applicable for ☒ MDR, and ☒ IVDR

2017-2

Guidance on the Information Required for Conformity assessment bodies' Personnel Involved in Conformity Assessment Activities

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

1. Introduction

The Regulations (Regulation (EU) 2017/745 on medical devices (hereafter MDR) and Regulation (EU) 2017/746on *in vitro* diagnostic medical devices (hereafter IVDR)) require that conformity assessment bodies (CABs) have the necessary personnel and have access to all competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities and for the type of devices in relation to which they are designated.

To ensure consistency and transparency, the CAB will have a procedure(s) in place to ensure that the selection, training and authorisation of personnel are fully documented. The documentation of qualification, training and authorisation of personnel will allow the CAB to demonstrate that knowledge and experience of each person is sufficient to fulfil the qualification criteria and enable them to address the relevant regulatory requirements concerning safety and performance of medical devices (associated with their design, production and use).

The information on the person's background education, work experience, training and/or professional development will demonstrate the person's knowledge and experience on each type of device for which they are authorised, with particular reference to processes, technologies or areas (e.g. biological safety or clinical assessment) related to the scope of their activities (roles for specific codes). To this end, this information should form a coherent and consistent personnel file[1] that readily relates to the role and to the tasks the person is authorised.

The personnel's competence will be maintained and reviewed at pre-defined regular intervals and their authorisation updated accordingly in order to ensure that the supporting evidence underpinning staff's competence and authorisation is kept up to date. The CAB should carry out a yearly review of its full competence in order to verify that it can fulfil its scope of designation based on the internal and external expertise. Ideally each person's competence should be reviewed at least once every three years for its full scope of activities.

[1]This personnel file should contain all of the available supporting evidence underpinning internal and external competence and authorisation for each CAB's personnel. It should be available for the relevant designating authority upon request and also for the joint assessment team during the on-site joint assessment.

2. Scope

This document gives guidance for CABs on the knowledge, experience and training that their personnel should have and on the preparation of the supporting documentation they are required to hold for each of its medical device personnel to demonstrate the satisfaction of qualification criteria[2].

3. Definitions

3.1. Qualification: education, full set of knowledge and experience which makes staff suitable to carry out specific tasks or roles.

3.2. Authorisation: approval of personnel to certain conformity assessment activities and types of devices with associated NANDO codes or areas of expertise based on established qualification criteria.

3.3. Allocation: assignment of staff to specific conformity assessment tasks in the context of an individual conformity assessment application.

3.4. Education: formal academic studies carried out on the context of national education programmes (e.g. technical diploma or bachelor degree).

3.5. Knowledge: understanding of a given subject that is acquired by training or experience which can be measured in an objective and reproducible manner.

3.6. Experience: skills usually acquired in a working environment that are related to the specific tasks and responsibilities exerted by the person.

3.7. Function: set of tasks within the conformity assessment process such as auditing, product evaluation or testing, technical documentation review, final review and decision-making. Different functions might be covered under one role (e.g. auditing and testing).

3.8. Training: set of activities aimed to acquire and maintain certain level of skills which are needed to carry out a given task.

3.9. Role: position that a person has been assigned to within the CAB, for which a set of responsibilities and functions have been defined.

4. Supporting Documentation

This supporting documentation should refer to knowledge, experience and training, and should be used for the authorisation of personnel to their tasks. It is expected that documentation to justify the authorisation of staff should be specially prepared for this purpose. The suggested format is NBOG F 2017-7 and NBOG F 2017-8 on "Qualification and authorisation of Personnel".

This NBOG form should be completed for each individual participating or planning to participate in conformity assessment activities, according to the roles defined in section 4 of this guidance. The CAB should ensure that only verified information is included in this form (i.e. information provided in the CV for which supporting documentation has been provided).

[2] In exceptional cases where the fulfilment of the qualification criteria cannot be fully demonstrated, the CAB will justify the authorisation of these members of the personnel to carry out specific assessment activities.

The different sections of the form should show a clear trail between the relevant entries (related to knowledge, experience and training) and the subsequent assessment concerning the fulfilment of the relevant qualification criteria for the personnel role and type of devices or areas for which they will be authorised.

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 should 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.

Data related to consultancy activities may also be provided as part of the supporting documentation. This data should be taken into account in the allocation of personnel to specific projects but, depending on the CAB's authorisation system, it may also be important in the authorisation of personnel to specific codes and areas of expertise.

5. Roles

The CAB will establish qualification criteria at least for each of the following roles in accordance with Annex VII of the Regulations. The functions related to each role are specified below. If the CAB wishes to establish a different terminology for these roles (or split/merge them in different –roles), cross-reference and matching to the roles defined in this section should always be available.

5.1. Site auditor

Internal or external personnel responsible to carry out audits of the manufacturer's quality management system (QMS) and of its suppliers and/or subcontractors when appropriate and to draw up records and reports on the corresponding audits.

These personnel should have expertise in auditing[3] of healthcare products and therefore their authorisation as site auditors should always be based on technology codes MDT or IVT.

5.2. Product reviewer

Internal or external personnel that is responsible for carrying out product related reviews and drawing up records and reports about the corresponding assessment. In particular they should be responsible for one or several of the following tasks:

- Review of the manufacturer's technical documentation for the entire documentation or for specific aspects of this documentation such as biological safety, clinical evaluation, software or sterilisation validation.
- Carry out conformity assessment activities related to type examination, including establishment of test plans.
- Carry out conformity assessment activities related to the product verification, including establishment of test plans.

[3] Work experience in medical devices industry or closely related industries (e.g. pharmaceutical industry) such as manufacturing or quality management or in other institutions carrying out inspections or audits in the field of medical devices or other healthcare products, including notified bodies.

- Advise the audit team, and in particular the audit team leader, on aspects of the manufacturer's design or production processes which could be of particular relevance for the on-site audit.

In order to accomplish any of the tasks listed above, these personnel should always be authorised to specific MDR or IVR codes or horizontal MDS and/or IVS/IVP/IVD.

5.3. Project leader

As established in 4.4 of Annex VII, a Project leader is an individual responsible for ensuring that the assessment of an individual application is conducted properly, observing the CAB's procedures (in accordance with the relevant legislation, guidance documents, CS and/or harmonised standards). This person will ensure that the appropriate resources are utilised for each of the tasks of the assessment.

The CAB should define specific criteria for project leaders. Criteria for these personnel are not covered in this guidance.

5.4. Personnel with relevant clinical expertise (hereafter internal clinician)

Internal staff (where possible) that are responsible for the oversight of the clinical assessment of the technical documentation and fully integrated in the CAB's assessment and decision-making process. Specific tasks are defined in section 3.2.4 of Annex VII to the Regulations.

It is expected that the internal clinician will review and scientifically challenge the clinical data contained in the clinical evaluation and any associated clinical investigations provided within the technical documentation. This person could delegate – according to the internal procedures of the CAB – the review of part or all the clinical aspects to external experts (i.e. clinical specialists), in which case he/she will make a clinical judgment of the opinion provided by these experts. Such delegation will take place when clinical expertise on the clinical field related to the device in question or the clinical condition in which it is utilised is required and the internal clinician does not have this expertise. For instance, clinical specialist's input should be sought when the product is innovative (in terms of application and/or technology) and/or of high risk (implantable devices or class III under the MDR and class C and D devices under the IVDR).

In addition, the internal clinician may in certain circumstances identify other appropriately qualified experts as delegates including product reviewers. The internal clinician will oversee their work, this particular case is further described in section 7.1.2.

The internal clinician will also be responsible for drawing up records and reports on the corresponding clinical assessments, including the justification for the delegation of tasks. In this case, a recommendation to the CAB's decision maker should also be included.

5.5. Clinical specialist

External personnel (usually) that is responsible for the review of part or of all the clinical aspects of the technical documentation as required by the internal clinician in accordance with the CAB's procedures. They should also document the outcome of the clinical assessments, according to the CAB's procedures.

These experts with relevant clinical expertise in specific areas should be authorised by the CAB to specific MDR/IVR codes and specific medical areas and trained by the internal clinical as described in 3.2.4 Annex VII.

5.6. Final reviewer

Internal staff that is responsible for ensuring that all of the assessments have been conducted in accordance with the CAB's procedures (in accordance with the relevant legislation, guidance documents, CS and/or harmonised standards). In addition, they should ensure that reports and supporting documentation (including quality management system and technical documentation provided by the manufacturer) are complete and sufficient according to section 4.7 of Annex VII. The final reviewer will also be responsible for drawing up records and reports on the final reviews/he has carried out.

Final reviewers should be authorised for the specific MDR/IVR or horizontal MDS/MDT and/or IVS/IVT/IVP/IVD codes as final reviewers and taking into account that their knowledge and expertise should cover a broader base. Therefore, qualification criteria for final reviewers should take into account that knowledge on the device technologies, the device industry and the design and manufacture of devices is not expected to be as specific as knowledge required for other roles such as product reviewers. For instance, final reviewers could be authorised for the review of active devices.

They final review might be performed individually or as a group. In the former case, the individual should be authorised to every code identified in the specific project. In the latter case, the authorisation of the group should cover all the codes involved. The internal clinician should always act as final reviewer with regard to clinical aspects according to section 3.2.4 of Annex VII.

5.7. Decision maker

Internal staff that are responsible for making the decisions on issuing, suspending, restricting, re-instating or withdrawing of certificates and for defining the period of certification. This staff should base their decision on the final review report and supporting documentation according to Section 4.8 of Annex VII. The final decision should be documented.

These personnel should be authorised for specific MDR/IVR or horizontal MDS/MDT and/or IVS/IVT/IVP/IVD as decision makers and taking into account that their knowledge and expertise should cover a broader base. Therefore, qualification criteria for decision makers should take into account that knowledge on the device technologies, the device industry and the design and manufacture of devices is not expected to be as specific as knowledge required for other roles such as product reviewers.

5.8. Internal personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities (hereafter authorising personnel)

These internal personnel are not expected to be authorised for this role to specific codes. They should normally carry out the following tasks:

- establish qualification criteria
- selection of the personnel to be authorised to carry out conformity assessment activities within the organisation,
- verification of the knowledge and experience of this personnel,
- authorisation of the personnel to their tasks,

In addition, this person may also conduct the verification of the performance of the personnel and the definition and the verification of their initial and ongoing training.

These personnel will draw up records and reports documenting the tasks carried out.

6. Qualification criteria per role

The CAB will establish qualification criteria for all of the roles described in the previous section and for any other role it may establish. These criteria should be clear and objective in order to allow transparency and reproducibility and should take account of the following aspects:

- **Background education**: in general, personnel involved in conformity assessment activities will have completed a university or a technical college degree or equivalent qualification in relevant sciences, for example medicine, pharmacy, engineering, biology, microbiology, chemistry, materials science, veterinary medicine, physiology, toxicology or physics.
- **Work experience**: Personnel involved in conformity assessment activities will have sufficient work experience (i.e. at least four years) in the field of healthcare products[4] in order to justify their selection and authorisation to their roles.
- **Training:** the Regulations establish certain areas of knowledge that the CAB's personnel should have prior to be authorised to different roles. The CAB will provide its personnel with initial and on-going training according to its system for training and education programme. All training activities should be documented, and all training materials and plans should be available to the designating authority and the joint assessment team upon request. Effectiveness or training activities should be assessed and documented. Any training activities that are used for personnel's authorisation should be either provided in-house or verified by the CAB.
- **On the job training**: the CAB should make sure that every person that is selected is aware and understand CAB's procedures and has an adequate knowledge of the relevant requirements before the authorisation is granted and / or updated and subsequently introduced in the qualification matrix. To this end, appropriate on-the-job training criteria should be established for certain roles in relation to type of devices or areas. This type of training should also be systematic and continuous throughout the professional life and may be linked to the criteria for maintaining competence (see section 8).

The CAB will ensure that its personnel's knowledge is directly related to their roles (in accordance with sections 3.2.3 to 3.2.7 of Annex VII to the regulations) and to the scope of their activities. Therefore, the requirements established in this section will be applied depending on the specific roles and tasks to be performed and will usually be linked to the specific codes pertaining to the individual's scope of activities. They will provide a sufficient level of detail for the required qualification within the subdivisions of the specific scope descriptions.

[4] In general terms, work experience in the field of healthcare products or related activities will be understood as:

- work in medical devices industry or closely related industries (e.g. pharmaceutical industry) such as research and development, manufacturing, quality management, regulatory affairs;
- work in health services, universities, foundations or other institutions carrying out inspections, audits, clinical evaluations, experimental and/or clinical research, including notified bodies.
- 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.

6.1. Site auditors

6.1.1. Background education

The site auditor's background education should be held in a relevant technology or equivalent in relation to which they wish to be authorised (MDT/IVT), such as pharmacy, engineering or other relevant sciences.

6.1.2. Work experience

Each site auditor will demonstrate:

- four years' professional experience in the field of healthcare products or related activities; and
- two out of these four years will be in the area of quality management
- when their authorisation is related to specific production technologies it is expected that they will have experience related to the specific code (MDT and/or IVT).

6.1.3. Training

Site auditors will have knowledge on EU devices legislation, CS, harmonised standards and relevant guidance documents including knowledge on the general safety and performance requirements (set out in Annex I of the Regulations). This knowledge will usually be acquired by means of training. The CAB should provide its auditors with at least, an initial training on the relevant legislation and guidance documents. This training should normally cover general aspects of the legislation and consist of 40 hours. This training programme may be adjusted if auditors are able to provide evidence of the required knowledge based on previous training or experience.

The CAB should provide its auditors with an initial training on its procedures, covering conformity assessment audits laid down in Annexes IX and XI. These training activities should also include the forms in order to ensure that auditors are able to draw up appropriate records and reports

In addition, taking into account previous experience and the role of the individual, more specific trainings may be envisaged. In particular, the CAB should provide its auditors with an initial training on auditing techniques and quality management systems. These trainings should usually last 40 hours (e.g. EN-ISO13485 lead auditor). Other necessary trainings will cover risk management and related device standards.

The CAB will update and build on the knowledge on this matter as part of its system of exchange of experience. Regular updates will also take place as on-going training.

6.1.4. On the job training

The CAB should establish a minimum number of witness audits or audits for training purposes that each person to be authorised to this role should perform before their authorisation (this should be applicable also in case that the auditor provides evidence of authorisation to in other CABs, although the number of audits could be revised). All on-the-job training activities should be documented, and a system for its assessment should be developed and followed.

6.2. Product reviewers

6.2.1. Background education

The background education of product reviewers will be held in a relevant product or medical area (e.g. medicine, pharmacy, engineering or other relevant sciences) that will be

considered as a strong basis for the authorisation of codes for which they wish to be authorised (MDR/IVR and horizontal areas MDS and/or IVS/IVP/IVD).

6.2.2. Work experience

Their authorisation will link each code (MDR/IVR and horizontal areas MDS and/or IVS/ IVP/IVD) to specific devices and scientific aspects to be assessed for which the individual can prove to have sufficient work experience. Each product reviewer will demonstrate:

- four years' professional experience in the field of healthcare products or related activities, such as in manufacturing, auditing or research; and
- two out of these four years will be in the design, manufacture, testing or use of the device or technology to be assessed or related[5] to the scientific aspects to be assessed.

6.2.3. Training

Product reviewers will have knowledge on EU devices legislation, CS, harmonised standards and relevant guidance documents including knowledge on the general safety and performance requirements (set out in Annex I of the Regulations). This knowledge will usually be acquired by means of training. The CAB should provide its product reviewers with at least, an initial training on the relevant legislation and guidance documents. This training should normally cover general aspects of the legislation and usually consist of 40 hours. This training programme may be adjusted if auditors are able to provide evidence of the required knowledge based on previous training or experience.

The CAB should provide product reviewers with an initial training on its procedures, in relation to conformity laid down in Annexes IX to XI, in particular of technical documentation assessment and other relevant aspects (e.g. testing). These training activities should also include the forms in order to ensure that product reviewers are able to draw up appropriate records and reports.

In addition, taking into account previous experience and the role of the individual, more specific trainings may be envisaged. In particular, the CAB should provide product reviewers with risk management and related device standards training, in order to ensure that product reviewers have appropriate knowledge of the devices which they are assessing, including clinical evaluation in case they fulfil the criteria for carrying out this task (see 7.1.2).

The CAB will update and build on the knowledge on this matter as part of its system of exchange of experience. Regular updates will also take place as on-going training.

6.2.4. On the job training

Product reviewers will need training related to the review of technical documentation, such as mirror reviews or reviews under supervision. The CAB should establish a minimum number of reviews per type of devices or areas to be performed before the final authorisation. All on-the-job training activities should be documented, and a system for its assessment should be developed and followed.

6.3. Internal clinicians

6.3.1. Background education

They will normally be qualified physicians.

[5] Experience related to the specific aspects to be assessed should include, but not be limited to, extensive experience in conformity assessment activities in a specific type of device or technology gained within a CAB. For instance, experience on the review of design aspects of an intrauterine device could be performed by a product reviewer with extensive and traceable experience on this sub-type of devices.

6.3.2. Work experience

They will have several years' work experience (at least two) with the assessment of clinical data for medical devices (closely related products like pharmaceuticals could also be considered), in order to demonstrate:

- a sound knowledge of the fundamental principles of the assessment of clinical data for medical devices and medical statistics; and
- direct work experience in patient care and/
- clinical research, or related experience, in particular in conducting or assessing preclinical or clinical trials or clinical data.

In case the internal clinician is authorised for the review of the clinical aspects of the technical documentation, ideally his/her authorisation will be linked to MDR/IVR codes related to the clinical areas in which the clinician can prove to have sufficient clinical experience.

6.3.3. Training

Internal clinicians will have knowledge on EU devices legislation and relevant guidance documents including knowledge on the general safety and performance requirements (set out in Annex I of the Regulations). This knowledge will usually be acquired by means of training. The CAB should provide its personnel with at least, an initial training on the relevant legislation and guidance documents. This training should normally cover general aspects of the legislation and consist of 40 hours. This training programme may be adjusted if internal clinicians are able to provide evidence of the required knowledge based on previous training or experience.

The CAB should provide the internal clinician with an initial training on its procedures, in relation to conformity laid down in Annexes IX to XI, in particular of clinical evaluation assessment. These training activities should also include the forms in order to ensure that product reviewers are able to draw up appropriate records and reports.

In addition, taking into account previous experience and the role of the individual, more specific trainings may be envisaged. The CAB will update and build on the knowledge on this matter as part of its system of exchange of experience. Regular updates will also take place as on-going training.

6.4. Clinical specialists

6.4.1. Background education

They are normally medical specialists (or alternative holders such as a degree in dentistry) with certified specialisation in a medical field that is relevant for the MDR/IVR codes to which the individual is to be authorised.

6.4.2. Work experience for clinical specialists

They should be medical practitioners (currently registered and having clinical experience in using the device or similar devices, the pathology of the condition being treated, the usual treatment and other medical alternatives. The authorisation of these clinicians will be linked to the MDR/IVR codes or medical areas for which they can prove sufficient experience. For instance, it is expected that the clinical evaluation and data of a vaginal mesh will be assessed by a gynaecologist/urologist or that a breast implant will be assessed by an aesthetic or cosmetic surgeon.

6.4.3. Training

Clinical specialists will have basic knowledge on EU devices legislation and relevant guidance documents including knowledge on the general safety and performance requirements (set out in Annex I of the Regulations). This knowledge will usually be acquired by means of training. The internal clinician will provide these staff with specific and regular training. These training activities should also include the forms in order to ensure that product reviewers are able to draw up appropriate records and reports.

In addition, taking into account previous experience and the role of the individual, more specific trainings may be envisaged. The CAB will update and build on the knowledge on this matter as part of its system of exchange of experience. Regular updates will also take place as on-going training.

6.5. Authorising personnel, final reviewers and decision makers

6.5.1. Background education

It is preferable that their education is related to the healthcare products field as it will ensure they are in a better position to understand all of the conformity assessment activities carried out.

6.5.2. Work experience

Authorising personnel will have adequate experience in conformity assessments on medical devices under the Regulations or previously applicable law that should have been acquired by working in a CAB.

Work experience for final reviewers and decision makers will be related to the healthcare products field. These personnel should preferably have been working as site auditor and/or product reviewer for a minimum of two years (in a CAB) in order to ensure their knowledge of applicable legal requirements and CAB's procedures is sufficiently broad.

6.5.3. Training

Authorising personnel, final reviewers and decision makers will have knowledge on EU devices legislation, CS and relevant guidance documents including knowledge on the general safety and performance requirements (set out in Annex I of the Regulations). This knowledge will usually be acquired by means of training. The CAB should provide its personnel with at least, an initial training on the relevant legislation and guidance documents. This training should normally cover general aspects of the legislation and consist of 40 hours. This training programme may be adjusted if authorising personnel are able to provide evidence of the required knowledge based on previous training or experience.

The CAB should provide these personnel with an initial training on its procedures, in relation to conformity laid down in Annexes IX to XI and qualification criteria, as appropriate. These training activities should also include the forms in order to ensure that staff is able to draw up appropriate records and reports.

In addition, taking into account previous experience and the role of the individual, more specific trainings may be envisaged. In particular, the CAB should provide its personnel with risk management and related device standards training, in order to ensure that this staff have broad base of knowledge of device technologies and the design and manufacture of devices.

The CAB will update and build on the knowledge on this matter as part of its system of exchange of experience. Regular updates will also take place as on-going training

6.5.4. On the job training

Final reviewers and decision makers will need training related to the review of documentations on conformity assessment procedures, such as mirror reviews or reviews under supervision. The CAB should establish a minimum number of reviews per type of devices or areas to be performed before the final authorisation.

Other on the job training criteria could also be developed for authorising personnel and decision makers.

All on-the-job training activities should be documented, and a system for its assessment should be developed and followed.

7. Maintaining of competence and professional development

7.1. Maintaining of competence

The CAB should establish criteria for maintaining competence linked to the specific roles and tasks to be performed and type of devices or areas for which they will be authorised. These criteria should be linked to the monitoring of staff competence and performance and should be objective (e.g. minimum number of audits or product reviews per code in a certain period of time or successful review under supervision per code every three years).

CABs should build a tailored-made program after the periodic review of individual competence in relation to each individual's qualification in order to ensure that their knowledge is adequate already at an early stage and remains current subsequently. The training should be provided when the review of the competence reveals gaps in the individual's knowledge (e.g. the medical device expertise was gained more than 5 years before the authorisation and there is no evidence proving that it has been kept up to date) prior to the authorisation (or renewal of the authorisation) of the individual.

In addition, the CAB should organise activities for exchanging of experience intended to harmonise staff practices and to raise awareness in relation to guidance, legislation or standardisation.

7.2. Professional development

Any relevant courses attended that have further developed the persons expertise should be identified, indicating the organisation responsible, objectives and length (number of hours). If the course was organised by the CAB, it should be linked to verification of effectiveness, for example an examination. This should be stated in the CAB's criteria and documented.

Self-study of guidance document and standards could be considered as an additional method of professional development, especially in those areas where external training is not available. If the CAB wishes to accept this type of training to fulfil the satisfaction of a qualification criterion, a system for assessing knowledge acquired (including measurable and consistent specifications) and for verifying the effectiveness of this training should be in place.

7.3. Extension of competence

When the individual wishes to add a code or role to his/her scope of activities (e.g. when work experience background in a different but closely related sector could serve as a basis for the authorisation of an individual for an extra MDR/IVDR code but the assessment of knowledge shows gaps to be filled in with training).

8. Specific qualification criteria

The regulations establish the need for defining special qualification criteria for a number of areas. Some of these areas are already covered by specific designation codes. The criteria defined in this section contain general principles and therefore no reference is made to the specific roles.

8.1. Specific criteria defined in Annex VII of the MDR

8.1.1. Pre-clinical evaluation

The CAB will define criteria applicable to different type devices and areas in which aspects related to pre-clinical evaluation should be included. The assessment of the preclinical evaluation is expected to be performed by product reviewers, but it could be carried out by specific experts if the CAB wishes to define horizontal pre-clinical evaluation criteria.

Pre-clinical evaluation, within the scope of the qualification system, addresses aspects of the device such as biological safety, physical, chemical and microbiological characterization, electrical safety and electromagnetic compatibility, software verification and validation, stability, shelf life, performance and safety. Pre-clinical evaluation should take into account pre-clinical testing, and literature search.

As an example, the criteria for personnel assessing pre-clinical evaluation for medical devices should make clear what training and/or experience they have. In particular they should have:

- Relevant educational background such as biology, toxicology, medicine, veterinary medicine, pharmacy, engineering and materials or biomaterials science;
- A sound knowledge of the fundamental principles of the assessment of pre-clinical evaluation for medical devices;
- A sound knowledge/training in the current common specifications, harmonised standards (e.g. EN/ISO 10993 series) and guidance documents;
- Practical experience in conducting pre-clinical testing or assessing preclinical data.

It is anticipated that the competencies above should have been gained from at least two years' work experience with the assessment of pre-clinical data for medical devices (closely related areas like pharmaceuticals pre-clinical data assessment may also be considered).

8.1.2. Clinical evaluation

The clinical evaluation criteria are detailed under the internal clinician / clinical specialist roles (see sections 5.3 and 5.4) as the assessment of the clinical evaluation will normally be performed by either the internal clinician or clinical specialists. Nevertheless, the CAB could define horizontal clinical evaluation criteria to authorise product reviewers with specific clinical expertise whose assessment will be directed and overseen by the internal clinician. In this case, the criteria and supporting documentation for experts with clinical expertise should include all of the following:

- Relevant educational background such as medicine doctorate, nursing degree or degree on dentistry.
- A sound knowledge of the fundamental principles of the assessment of clinical data for medical devices;
- A sound knowledge/training in the current common specifications, harmonised standards (EN/ISO 14155) and guidance documents (MEDDEV 2.7/1-4);
- Practical experience in conducting or monitoring clinical investigations/trials or assessing clinical data.

It is anticipated that the competencies above should have been gained from at least two years' work experience in medical devices or closely related products like pharmaceuticals.

8.1.3. Tissues and cells of human and animal origin

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

- Relevant educational background such as human medicine, veterinary medicine, pharmacy or biology
- Persons authorised to assess systems to minimise the risk of infection should have:
    - experience and/or training in the application of current common specifications, harmonised standards (e.g. EN 22442 series), and best practice documents;
    - an ongoing training program for maintaining this expertise up-to-date with scientific developments and changes in clinical and manufacturing practice
    - sound knowledge of the requirements and interpretation of the medical devices legislation (including Regulation 722/2012), and specific legislation (e.g. Directive 2004/23/EC and Directive 2002/98/EC)
    - adequate knowledge of scientific opinions, for this subject area;
    - sound knowledge of risk analysis/management related aspects.

- The sort of experience and background relevant to assess measures to reduce/eliminate risk include many of the following:
    - At least two years' industrial or academic experience in medical device technology utilising animal or human cells, tissues or derivatives;
    - a sound knowledge of the fundamental principles behind the sourcing controls and validation of inactivation methods, including donation, procurement and testing (e.g. for animal tissues those described in the standard EN 22442);
    - knowledge of the biological materials available to the healthcare market;
    - assessment experience of medical devices utilising animal or human cells, tissues or derivatives;
    - knowledge of alternative non-animal and non-human materials.

8.1.4. Functional safety

The CAB will define criteria applicable to different type devices and areas in which aspects related to functional safety evaluation should be included. The assessment of the functional safety is expected to be performed by product reviewers, but it could be carried out by specific experts if the CAB wishes to define horizontal functional safety evaluation criteria (e.g. for active devices utilising ionizing radiation or long-term mechanical testing or simulation of implants).

The functional safety assessment should take into account performance, verification and validation testing (e.g. mechanical, electrical, radiation, usability) and literature search.

The information for persons assessing functional safety for medical devices should make clear what training and/or experience they have. In particular they should have:

- Relevant educational background such as mechanical engineering, biomedical engineering, material / biomaterial science, or related engineering / science discipline, physics, chemistry;
- A sound knowledge of the fundamental principles of the assessment of performance, verification and validation testing for in scope medical devices;

- A sound knowledge/training in relevant and current common specifications, harmonised standards and guidance documents;
- Practical experience in conducting performance, verification and validation testing and/ or assessing performance, verification and validation test protocols, data and results.

It is anticipated that the competencies above should have been gained from at least two years' work experience with the assessment of performance, verification and validation testing data for medical devices or closely related products.

8.1.5. Software

The CAB will define criteria for software evaluation linked to specific codes when the software is embedded in the device or in relation to standalone software. The software assessment should take into account performance evaluation, the software development life cycle process used, verification and validation testing and literature search.

The information for persons assessing software for medical devices should make clear what training and/or experience they have. In particular, they should have:

- Relevant educational background such as software/ biomedical/electronics/information technology / computer science or related engineering/science discipline.
- A sound knowledge of the fundamental principles of programming, software development life-cycle processes, software verification and validation testing, software configuration management and problem resolution techniques along with medical device cybersecurity, interaction between medical software and its environment and data protection.
- A sound knowledge/training in relevant and current common specifications, harmonised standards and guidance documents;
- Practical experience in programming demonstrating knowledge of one or more programming languages, software testing and debugging techniques.

It is anticipated that the competencies above should have been gained from several years (at least two) work experience with the assessment of software evaluation, verification and validation testing data for medical software or other critical software.

8.1.6. Packaging

The CAB will define criteria applicable to different type devices and areas in which aspects related to packaging should be included. The assessment of the aspects related to packaging is expected to be performed by product reviewers, but it could be carried out by specific experts if the CAB wishes to define horizontal criteria for packaging. The packaging evaluation should take into account the packaging system and materials.

The information for persons assessing packaging for medical devices should make clear the background / training and / or experience they have in this area. In particular, they should have:

- Relevant educational background such as mechanical engineering, biomedical engineering, material / biomaterial science, or related engineering / science discipline;
- A sound knowledge of the fundamental principles of the assessment of design and development of packaging systems, including material selection and process validation, for medical devices;
- A sound knowledge/training in relevant and current common specifications, harmonised standards and guidance documents;
- Practical working experience in conducting performance, verification and validation testing and/ or assessing performance, verification and validation test protocols, data and results.

8.1.7. Devices incorporating as an integral part a medicinal product

The CAB will define specific criteria for staff assessing devices incorporating medicinal products. This staff should also assess those medical devices containing substances which, if used separately, could be considered active substances as defined in Article 1 of Directive 2001/83/EC (e.g. including. herbal substances) and borderline cases.

The information for persons assessing medical devices incorporating medicinal substances should make clear what training and/or experience they have. In particular they should have:

- Relevant educational background such as degree in pharmacy, pharmacology or biochemistry;
- A sound knowledge of pharmaceutical chemistry, pharmacokinetics and pharmacodynamics;
- A sound knowledge of the fundamental principles of pharmacognosy;
- Knowledge of guidance documents (MEDDEV 2.1/3), borderline manual and pharmacopoeias (including the European Pharmacopoeia);
- A sound knowledge of the quality and safety regulatory requirements for authorisation of medicinal products including regulatory submissions of documentation pertaining active medicinal products (i.e. common technical documentation (CTD))

8.1.8. Devices that are composed of substances or of combinations of substances that are absorbed by or locally dispersed in the human body

The requirements defined in the previous section are also applicable for this section.

8.1.9. Different types of sterilisation processes

The information in support of persons assessing sterilisation processes and environmental controls should demonstrate an appropriate level of awareness of microbiology, the principles of environmental control and sound knowledge of microbial inactivation methods.

- Persons authorised to assess general environmental controls and sterilisation process should have:
    - training and expertise in auditing quality systems;
    - training and expertise in process validation;
    - training in the application of current common specifications, harmonised sterilisation standards relevant to the sterilisation methods being assessed;

  - sound practical experience of auditing sterilisation processes, relevant to the sterilisation methods being assessed;
  - training in the application of current environmental control standards;
  - sound practical experience of auditing controlled environment areas.

- Persons authorised to assess the effectiveness of a sterilisation process should 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 should have been gained from several years' work experience (at least two) with each medical device sterilisation technology being assessed.

8.2. Specific criteria defined in Annex VII of the IVDR

8.2.1. Biological safety

The criteria for personnel assessing biological safety for *in vitro* medical devices should make clear what training and/or experience they have. In particular they should have:

- Relevant educational background such as biology, toxicology, medicine, veterinary medicine, pharmacy, and materials or biomaterials science;
- A sound knowledge of the fundamental principles of the assessment of biological safety for *in vitro* medical devices;
- A sound knowledge/training in the current common specifications and guidance documents;
- Practical experience in conducting or assessing biological safety testing.

It is anticipated that the competencies above should have been gained from several years (at least two) work experience with the assessment of biological safety data for medical devices.

8.2.2. Performance evaluation

The CAB will define specific criteria for performance evaluation. The assessment of performance evaluation should take into account performance studies and literature search.

The information of personnel assessing performance evaluation should make clear the background / training and / or experience they have in this area. In particular, they should have:

- Educational background: degree in pharmacist, biochemistry, medical doctor and veterinarian, certified nurse, biomedical science;
- A sound knowledge of the fundamental principles of the assessment of data generated from performance studies for in-vitro medical devices;
- A sound knowledge/training in the current Common Specifications (CS) harmonised standards and guidance documents;
- Practical experience in conducting or monitoring performance studies or assessing data generated from performance studies.

8.2.3. Devices for self and near patient testing

The CAB will define specific criteria for devices for self-testing and devices for near-patient testing. The assessment of such kind of devices should take into account knowledge and training of the users and use environment.

The information of personnel assessing devices for self and near patient testing should make clear the background / training and / or experience they have in relation to such devices. In particular, they should have:

- Educational background: degree in pharmacist, biochemistry, medical doctor and veterinarian, certified nurse, biomedical science.
- Sound knowledge of design aspects related to the suitability of the device to be used as self-testing or near-testing
- Sound knowledge on analytical performance characteristics such as accuracy, sensitivity and specificity.
- A sound knowledge/training in the current Common Specifications (CS) harmonised standards and guidance documents;
- Direct work experience in the healthcare setting in which in vitro diagnostic devices are used.

8.2.4. Companion diagnostics

The CAB will define specific criteria for companion diagnostics. The assessment of such kind of devices should take into account the suitability of the device in relation to the medicinal product concerned.

The information of personnel assessing devices for companion diagnostics should make clear the background / training and / or experience they have in relation to such devices. In particular, they should have:

- Educational background: degree in genetics, biology, pharmacy, biochemistry, medical doctor, biomedical sciences,
- Sound knowledge of genetics, cell and molecular biology, chemistry depending on the specific application, biomarker and analytical technology
- Sound knowledge on the design features and technology related to the device in relation to the indication and administration of the specific medicinal product.
- Sound knowledge on analytical performance characteristics such as accuracy, sensitivity and specificity.
- A sound knowledge/training in the current Common Specifications (CS) harmonised standards and guidance documents;
- Work experience in the healthcare setting in which the specific type of devices and/or biomarkers are used or experience in drug development or assay validation at industry level, analytical setting or academic research involving direct use of the related technologies.

8.2.5. Functional safety

See section 7.1.4

8.2.6. Software

See section 7.1.5

8.2.7. Packaging

See section 7.1.6

8.2.8. Different types of sterilisation process.

See section 7.1.9

9. References.

References

Regulation (EU) 2017/745 Chapter IV

Regulation (EU) 2017/746 Chapter IV

Sources

[1] NBOG F 2017-1 Application form to be submitted when applying for designation as a notified body under the medical devices Regulation (MDR)

[2] NBOG F 2017-2 Application form to be submitted when applying for designation as a notified body under the *in vitro* diagnostic devices Regulation (IVDR)

[5] NBOG F 2017-7 Review of qualification for the authorisation of personnel – Regulation (EU) 2017/745

[6] NBOG F 2017-8 Review of qualification for the authorisation of personnel – Regulation (EU) 2017/746

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