

Sterilisation

3.13 B 30

Guidance on the Information Required for Notified Body Medical Device Personnel Involved in Conformity Assess- ment Activities

Herkunft	Notified Body Operations Group
Quellen	NBOG BPG 2014-2
Bezug	90/385/EEC, 93/42/EEC, 98/79/EC, Commission Regulation (EU)
Schlüsselwörter	clinical expert, decision maker, experience, notified body, quality management system auditor / site auditor, (final) reviewer, product reviewer, technical expert, qualification criteria
Stand	November 2014



Guidance on the Information Required for Notified Body Medical Device Personnel Involved in Conformity Assessment Activities

“Personnel involved in conformity assessment activities” cover all those who will undertake activities under the medical device regulations, including quality management system auditors / site auditors, product reviewers, technical experts, clinical experts, (final) reviewers and decision makers, and regardless of whether it is internal or external personnel.

1 Background

- 1.1 The Medical Devices Directives require a Notified Body to have staff with sufficient expertise to carry out its tasks. This document gives guidance for Notified Bodies on the knowledge and experience that their medical device personnel should have and on the preparation of the information they are required to hold for each of its medical device personnel to demonstrate this.
- 1.2 The information should be specially prepared for this purpose. CVs prepared to apply for employment by a Notified Body may only be supportive. A suggested format is [NBOG F 2014-2 “Qualification of Personnel”](#).
- 1.3 The information shall be prepared in the light of the scope of activities that the Notified Body is authorising the person to carry out.
- 1.4 These persons may be involved in a number of ways in the conformity assessment activities provided by the Notified Body:
 - as a member of a team auditing a manufacturer’s quality system;
 - as a technical expert advising the audit team, and in particular the audit team leader, on aspects of the manufacturer’s design or production processes;
 - as an expert assessing the manufacturer’s technical files and or / design dossiers;
 - as an expert assessing manufacturer’s clinical evaluations;
 - as an expert in testing, or
 - as a (final) reviewer and decision-maker on certification.

This guidance addresses the information required for all these activities.

2 General Principle

Since persons will usually be employed to assess specific types of medical devices and / or associated processes, the information shall contain adequate detail to demonstrate that the person’s education, qualifications, work experience and training are sufficient to enable them to address the relevant regulatory requirements for medical devices. This includes the safety and performance of medical devices arising from the way in which they are made, how they work and how they are used.

3 Education and qualification

- 3.1 The person's education and qualification is most likely to be in one or more of the following:
- biology or microbiology;
 - chemistry or biochemistry;
 - computer and software technology; programming;
 - electrical, mechanical or bioengineering;
 - materials or biomaterials science;
 - medicine, veterinary medicine;
 - medical technology;
 - pharmacy, pharmacology, toxicology;
 - physics or biophysics;
 - physiology;
- 3.2 The minimum education and qualification will generally be at degree or equivalent level. However, in the case of experts with extensive industrial or medical device user experience a lesser qualification may be acceptable.

4 Work experience

- 4.1 The previous work experience of Personnel involved in conformity assessment activities is most likely to be:
- work in medical devices industry or closely related industries (e.g. pharmaceutical industry) such as research and development, manufacturing, regulatory affairs;
 - work in health services, universities. Foundations or other institutions carrying out inspections, audits, clinical evaluations, experimental and/or clinical research;
 - work in the application of device technology and its use in health care services and with patients;
 - testing devices for compliance with the relevant national or international standards;
 - conducting performance testing, evaluation studies or clinical trials of devices.
- 4.2 The work experience shall be relevant to current safety and performance aspects of the type of medical devices or the specific technology or area (e.g. sterilisation, preclinical or clinical assessment) with which the expert will work.
- 4.3 The information should identify:
- the companies or organisations with whom the experience was gained;
 - the dates when the person was directly involved with activities that enabled them to develop their expertise;
 - their roles and responsibilities;
 - the medical devices (specific or generic types), processes or technologies with which they were directly involved.

5 Training or professional development

- 5.1 When the person's major work experience background has been in a different but closely related industrial sector (i.e. not specifically medical devices), or where medical device expertise was gained some time in the past and has not been kept up to date, it is expected that special training will have been given to the person. This should have been based on an assessment of the gaps in the person's knowledge and understanding of manufacturing, safety, performance and use of the medical devices or technologies. Where appropriate, the training could involve accompanying other recognised experts as part of a systematic programme for acquiring the necessary medical device or technology expertise.
- 5.2 Additional training shall have been undertaken in areas related to the medical devices, their manufacture, safety and use, or in the auditing of manufacturers against the regulatory requirements of the European Medical Devices Directives or relevant (harmonised) standards (for example EN ISO 13485).
- 5.3 Specifically, any relevant courses attended that have further developed the persons expertise should be identified, indicating the organisation responsible, objectives and dates. If the course involved an examination this should be stated.
- 5.4 In service training should be systematic throughout the professional life.

6 Regulatory knowledge

- 6.1 All personnel (including external) must have proven knowledge of the Medical Devices Directives and their application to the medical devices scope in which they will work.
- 6.2 The information should demonstrate that training in medical device regulations has been received. This should include identification of the organisation responsible for the training, its scope and duration. Knowledge or experience gained on the application of the regulatory requirements in practical work should also be stated.

7 Special processes, technologies, areas

- 7.1 Special processes are for example those as defined in EN ISO 13485 (for example, sterilisation, software, welding etc.). The information shall make clear whether the person has training and/or experience for specification, design, validation or use. In addition, specific qualification and experience is also needed for some areas like assessment of biocompatibility or clinical data.
- 7.2 Specific requirements for sterilisation
- The information in support of persons (generalist and specialist) assessing sterilisation processes and environmental controls shall demonstrate an appropriate level of awareness of microbiology, the principles of environmental control and knowledge of microbial inactivation methods.
- 7.2.1 Persons authorised to assess **general** environmental and sterilisation process controls shall have:
- training and expertise in auditing quality systems;
 - training and expertise in process validation;
 - training in the application of current harmonised sterilisation standards relevant to the sterilisation methods being assessed;
 - practical experience of auditing sterilisation processes, relevant to the sterilisation methods being assessed;

- training in the application of current environmental control standards;
- practical experience of auditing controlled environment areas.

7.2.2. Persons authorised to assess the effectiveness of a sterilisation process shall be able to demonstrate:

- full expertise in the competencies listed for generalists listed above
- a sound knowledge of the fundamental principles behind the validation methods and microbial inactivation kinetics described in the harmonised sterilisation standards relevant to the sterilisation methods being assessed.

It is anticipated that the competencies above will have been gained from several years work experience with the medical device sterilisation technologies being assessed.

7.3. Specific requirements for animal tissues.

The information for persons assessing medical devices utilising tissues or derivatives originating from animals shall make clear what training and/or experience they have of the relevant sourcing controls and inactivation processes.

7.3.1 The following areas of education and qualification are likely to be most relevant:

- Veterinary medicine
- Biology or microbiology
- Chemistry or Biochemistry

7.3.2 Persons authorised to assess systems to minimise the risk of infection shall have:

- experience and/or training in the application of the standards, esp. EN 22442, and best practice documents;
- evidence of a structured program to keep up-to-date on relevant issues;
- knowledge of the requirements and interpretation of the Medical Devices Directives, including Commission Decisions and scientific opinions, for this subject area;
- Knowledge of risk analysis/management.

7.3.3 The sort of experience and background relevant to assess measures to reduce/eliminate risk are most likely to include many of the following:

- several years industrial experience in medical device technology utilising animal tissues or derivatives;
- a sound knowledge of the fundamental principles behind the sourcing controls and validation of inactivation methods described in the standard EN 22442;
- knowledge of the biological materials available to the healthcare market;
- assessment experience of medical devices utilising animal tissues or derivatives;
- knowledge of alternative non animal materials.

7.4. Assessment of biocompatibility or clinical data

The information for persons assessing biocompatibility or clinical data for medical devices shall make clear what training and/or experience they have.

The following areas of education and qualification are likely to be most relevant:

- Medicine or veterinary medicine;

- Biology or toxicology;
- Chemistry or Biochemistry (biocompatibility only);
- Materials or biomaterials science (biocompatibility only).

Persons authorised to assess biocompatibility or clinical data shall have:

- a sound knowledge of the fundamental principles of the assessment of biocompatibility or clinical data for medical devices;
- a sound knowledge/training in the current harmonised standards and guidance documents relevant to biocompatibility or clinical assessment for medical devices;
- practical experience in conducting or assessing preclinical or clinical trials or data.

It is anticipated that the competencies above will have been gained from several years work experience with the assessment of biocompatibility or clinical data for medical devices or closely related products like pharmaceuticals.

The Notified Body shall also be in the position to get input from medical practitioners having clinical experience with the medical devices being assessed or in the medical area the medical devices are used in. The information for these clinicians shall make clear what training and/or experience they have in which medical area.

8 Standards / CTS

- 8.1 Standards provide a link between academic and other knowledge and medical devices or technologies. The extent of the person's working knowledge of the relevant National, European or International standards shall be identified.
- 8.2 For persons working with in-vitro diagnostic medical devices, information supporting their knowledge and experience of Common Technical Specifications (CTS) shall also be included.

9 Other supportive information

- 9.1 Where there is additional information that demonstrates specific expertise or links between academic and other knowledge (e.g. public reports or journal articles etc.) this shall be a part of the information. The published documents or reports of evaluations, studies or test activities where the person had a direct involvement should be listed, or if extensive summarised with the key titles listed.

10 Summary

- 10.1 The information on education, qualifications, work experience and training or professional development should form a coherent and consistent package that readily relates to the proposed scope of the person's activities for the Notified Body. The information shall demonstrate the person's knowledge and experience of the medical devices, processes, technologies or areas (e.g. preclinical or clinical assessment) with which they will work.
- 10.2 The person's scope of activities for the Notified Body shall be defined in such a way as to make clear the boundary of those medical devices or technologies included and excluded. (e.g. orthopaedic implants, excluding sterilisation processes).
- 10.3 The Notified Body shall ensure that the information is kept up to date on a regular basis and is held on file by them.

References	90/385/EEC ¹ Annex 8 93/42/EEC ² Annex XI 98/79/EC ³ Annexes IX Commission Regulation (EU) No 722/2012 ⁴
Keywords	clinical expert, decision maker, experience, notified body, quality management system auditor / site auditor, (final) reviewer, product reviewer, technical expert, qualification criteria
Date of issue	November 2014

¹ Directive 90/385/EEC on Active Implantable Medical Devices, O.J. L 189, 20.7.1990, p. 17, as amended

² Directive 93/42/EEC on Medical Devices, O.J. L 169, 12.7.1993, p. 1, as amended

³ Directive 98/79/EC on *in vitro* diagnostic Medical Devices, O.J. L 331, 7.12.1998, p. 1, as amended

⁴ Commission Regulation (EU) No 722/2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin, O.J. L 212, 9.8.2012, p. 3