EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 April 2021
EMA/503895/2018
Information Management

New Organization First User QPPV/RP or Change of EU QPPV/RP

If a change of qualified person for pharmacovigilance/responsible person for EudraVigilance (QPPV/RP), named person or legal representative within the organisation occurs, you need to notify EMA.

There are 2 possible scenarios, please choose the one relevant to your case.

A) There is still a QPPV/RP in your organisation – change of QPPV/RP

1. Log in to EMA Account Management portal > manage access> remove access and ensure you remove all the roles you have for the profile you wish to become RP/QPPV for. See Registration manual

2. The leaving QPPV/RP will need to remove his/her role as QPPV/RP via the EMA Account Management portal. Then obtain a Request ID that needs to be included in the cover letter mentioned in #3.

3. Raise a ticket via EV Registration Service Desk, requesting the validation of your new role as QPPV/RP, stating your organisation ID and name, attaching the following documents:

- A **cover letter** should be sent from the headquarters level of the organisation on a headed paper.
  - The cover letter should be signed by the new QPPV/RP or by a person in a position above that at headquarters level (i.e. director of the organisation or similar), or by the legal representative for Commercial and Non-Commercial Sponsors.
  - The cover letter should state the name and position of the previous QPPV/RP and the name, position and contact details of the new QPPV/RP as well as confirm that the QPPV resides within the EU/EEA.
- A **copy of the ID card or driver's license or passport.**
  - We require that the full name and signature are visible. You may black out any other information contained on the ID document.
  - This information will be used to verify the identity of the registering person and will be treated as confidential and will not be published or included in any user list[i].
- The **user declaration form for QPPV/RP,** including the type and name of the organisation, user's details and dated and signed by the user (download here).

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

- A **declaration from the QPPV/RP** that the organisation has a suitably trained person for submission of **ICSRs** and **XEVPRMs**.

  This declaration can be included in the cover letter or on the body of the email submitted via the EV Registration Service Desk. Submitting copies of ICSR and XEVMPD certificates is not necessary when changing the QPPV/RP. Please note, training certificates do not have to be in the name of the new QPPV/RP, but in the name of any active user of the profile who has completed the above courses and is related to the respective organisation.

Sponsors should additionally provide the following documents:

- **Form A** - signed by the sponsor's legal representative person appointing the new responsible person for clinical trials, including the name and the contact details of this person (download Form A here). The legal representative person and responsible person address should be for the respective organisations they work for.
- **For Sponsors based outside EEA only - Form B** should be also sent, signed by someone from the sponsor appointing the sponsor's legal representative person in the EEA, including the name and the contact details of this person (download Form B here). The legal representative person address should be for the organisation the legal representative works for. If Form B has been previously submitted for the previous RP registration and the legal representative of the sponsor is unchanged it does not need to be completed again.

4. EMA will confirm the removal of the previous QPPV/RP and then the new QPPV/RP will need to request the role of QPPV/RP via the EMA Account Management portal.

5. EMA will validate your QPPV/RP role once the provided documents are checked. You will receive an email notification that your role has been approved

B) There is no QPPV/RP in your organisation – first user QPPV/RP of a new organisation

1. Register yourself in EMA Account Management portal and request EU QPPV or Responsible Person role. For further details, please see EV Registration manual.

2. Provide the following supporting documents:

- A **cover letter** should be sent from the headquarters level of the organisation on a letter headed paper.
  - The cover letter should be signed by the new QPPV/RP or by a person in a position above that at headquarters level (i.e. director of the organisation or similar), or by the legal representative for Commercial and Non-Commercial Sponsors.
  - The cover letter should state the name, position and contact details of the new QPPV/RP as well as confirm that the QPPV resides within the EU/EEA.
- **EMAIL confirmation from the OMS** Data Stewards acknowledging the successful creation of the new organisation.
- A **copy of the ID card or driver's license or passport.**

  - We require that the full name and signature are visible. You may black out any other information contained on the ID document.
  - This information will be used to verify the identity of the registering person and will be treated as confidential and will not be published or included in any user list[ii].

- The **user declaration form for QPPV/RP,** including the type and name of the organisation and, user's details. The form should be dated and signed by the user (download here).
- **For MAHs only** - A **copy of the trade register** for pharmaceutical companies.
- **For MAHs only** - **Proof of an EEA marketing authorisation or application for an EEA marketing authorisation** for at least one product.
- **For Sponsors only - Form A** - signed by the sponsor's legal representative person appointing the new responsible person for clinical trials, including the name and the contact details of this person (download Form A here). The legal representative person and responsible person address should be for the respective organisations they work for.
- **For Sponsors based outside EEA only** - **Form B** - signed by someone from the sponsor appointing the sponsor's legal representative person in EEA, including the name and the contact details of this person (download Form B here). The legal representative person address should be for the organisation the legal representative works for.
- **For Sponsors only** - A **EudraCT number** for a study the sponsor is conducting.
- A copy of the **notification of successful completion of the EudraVigilance ICSR and XEVMPD knowledge evaluation** for at least one user to access the production environment, as applicable. Please note: training certificates do not have to be in the name of the new QPPV/RP, but in the name of any active user of the profile who has completed the above courses and is related to the respective organisation.

EMA will validate your QPPV/RP role once the provided documents are checked. You will receive an email notification that your role has been approved.

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[i] *The European Medicines Agency will process this information to verify the identity of the registering person and it will be handled in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. The name of the QPPV/RP and contact details are accessible to the registered organisation in the restricted area of the EudraVigilance and are not made public. For more information, please click here.*