

## **Certification of Substances Division**

NF/CB

### **PUBLIC DOCUMENT**

(LEVEL 1)

*English only*

**PA/PH/CEP (10) 86 1R**

Strasbourg, September 2015

**Certification of suitability to the Monographs of the European Pharmacopoeia**

**Changes in contact details to be notified to EDQM**

This document describes the procedure to notify the EDQM of changes to the contact person and/or to contact details for Certificates of Suitability (CEP) applications.

## 1. Scope

In order to ensure timely and efficient communication with the EDQM for CEP applications and EDQM inspections, it is important to keep the details of the official contact person up-to-date, and it is the responsibility of applicants and holders of CEPs to ensure that this is done for their applications. The contact person is authorised for communication on behalf of the applicant or the holder of CEPs, and this person receives all communication from EDQM related to the application(s), even after a CEP has been granted.

There have been a number of cases when the contact person for one or several CEP dossiers had changed without the EDQM being notified.

Companies are reminded that the EDQM communicates only with the official contact person appointed in a CEP application, and to protect confidentiality, does not share information with other people. In addition, not receiving communication from EDQM may lead to the closure of an application or to the cancellation of a CEP, as a consequence of a delayed response or absence of response.

## 2. How to proceed

The details of the contact person may be updated at any time during the lifecycle of a CEP application, without any fee being applied.

To update the details of the contact person for one or several CEP applications, there are two options:

- The applicant/holder may notify the EDQM of the change(s) by including the new details directly in the table 2.2 of the application form, in situations where the submission of a full application form is required (e.g. during the submission of a request for revision/renewal).

- The applicant/holder may notify the change(s) by sending the EDQM form "Change of contact details for a CEP" (available on the EDQM website), filled in with updated information and annex 1 if relevant. This form may be sent preferably by the CESP, or by e-mail to the e-mail address communicated to applicants and holders. If none of these routes of submission can be used, the company may also use the Helpdesk on the EDQM website (<https://www.edqm.eu/en/EDQM-FAQ-and-Helpdesk-List-630.html>).

This option should be used when there is no need to submit a full application form e.g. when the assessment procedure has already started, in a reply to a request for additional information sent by EDQM, or when there is no on-going assessment procedure.

In situations where several CEP applications are concerned by the change to the contact person and/or contact details, one form only should be sent together with a list of all related dossier numbers and substances.