



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Guidance on the interpretation of document: Confidentiality Undertaking for network Product Owner and Subject Matter Experts (SMEs) in European Medicines Agency's agile way-of-working (EMA/250671/2022)

The purpose of this document is to support representatives in the roles of either Product Owner or Subject Matter Experts in their interpretation of the Confidentiality Undertaking that they are required to sign in that role.

A key requirement in the role as Product Owner and Subject Matter Experts ("SMEs"), as stated in the Terms of Reference, is to **represent the community for which they are delegates of**. Namely, they 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".

To enable them to do so, it is crucial that they are **effectively and frequently engaging with the community which they represent**, enabling them to act as a liaison between the EMA and the partners¹ and stakeholders² they represent on the specific topic.

On the one hand, they must communicate and troubleshoot the proposed solutions being considered and designed by the EMA Product Team, to ascertain their feasibility and value to the customers. On the other hand, they must liaise with the relevant experts in their community (i.e., for an NCA delegate, other NCAs; for a trade association representative, peers from their trade association or other trade associations) to bring the consolidated point of view to the EMA Product Team and ultimately to contribute to the IT product development.

As such, Confidential Information and Confidential Documents (as defined in the Confidentiality Undertaking) will be provided to the Product Owners and SMEs, and can be used in their engagement with the communities which they represent, for this specific purpose. It should be noted however, that they cannot authorise those who they justly share it with to disclose it to third parties (see point vi. in the Confidentiality Undertaking).

It should be noted that the Product Owner and SMEs may share such information and documentation only with their **immediate community**, i.e. the respective community for which they are acting as delegates of, namely Network Product Owner and SMEs with the NCA community, and Industry SMEs

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.



with the trade associations and members. Therefore, the Confidential information and Confidential Documents should not be shared beyond that community, that is with third parties that are not within the scope of the partners or stakeholders that are impacted by the EMA's development of the product. In addition, the Product Owner and SMEs must inform their respective community peers that the relevant Confidential Information and Confidential Documents must be treated as such by that community recipients, who are expected to comply with the same obligations assumed by the disclosing Product Owner and SMEs.

Examples of **Confidential Information or Confidential Documents that representatives are not authorised to communicate** beyond their respective community include, for instance, those related to other EMA Product Teams than their own (for example, those the Product Owner or SME has become privy to during inter-dependency discussions during a PI Planning); or commercially confidential information regarding the contract management of EMA's suppliers of IT development capabilities (contractors).

When in doubt, the Product Owner or SMEs should **consult the EMA Product Team** as to whether specific Confidential Information and Confidential Documentation can be shared with their respective community, for instance on the occasion of meetings or other collegiate discussions attended by individuals not belonging to the Product Owner's and SMEs' respective communities. Alignment between the EMA Product Team and external representatives in PO and SME roles in how to engage the wider community is expected to ensure that there is transparency and constructive collaboration.