**Minimální požadavky na klinické specialisty**

**GUIDE NBOG 2017-2 , Guidance on the Information Required for Conformity assessment bodies’ Personnel Involved in Conformity Assessment Activities**

1. **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 products4 in order to justify their selection and authorisation to their roles.

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.

**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.**

**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.

**6.4 Clinical specialists**

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 codes to which the individual is to be authorised.

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.

* + 1. **Clinical evaluation**

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 and guidance documents;
			* 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.