the experience requirements are met, there may be no need for additional recruitment.

There are two minor derogations for manufacturers of custom made devices. Firstly, the experience requirement is reduced to two years regardless of academic qualification. Secondly, there is no need for custom manufacturers who are "micro-enterprises" as defined by Regulation 2003/361/EC to have a QP.

ROLE AND FUNCTION OF A QP

The Proposal says that the QP is responsible for ensuring the following:

(a) that the conformity of the devices is appropriately assessed before a batch is released;
(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;
(c) that the reporting obligations in accordance with Articles 61 to 66 are fulfilled;
(d) in the case of investigational devices, that the statement referred to in point 4.1 of Chapter II of Annex XIV is issued.

In other words, the QP is responsible for ensuring the requirements of the Regulation are met by the manufacturer. There is an analogy with the ISO 9001 and ISO 13485 requirement for a "Management Representative":

"Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes …… ensuring that processes needed for the quality management system are established, implemented and maintained."

In the case of the proposed Regulation, the function is to ensure and maintain regulatory compliance and in the case of the QMS standards, the function is to ensure and maintain the QMS.

Finally, the proposed Regulation says that:

"The qualified person shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties."

This appears to mirror the QMS phrase "irrespective of other responsibilities" in giving QPs freedom to discharge their responsibilities without fear or favour.

QUALIFICATIONS AND ANALOGY WITH THE PHARMACEUTICAL EQUIVALENT

It can be seen from the foregoing that, although the role and responsibility of the QP is similar in principle between the pharma and medical device worlds, the differences in detail are significant:

- The educational requirements are different in that the medical device QP can rely on professional experience alone
- Batch release is a major factor in the pharma world, but it plays a much smaller role in the medical device world. In practice the requirement for the QP to ensure that the "conformity of the devices is appropriately assessed before a batch is released" is probably more to do with ensuring that the conformity assessment has been properly carried out and that there is a quality system in place for product release rather than with physically releasing each batch.

Because of these differences, it has been argued that the term "QP" should be changed for medical devices to avoid confusion with and "mission creep" towards the pharmaceutical term.

On the other hand, any medical device manufacturer wishing to comply with the Harmonised Standard for a quality management system, EN ISO 13485 will take note of the Human Resources requirement in para 6.2 that:

"Personnel performing work affecting product quality shall be competent on the

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basis of appropriate education, training, skills and experience."

Manufacturers may therefore wish to implement a training programme to ensure their QPs have a good theoretical and practical knowledge of the regulations, covering the whole area rather than just relying on what they have picked up "on the job".

CONCLUSIONS

The QP requirement should not be onerous as most manufacturers placing product on the market in compliance with the medical devices directives are de facto implementing the requirement already. However, manufacturers may wish to give some thought to a formal training programme to ensure that they meet not just the letter but also the spirit of the requirement, and to ensure their compliance with its QMS aspects as set out in EN ISO 13485.

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About the author: *John Worroll is a senior consultant with NSF Health Sciences Medical Devices, part of NSF Health Sciences, a division of NSF International. Before that, he worked for MHRA for 27 years in a variety of regulatory roles, followed by 8 years at the BSI Notified Body for medical devices where he was responsible for their regulatory compliance world-wide. He can be reached at EUdevices@nsf.org*