Biomedical Alliance in Europe

Call for experts for the evaluation of medical devices open

Facts & Figures

- **Deadline: 10 November 2019**
- Experts will contribute to the evaluation of medical devices and IVDs
- 246 experts needed
- 1000 experts needed for a general list
- 11 Panels for different disciplines a screening panel will be established
- Sub-groups may be created
- Time commitment: max 2-3 days per month, mostly remote work
- Remuneration: €450 per day worked
- Application form: https://ec.europa.eu/eusurvey/runner/mdexperts2019

Introduction

On 27 September, the European Commission launched a call to recruit medical professionals that will be appointed to expert panels that assess the safety of medical devices which will be sold on the European market. To ensure the safety and quality of medical devices, it is of the utmost importance that a broad pool of medical professionals from different disciplines apply to help make medical devices safer for patients.

The new Medical Device Regulation and the In Vitro Diagnostic Regulation, which come into effect in 2020 and 2022 respectively, require the establishment of expert panels to enhance the safety of high-risk medical devices and certain in vitro diagnostics.

The Call for experts was launched on 27 September and is open until 10 November. Applications can be submitted here.

Tasks

⇒ Expert panels will be consulted by notified bodies in the clinical evaluation process of certain high-risk medical devices and certain in vitro diagnostics.

⇒ They will also provide advice on other matters related to medical devices.

Expert panels will provide advice regarding the clinical evaluation of certain high-risk devices, and the performance of in-vitro diagnostics. Notified Bodies are obligated to consult expert panels in the context of conformity assessment of certain high-risk devices and IVD tests. These high-risk devices mainly include active devices that administer or remove a medicinal product or that are implantable devices.

Secondly, ad hoc advice may be provided at the request of certain actors such as the European Commission, Member States, the Medical Device Coordination Group, Notified Bodies and manufacturers. Panels may also contribute to the development of relevant documents such as standards, guidance documents and Common Specifications

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Composition

Expert panels

In total, 12 expert panels will be appointed on the basis of broad disciplines. The European Commission will appoint experts on the basis of the educational and professional background and the expertise of applicants. The number of experts in the different panels differ according to the expected workload and experts will be appointed for 3 years.

Panels will elect a chair and vice chair, and they may create subgroups to tackle specific thematic areas.

In addition to the 11 specialised panels, the Commission will create a screening panel which decides on the basis of set criteria whether or not to provide a scientific opinion on the clinical evaluation assessment report of notified bodies for specific devices (see the MDR, Annex IV, Chapter 5.1).

Expert Panels:

- Screening panel (86 experts)
- Orthopaedics, traumatology, rehabilitation, rheumatology (35 experts)
- Circulatory system (30 experts)
- Neurology (15 experts)
- Respiratory, anaesthesiology, intensive care (5 experts)
- Endocrinology and diabetes (5 experts)
- General and plastic surgery, dentistry (20 experts)
- Obstetrics and gynaecology, including reproductive medicine (5 experts)
- Gastroenterology and hepatology (5 experts)
- Nephrology and urology (5 experts)
- Ophthalmology (5 experts)
- In vitro diagnostics (IVD) (30 experts)

Central List

In addition to the 12 panels, there will be a ‘central list’ of 1000 experts appointed for a 5-year period. Applicants who have been included in the list of eligible and apt candidates, but who have not been appointed to an expert panel, may be included in this central list. The list may be used to appoint replacements, to provide advice or to support the work of expert panels as needed.

Eligibility & Selection

In order to be eligible to participate in the expert panels, applicants need to comply to the following criteria:

- Be a citizen of the EU, the EFTA or Turkey
- Have a university degree in a relevant medical or scientific area at graduate level
- Have at least 10 years of relevant professional experience (medical, non-medical, scientific and technical or regulatory)
- Have a proven capacity to work in English, as this will be the working language of the panels

- Do not have a financial interest or other interest in the medical device industry or in a notified body or any other organisation or sector, because this could affect their independence, impartiality and objectivity

In addition, the Commission will apply selection criteria to appoint the most suitable experts. Applicants will be selected by reviewing the following criteria:

- Educational background
- Professional experience in medical, scientific or technical areas relevant to the call
- Direct experience with the use of medical devices and IVDs, clinical investigation with medical devices, experience with quality assurance/standardisation of IVDs research & development, reports or analysis of medical device problems or failure
- Scientific impact of relevance to high risk medical devices (e.g. 20 most relevant publications, number and impact factor of publications)
- Experience in providing scientific advice and with analysing complex information— Experience in working in committees/organisation committees/expert groups
- Experience in a multi-disciplinary/international environment
- Experience as chairperson or coordinator (management of groups to deliver quality outputs and keeping deadlines)
- Experience in regulatory affairs of medical devices or in vitro diagnostic devices
- Experience in regulatory affairs of medicinal and/or combination products.

In addition to these criteria, consideration will also be given to geographical distribution and gender balance.

Conditions

All work will be done in English. The remuneration consists of €450 per day worked, and experts thus receive compensation for both preparatory work and participation.

Depending on demand and subject to fluctuations, experts are expected to be available for panel-related tasks (remotely) and to attend teleconferences, on average not exceeding 2 to 3 days a month. In addition, experts may be required to occasionally attend physical meetings.

Experts in the panels will be appointed for a term of three year, which may be renewed if they continue to comply to eligibility criteria. Experts included in the central list remain in the list for a period of 5 years.

Application

Applicants can apply on the website of the European Commission until 10 November 2019. Applications are individual and applicants should submit the following documents:

- The application form
- A CV (no longer than 4 pages)
- Copy of ID to prove citizenship
- A declaration of interests (DOI) form

A board composed of EU officials will select the experts, and EU officials indicated that the selection procedure should take around 6-8 weeks.

For more information, see: https://ec.europa.eu/growth/content/call-expression-interest-expert-panels-medical-devices-and-vitro-diagnostic-medical-devices_en