A 101 Guide to Qualified Person (QP) Release in Clinical Trial Supply

Understanding pharmaceutical legislation is vital for successfully navigating the complex global clinical trials market and ensuring the timely supply of your Investigational Medicinal Products (IMPs). In Europe the Qualified Person (QP) plays a crucial role in bringing safe and timely products to the market. For pharmaceutical companies based outside of Europe it is important to understand European GMP requirements and the role and responsibilities of the QP. In this Pharma IQ 101 we highlight role of a Qualified Person in clinical trial supply management and the regulations you need to know.

The QP is essential to the safe control of medicines and needs to have extensive training and in-depth critical understanding of all the aspects associated with pharmaceutical manufacturing. Each QP named on the Manufacturer's / Importer's License within the EC or EEA takes personal responsibility for the quality of the Investigational Medicinal Product (IMP) being released within the European Community/ European Economic Area (EC/EEA).

QP oversight has been extended to material for use in clinical trials since the introduction of EU Clinical Trials Directive 2001/20/EC of 4 April 2011. All IMPs must be certified by a QP prior to release for use in a clinical trial according to the Clinical Trial Directive 2001/20/EC and Annex 13 to the European GMP Guide.

The New Regulation No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC was recently published in the Official Journal on 27 May 2014.

Article 62 - Responsibilities of the qualified person

1. The qualified person shall ensure that each batch of investigational medicinal products manufactured in or imported into the Union complies with the requirements set out in Article 63 and shall certify that those requirements are fulfilled.
2. The certification referred to in paragraph 1 shall be made available by the sponsor at the request of the Member State concerned.

The Role of a Qualified Person (QP)

The QP must be a person named as QP on a relevant manufacturing licence in the EU, so he or she may be employed by the Packager or by the Importer, or indeed may in some cases be employed by the Sponsor, but since there can be only one QP responsible for certifying the product, he or she must have a knowledge of the quality systems operating throughout the supply chain.

The prime role of the Qualified Person is to certify that the investigational product has been:

– made and tested,
– imported,
– packaged and labelled

in compliance with the Product Specification File and the Clinical Trial Application,
And in premises that hold appropriate authorisations and licences
And in compliance with EU GMP

(Source: Importation of Clinical Trials Materials: Contracts, Technical Agreements and Qualified Persons)

The following contain further requirements for the tasks to be fulfilled by a Qualified Person in Europe

EU GMP Guide to Good Manufacturing Practices - Volume 4 Good manufacturing practice (GMP) Guidelines

Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.

Annex 16 to the EU Guide to Good Manufacturing Practice Certification by a Qualified Person and Batch Release

1.1 This annex to the Guide to Good Manufacturing Practice for Medicinal Products ("the Guide") gives guidance on the certification by a Qualified Person (Q.P.) and batch release within the European Community (EC) or European Economic Area (EEA) of medicinal products holding a marketing authorisation or made for export. The relevant legislative requirements are contained in Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC.

1.2 The annex covers in particular those cases where a batch has had different stages of production or testing conducted at different locations or by different manufacturers, and where an intermediate or bulk production batch is divided into more than one finished product batch. It also covers the release of batches which have been imported to the EC/EEA both when there is and is not a mutual recognition agreement between the Community and the third country. The guidance may also be applied to investigational medicinal products, subject to any difference in the legal provisions and more specific guidance in Annex 13 to the Guide.

1.3 This annex does not, of course, describe all possible arrangements which are legally acceptable. Neither does it address the official control authority batch release which may be specified for certain blood and immunological products in accordance with Article 11 point 5.4 and Articles 1091 and 110 of Directive 2001/83/EC.

1.4 The basic arrangements for batch release for a product are defined by its Marketing Authorisation. Nothing in this annex should be taken as overriding those arrangements.

Resources

Importation of Clinical Trials Materials: Contracts, Technical Agreements and Qualified Persons
http://www.cmbarnettpharma.co.uk/downloads/Importation%20of%20CTM%20-%20GOR.pdf

Directive 2001/20/EC
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF

EU Regulation No 536/2014
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2014:158:FULL&from=DE

Concept paper on Revising Annex 16 of the Guide to Good Manufacturing Practice: Certification by a Qualified Person and Batch Release
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2011/11/WC500117389.pdf

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"A great event with excellent content!" *Sr. Manager Clinical Supplies, Alexion Pharmaceuticals*

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