Become a certification assessor, a key player in the EDQM's CEP procedure

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European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Do you work for a competent authority that deals with the evaluation of marketing authorisation applications (MAAs)? If so, we are offering a unique opportunity for you to play a key role in the procedure for Certification of Suitability to the Monographs of the European Pharmacopoeia at the EDQM, and help protect the health of millions of people in Europe and beyond.

What is a Certificate of Suitability?

A Certificate of Suitability (CEP) proves that a substance meets the quality standards of the European Pharmacopoeia. For marketing authorisation holders, the CEP simplifies the MAA process because it can replace part of the extensive documentation required for the MAA or can be used as an alternative to the Active Substance Master File (ASMF).

Who are the Certification assessors?

Assessors are scientists with experience in the assessment of MAAs and solid competences in fields such as:

- chemical evaluation
- toxicology
- sterility
- herbals
- TSE

They are put forward by their competent authority in member states of the European Pharmacopoeia Convention (or, in some observer countries accepting CEPs, e.g. Canada, upon decision of the CEP Steering Committee), and are appointed based on established criteria regarding their skills and experience as described in the Terms of Reference of the **Certification Procedure**.

They are appointed for an unlimited period, provided they continue to meet the eligibility criteria and participate regularly (a couple of days every year) in CEP work.

Terms of Reference of the Certification Procedure

How to become a Certification assessor

To become an assessor, your competent authority must recommend you by submitting a **letter of proposal for appointment** to the EDQM, together with your **CV** demonstrating your **expertise** in relevant areas via **cep@edqm.eu**. The letter should confirm your ability to work independently and, if you have less than two years' experience as an assessor in your agency, you will need to justify your qualifications (e.g., relevant work in regulatory affairs consultancy or industry).

At receipt of the request you will be asked to fill in **a declaration of acceptance of the Code of Practice for the Certification Procedure (including absence of conflicts of interest)**.

When the application is complete, the EDQM will review it for approval.

Code of Practice for the Certification Procedure

Your role as a Certification assessor

As an assessor, you will:

- **scientifically assess** CEP applications from manufacturers of pharmaceutical substances covered by a Ph. Eur. monograph, according to European regulatory requirements;
- prepare **evaluation reports** based on EDQM templates.

Benefits of working with the EDQM as a Certification assessor

Becoming an assessor will give you:

the chance to **collaborate** and share knowledge by joining a **network** of colleague assessors from national authorities across Europe;

access to the EDQM's extensive **policy documents**, developed in collaboration with the Technical Advisory Board (TAB);

the opportunity to play a **key role** in ensuring the **quality** and **safety** of substances across Europe.

By nominating assessors to work with the EDQM, national authorities contribute to **streamlining the approval process**.

They **save** both **time** and **resources** through a single, harmonised assessment of the quality of pharmaceutical substances.

The CEP **eases** the management of **marketing authorisations** and their variations at national level.

How you would participate in CEP assessments

Once appointed, the EDQM will contact you to co-ordinate your participation in scheduled evaluation sessions and the number of days you will spend on CEP assessments. These sessions may take place at the EDQM premises in Strasbourg or remotely and are organised regularly over the year.

1. First-time assessors receive comprehensive introductory training to guide them through their duties and the use of the different EDQM tools.
2. A new CEP application is evaluated by two assessors: a **rapporteur**, who drafts the report, and a **co-rapporteur**, who reviews the application and contributes to an agreed outcome. Your expertise and the time available will determine which dossiers are assigned to you by the EDQM.

After participating in an on-site session, you may also join **remote evaluation sessions** through the EDQM's secure platform, ensuring flexibility and continued collaboration.

Travel expenses incurred by assessors for sessions at the EDQM are fully reimbursed (travel costs and a per diem fee). If necessary, additional financial arrangements between the agency and the EDQM may be made.

See also

Certification of Suitability (CEP)

CEP at a glance

CEP@edqm.eu