



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Network Product Owner and Subject Matter Experts in EMA Agile way-of-working

Terms of Reference (ToR)

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The European Medicines Agency launched its Agile transformation following the endorsement of the new governance model and way-of-working by the Management Board in June 2021. The inclusion of partner and stakeholder organisations at the strategic and portfolio level is ensured through their participation and the transparency provided by Agile ceremonies, and their relevant representation in governance bodies (for National Competent Authorities: Network Portfolio Advisory Group and Network ICT Advisory Committee). The inclusion of partners and stakeholder organisations, as well as other relevant stakeholders, at the execution layer is secured through their participation as Product Owners and/or Subject Matter Experts (SMEs).

The Agile way of working focuses on small, self-organising product teams working with the best available Subject Matter Experts to deliver features and user stories as prioritised by the business and in line with the Minimum Viable Product (MVP). This process is highly collaborative, intense, dynamic, with decisions made quickly based on the input/information available and in the scope of the MVP. SMEs from NCAs, representatives of Industry associations and other stakeholder groups will have an opportunity to become more involved in the development of solutions, by providing expertise on a specific business process or product. They do not form a 'permanent standing body' but are selected to participate upon the request of the Product Owner and Value Stream Owner.



A Product Owner can be nominated by an NCA, i.e. an EMA partner¹.

Subject Matter Experts can be nominated from EMA's partners or stakeholders².

1. Role and work descriptions

1.1. Product Owner

Role description:

Where appropriate the EMA Product Owner can request participation of an another Product Owner from the Network (most commonly from an NCA). The network Product Owner is a member of the Agile team and collaborates closely with the EMA Product Owner in developing a business solution or product of shared interest with the Network. The network Product Owner together with the EMA Product Owner is responsible for maximising the value of the product/business solution developed. The network Product Owner represents the EMA's partners and is the voice of the Network.

The network Product Owner collaborates with the EMA Product Owner across different layers in developing and implementing a business solution or product shared with the Network.

- At the Portfolio layer the network Product Owner supports the EMA Product Owner with the division of an epic into right-sized implementable features, which will be handed over to Product Teams;
- At the Value Stream layer the network Product Owner is responsible for breaking down features into user stories with the EMA Product Owner, and for providing an update on progress on feature and/or epic level;
- At the Execution layer the network Product Owner is responsible with the EMA Product Owner for managing the team backlog by ensuring that the user stories are well defined, estimated, prioritised, and refined for the Product Team to implement;
- The network Product Owner actively participates in the Scrum meetings at the team level (e.g. sprint planning, daily stand-up, sprint demo, retrospective) and sets priorities together with the EMA Product Owner. In addition, at the Value Stream level, both Product Owners actively participates in Agile ceremonies (Programme Increment (PI) planning, System Demo, Monthly Portfolio Sync).

1.2. Subject Matter Experts

Role description:

An SME has knowledge and expertise of a specific business solution or product that they can provide to a Product Team when requested (usually) by the Product Owner. As such, an SME is responsible for supporting consistent solution/product enhancement. Subject Matter Experts (SMEs) are not a permanent standing body but rather exist in the function for as long as the Product Team needs their knowledge and expertise.

¹ The term 'partners' distinguishes the Agency's operational links within the European regulatory network and encompasses the national competent authorities, the European Commission, European Parliament and other European Institutions. They also include international (organisations) partners, such as, the World Health Organisation (WHO), US FDA, Health Canada, and Japanese regulatory authorities (MHLW and PMDA), etc.

² 'Stakeholders' are defined as organisations, associations and parties interacting with the European Medicines Agency (the Agency or EMA hereafter), which have an interest in or are influenced by the work of the EMA and its partners.

An SME can contribute in different ways to developing and implementing a business solution or product.

- At the Portfolio layer an SME can be consulted in the process of definition of the minimum viable product (MVP) and epic draft sessions;
- At the Value Stream layer an SME can participate and provide – upon request - advice to the Agile delivery team in feature draft sessions (e.g., help estimate T-shirt sizes);
- At the Execution layer an SME can participate in implementing user stories when guidance is requested and collaborate with the Business Analyst in the formulation of business requirements to support the development of features and user stories, and support User Acceptance Testing (UAT), etc.;
- An SME can participate in Agile ceremonies as requested by the Product Owner, such as the Programme Increment (PI) Planning, when expert insight into epic dependencies is required, as well as support in feature estimations and mappings.

2. Modus operandi

Participation in Product Teams as a network Product Owner or Subject Matter Expert is predicated on the representative acting in accordance with the ToR and meeting the below requirements. The ToR and the requirements are shared with the call for interest, so that nominees are aware of them prior to taking on the role.

Terms of Reference: the representative must act in accordance with the ToR.

Confidentiality agreement: the representative must sign a confidentiality agreement and act in accordance with it.

Commitment to EMA's Agile approach: the representative is committed to the EMA's way of working and governance model, and working in line with Agile and SAFe principles as implemented at the Agency. Where appropriate training and coaching to become sufficiently familiar with these will be provided to the network Product Owner and SME.

Availability and participation: the representative must be willing and able to commit to a minimum attendance and participation, as specified in the call. Please note that the costs for working time is not covered by the Agency. The reimbursement of travel and accommodation costs for attendance ceremonies is dependent on the Product Team and will be clarified in the call for interest.

Participation as a delegate: network Product Owners and SMEs are participating as a delegate on behalf of the community which they are representing, and always contributing on behalf of the overall interest of their community to the best of their knowledge, in line with Agile principles. As such they are not representing solely their own or their employer's interests.

Additional requirements: there may be additional requirements for specific Product Teams, such as attending required training and coaching sessions, or the participation in particular ceremonies.

Failure to comply with the modus operandi may lead to the representatives being replaced by other nominees that better meet these requirements.

3. Process for nomination and selection

Transparent and balanced process

EMA is committed to following a standard process for the nomination and selection of network Product Owners and SMEs across partner and stakeholder organisations. It will run an open and transparent process, which fosters balanced representation and diversity (e.g. between bigger and smaller NCAs, as well as geographical spread; or different types of industry associations from e.g. from Human or Veterinary business). Calls for interest must be consistent: quantifying time and effort, as well as specifying the exact expertise and knowledge required from the nominees.

The selection of applicants to a call for interest will be based on the expertise and knowledge of the applicant; their commitment to the ToR and availability; and their ability and willingness to act as a representative of key communities.

4. Attendance, constructive participation and behaviour

To ensure the effective operation and delivery of Product Teams, including the crucial constructive participation and contribution made by Product Owners and SMEs, their attendance and participation will be monitored by the Product Team. Where attendance is not in line with the ToR and the required attendance and participation, action may be taken to mitigate any negative consequences, such as selecting new representatives for the role(s). Likewise, participation as a Product Owner and SME must be conducted in a respectful, professional and efficient manner. The role of Product Owner and SME within a Product Team is time defined for the period where the contribution of the role is required.