EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR data services - Q&A webinar for Industry

07 December 2017

Agenda

1. Introduction
2. Support & Additional Information
3. SPOR registration & on-boarding
4. Open questions session

EMA Participants

Hanna Palyszka	*eSubmissions Business Lead*
Jaume Gonzalez	*RMS Business Lead*
Anne-Christine Lantin	*Veterinary Regulatory & Organisational Support Division*
Cristina Rusu	*SPOR Data Support*
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Agnieszka Laka	*SPOR Business Change Lead*
Gabriel Boronat	*SPOR Business Change*

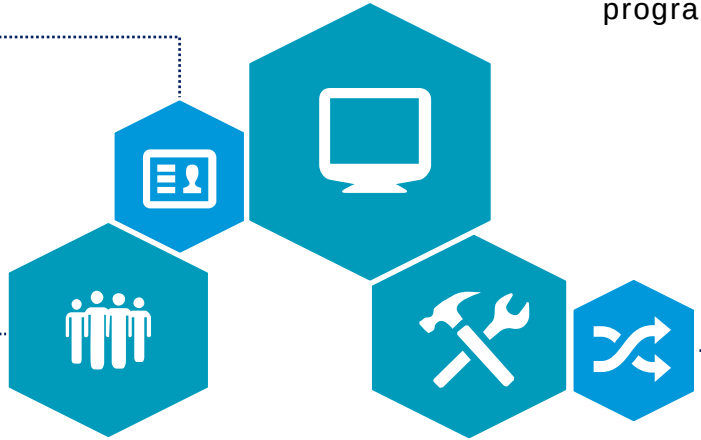
Introduction

- Summary of SPOR services
- Using RMS & OMS data in eAF
- Substances in eAF
- Summary of key milestones

Summary of SPOR data services

SPOR data accessible via the **SPOR web portal** and programmatically via **SPOR API** (application programming interface)

Lists of organisations, (OMS dictionary), **referentials** for stakeholders to use in EU regulatory activities



A specialised team of **EMA data stewards** will manage SPOR data and provide support to stakeholders

New process to register / update SPOR data before submitting regulatory applications.
Data entered once and reused in different processes

New **data management** approaches for industry, NCAs, and EMA:

- On-going data synchronisation.
- Possible need for data transformation/enrichment.

Using RMS & OMS data in eAF

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ISO IDMP compliant **RMS** & **OMS** **services live** in June 2017.
No impact on regulatory submissions at go live.

Use of RMS to submit change requests mandated from July

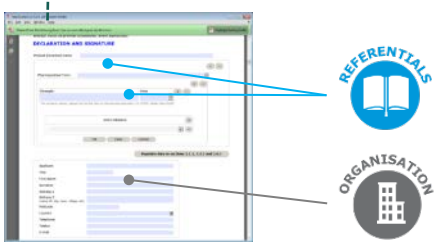
Industry stakeholders can start using RMS portal to submit change requests to register terms.

Use of OMS mandated

Industry stakeholders can start using OMS data in eAF

2017 | **2018**

Consultations with stakeholders taking place on the benefits of using SPOR services for different regulatory procedures



Q3/Q4 2018 CESSP planned to go live (*). Mandating of OMS aligned with CESSP.

June 2017
RMS replaces EUTCT.
RMS is already integrated with eAF (consumes RMS data)

15 December 2017
eAF integration with OMS scheduled to go live
(MA application, Renewals, Variations for Human and Veterinary)

* *subject to planning*

Using RMS Data in eAF

- **Referential terms should be registered before they are required to be used in a regulatory procedure.**
- Current process for applicants to request registration of terms is by sending email to mdms@ema.europa.eu
- From December 2017 applicants are encouraged to start using the RMS portal to submit change requests to register terms (mdms@ema.europa.eu *can still be used until end of June 2018*).
- From July 2018 change requests will only be accepted when submitted via RMS portal.

Using OMS Data in eAF

- **OMS** will be **integrated** in all four electronic application forms for all address fields **in eAF** release v1.22.0.0, planned to go-live on **15 December 2017**.
- **Use of OMS** in the **eAF** will **initially** be **optional**.
- Applicants are advised to perform a search from within the form to **familiarise** themselves **with the use of OMS** and to ensure that they are familiar with the process before its use becomes mandatory.

Two outcomes are possible after searching for an organisation:

1. If the **address/location is not found or is incorrect**, users can enter manually the address details using free text fields, as previously in the eAF. Users are advised to follow the OMS process to submit requests for adding or amending organisation data.
2. If the **address/location is correct**, users may proceed using the OMS-provided data.

- **Mandating of OMS is planned for Q3/Q4 2018.**

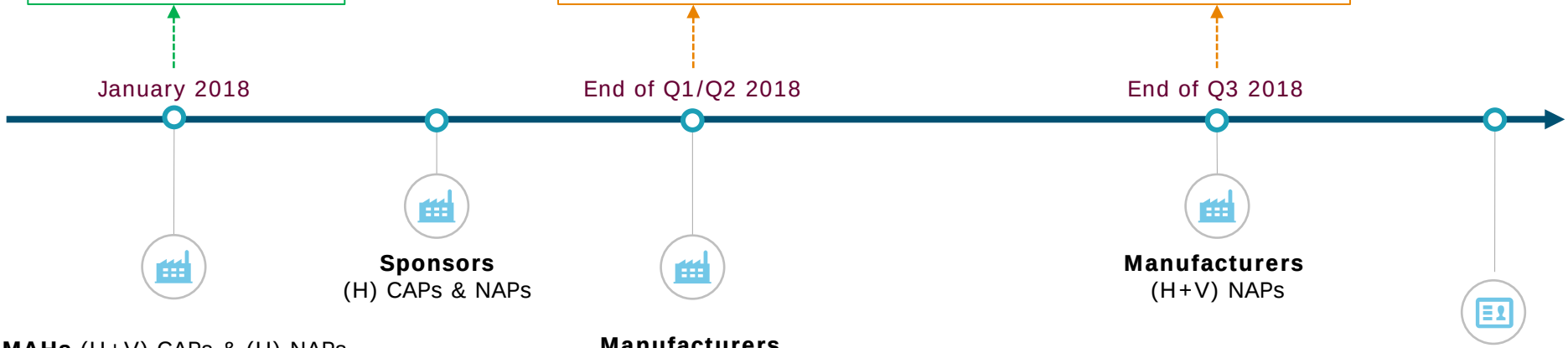
Using OMS Data in eAF

Key

Points at which new organisation data set is published/completed in OMS. **Communication will be provided closer to the publication of each data set.**

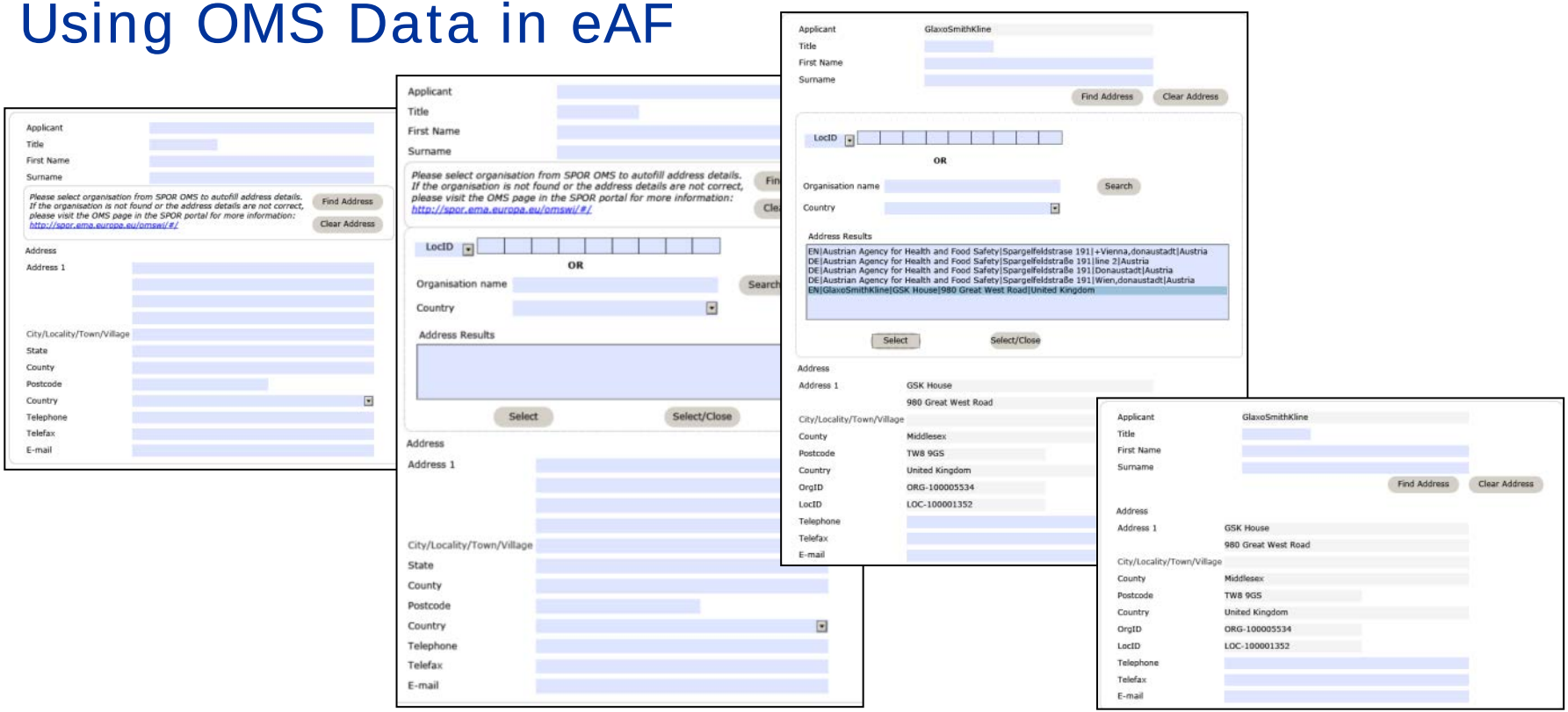
Stakeholders can start submitting the relevant OMS change requests

Publication of **Manufacturers** in the **OMS** dictionary is planned to be completed by **Q3 2018**, stakeholders are asked **not to submit OMS change requests for Manufacturer** organisations **until EMA** has **communicated** this data set has been added to the dictionary.



Additional Organisation data to be added in future; prioritisation defined at a later stage, *e.g.* Vet MAHs for non-CAPs.

Using OMS Data in eAF



Substances in eAF

- Substance-related lists remain in EUTCT until the Substance Management Services (SMS) is delivered.
- EUTCT should be used only for browsing and downloading Substances-related lists.
- Substance data remains in EUTCT until the Substance Management Services (SMS) is delivered.
- Commencing January 2018, new substance requests and updates should be submitted via requests made to the **EMA Service Desk**.
- When submitting a substance request to the EMA Service Desk please provide supporting documentation for the substance, *e.g.* product SmPC or substance specifications.
- mdms@ema.europa.eu email address will be discontinued in Q1 2018.

Support & Additional Information

1. Abbreviations
2. SPOR Training
3. User documentation

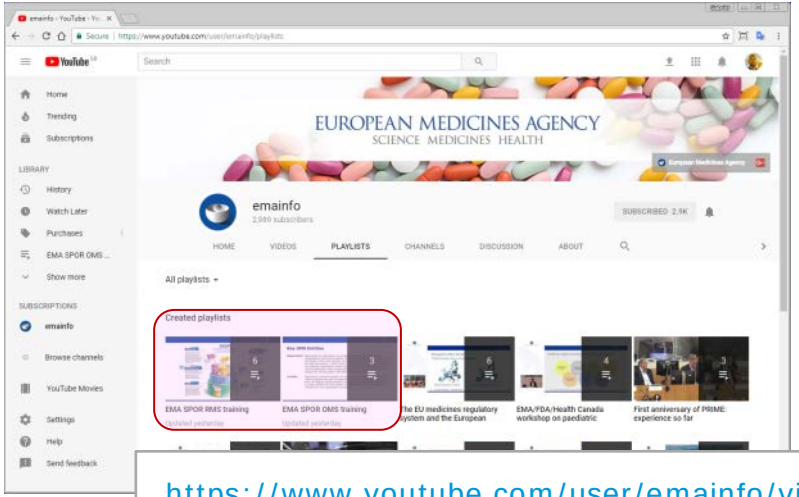
Common Abbreviations

SPOR	Substance, Product, Organisation, Referentials
SMS	Substance Management Services
PMS	Product Management Services
OMS	Organisation Management Services
RMS	Referentials Management Services
CAP	Centrally-Authorised Product
NAP	Nationally-Authorised Product or Non-Centrally Authorised Product
MRP	Mutual Recognition Procedure
DCP	De-Centralised Procedure
MDM	Master data management
eAF	Electronic Application Form

MAH	Marketing Authorisation Holder
MAA	Marketing Authorisation Applicant
EUPD	Clinical Trials EU Portal & Database
ISO	International Standards Organisation
IDMP	Identification of Medicinal Products
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
EU	European Union
EC	European Commission
EEA	European Economic Area
NCA	National Competent Authority
API	Application programming interface

SPOR Training Videos

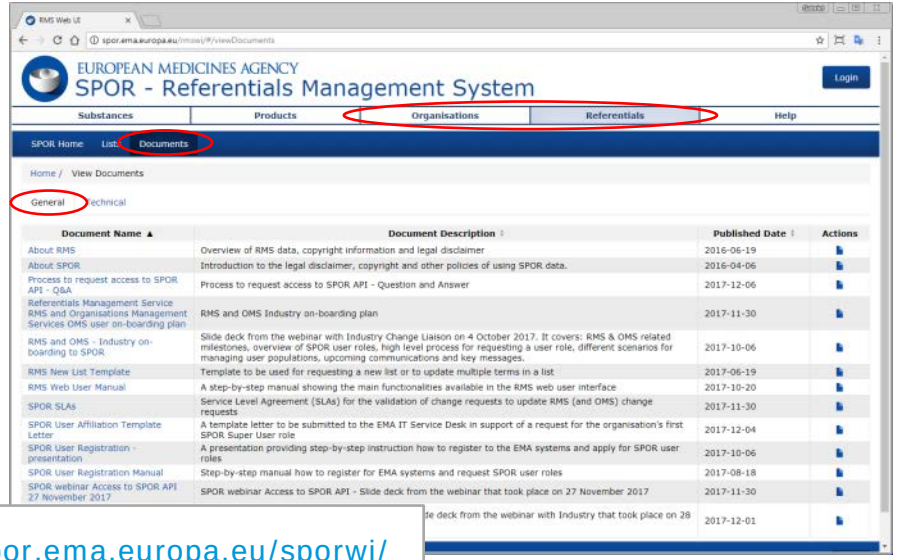
RMS and OMS training videos are published on the @emainfo YouTube channel. They are available freely and cover core functionality for users of RMS and OMS.



https://www.youtube.com/user/emainfo/videos

SPOR User Manuals

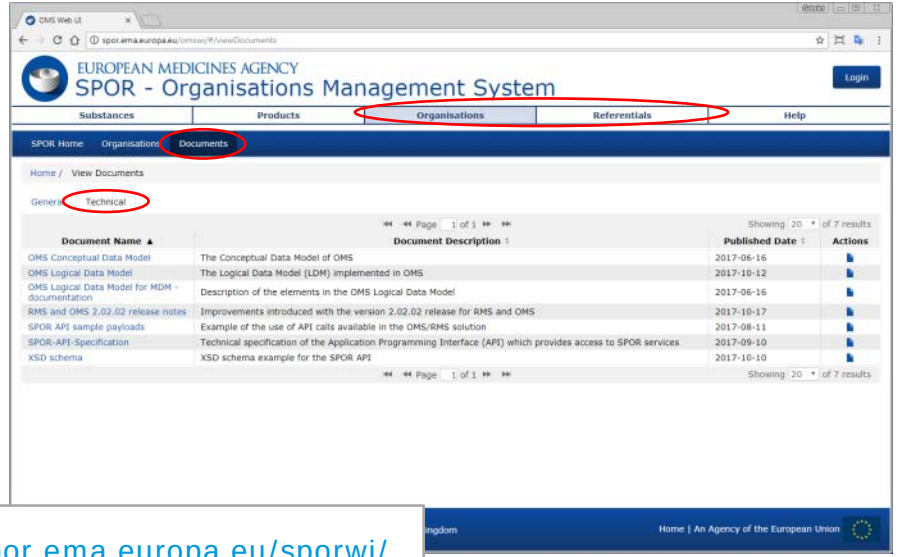
OMS and RMS web user manuals provide step-by-step guidance for the main functionalities available from RMS and OMS web user interfaces, *e.g.* searching and browsing data, requesting new data entries, and requesting changes to existing data.



http://spor.ema.europa.eu/sporwi/

SPOR Technical Documentation

Technical documentation for OMS and RMS covers the API specification, release notes, and data models. Freely available to view without registering.



http://spor.ema.europa.eu/sporwi/

SPOR Registration & On-boarding

Registration processes

1. Register first Industry Super User for an organisation.
2. Register additional Industry Super Users for an organisation.
3. Request a new organisation ID and register first Industry Super User.

1. Register first Industry Super User

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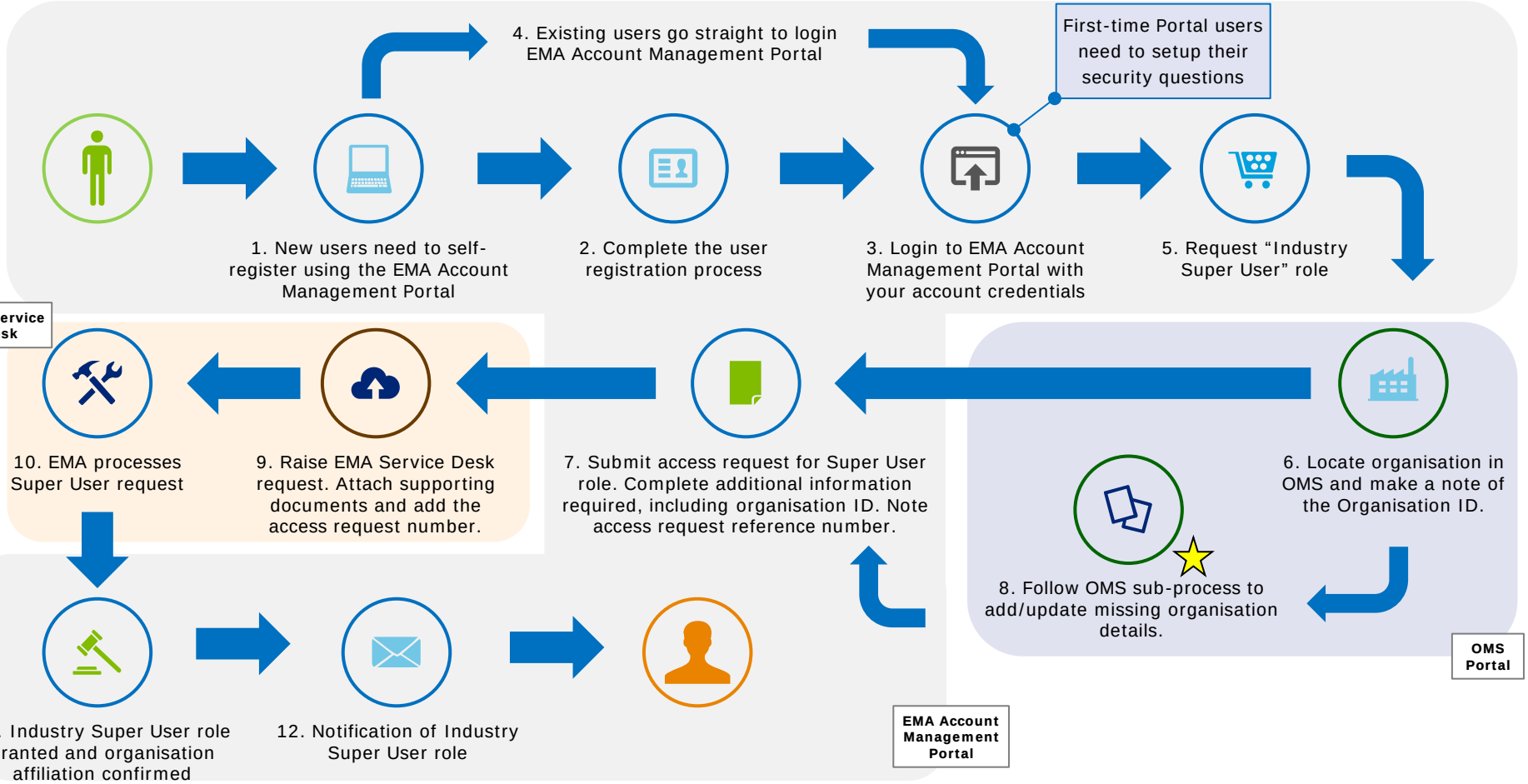

2. Register additional Industry Super Users

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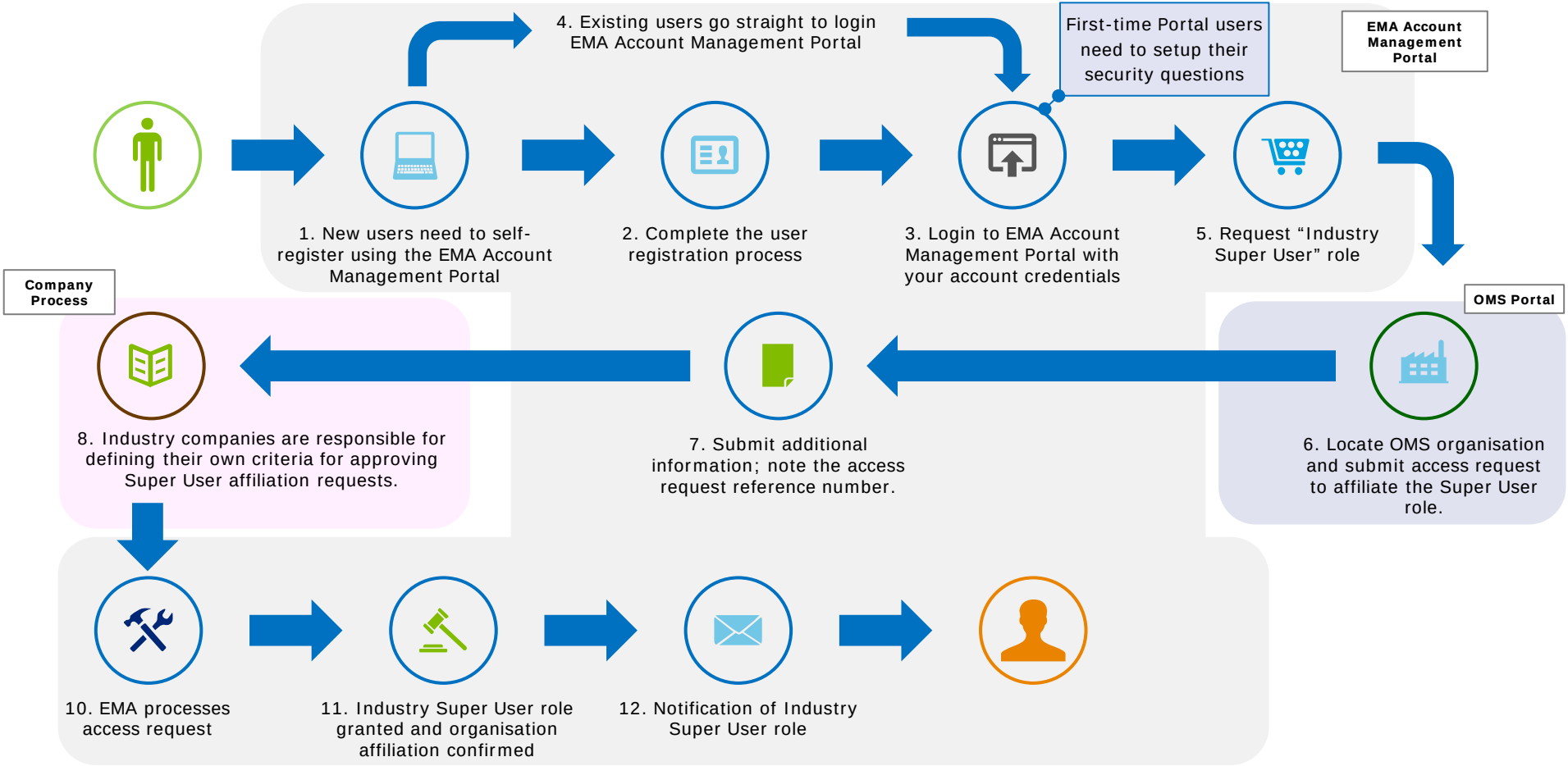

3. Request a new organisation ID

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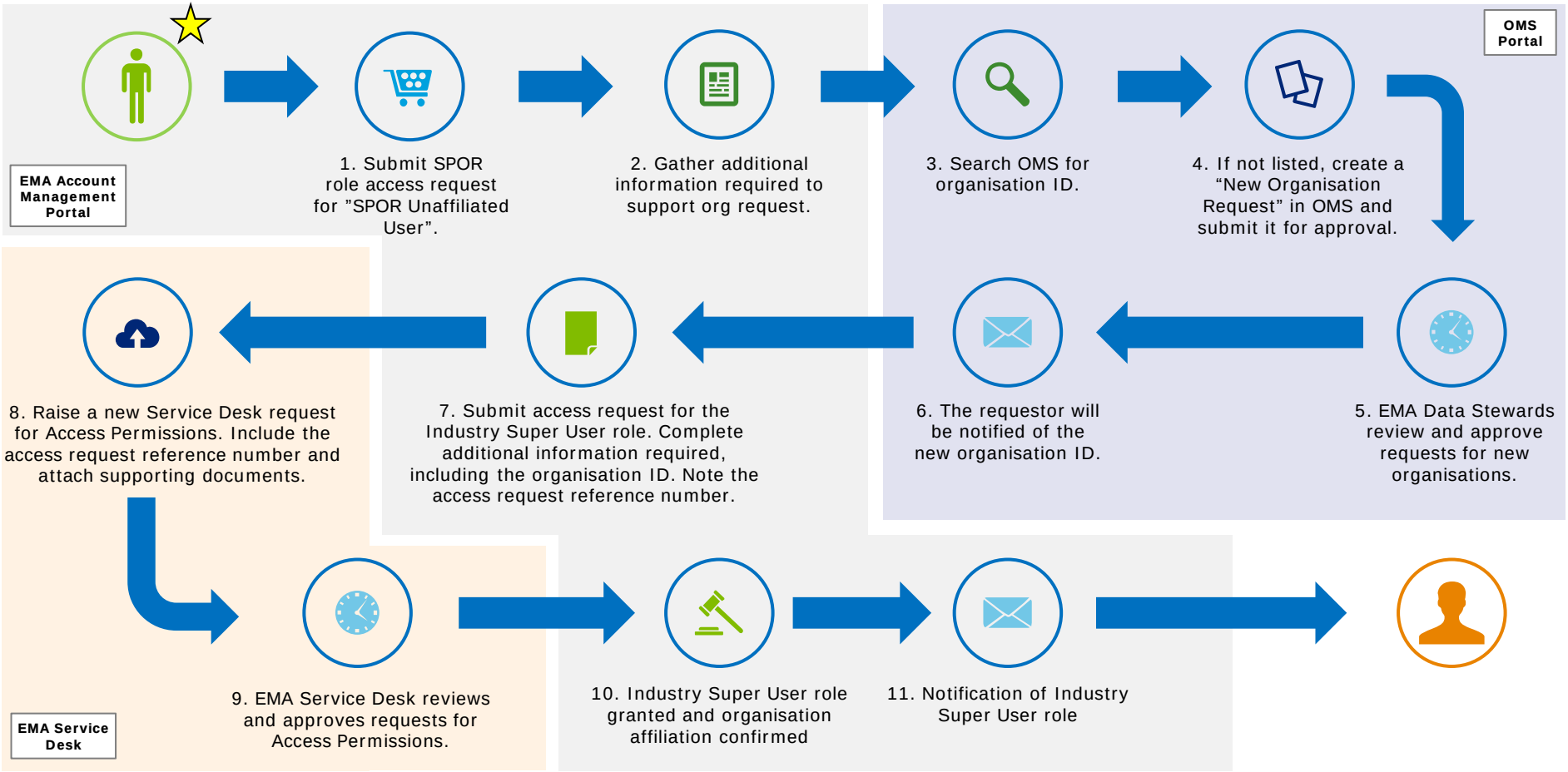
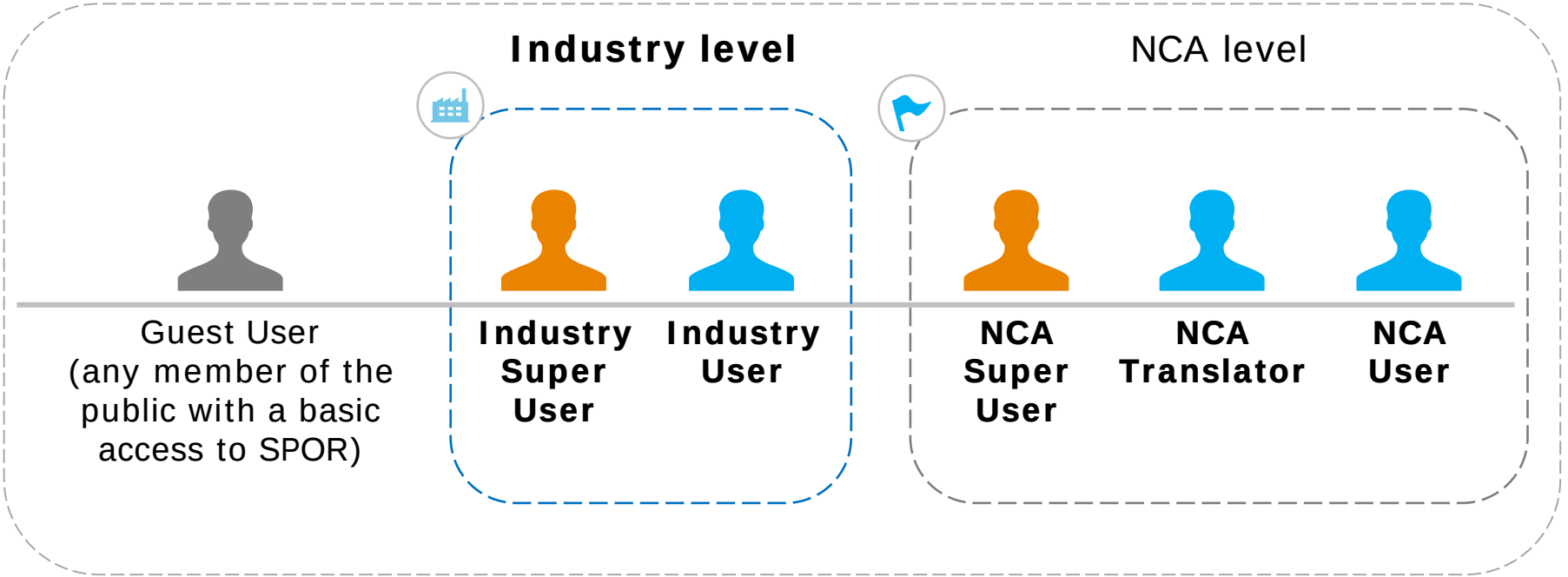
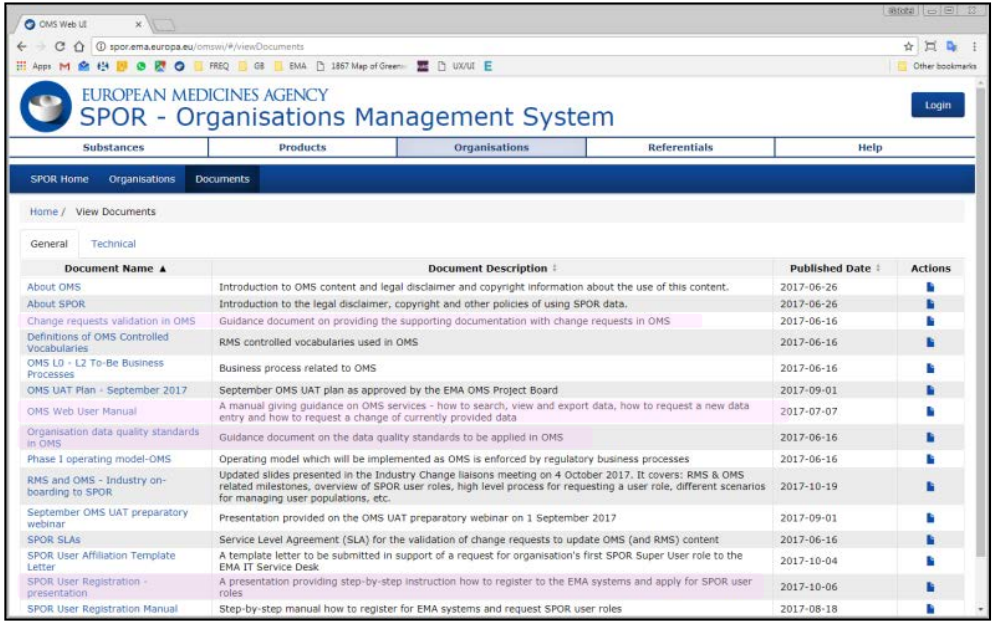


Different SPOR roles

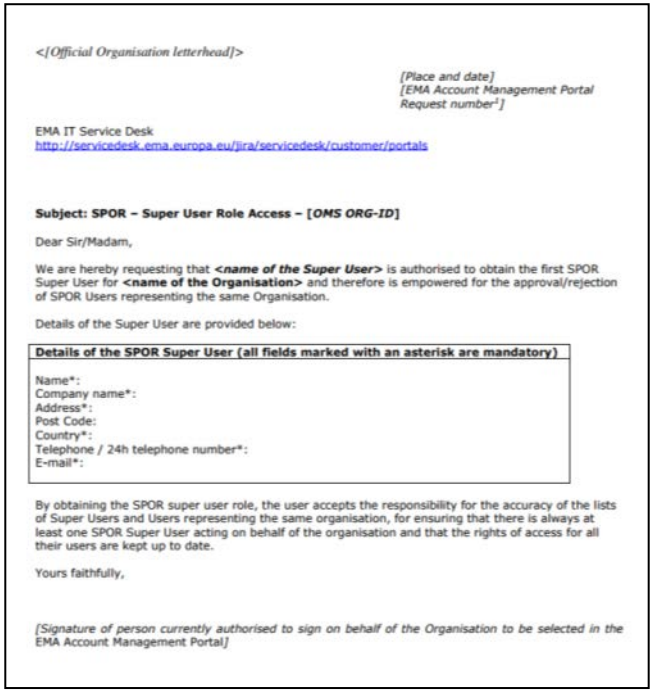


Registration Guidelines & Document Requirements

1. Change Request Validation in OMS
2. OMS Web User Manual
3. Organisation data quality standards in OMS
4. SPOR User Affiliation Template Letter



User Organisation Affiliation



<[Official Organisation letterhead]>

[Place and date]
[EMA Account Management Portal Request number[1]]

EMA IT Service Desk
http://servicedesk.ema.europa.eu/jira/servicedesk/customer/portals

Subject: SPOR – Super User Role Access – [*OMS ORG-ID*]

Dear Sir/Madam,

We are hereby requesting that ***<name of the Super User>*** is authorised to obtain the first SPOR Super User for **<name of the Organisation>** and therefore is empowered for the approval/rejection of SPOR Users representing the same Organisation.

Details of the Super User are provided below:

Details of the SPOR Super User (all fields marked with an asterisk are mandatory)
Name*: Company name*: Address*: Post Code: Country*: Telephone / 24h telephone number*: E-mail*:

By obtaining the SPOR super user role, the user accepts the responsibility for the accuracy of the lists of Super Users and Users representing the same organisation, for ensuring that there is always at least one SPOR Super User acting on behalf of the organisation and that the rights of access for all their users are kept up to date.

Yours faithfully,

[Signature of person currently authorised to sign on behalf of the Organisation to be selected in the EMA Account Management Portal]

Requesting New Organisation/Location

For an organisation established <u>within</u> the EEA:

1. A trade register document that includes the full company name and address, or
2. The EudraGMDP reference number or document for the Manufacturing Authorisation, Wholesale Distributor Authorisation, and/or Active Pharmaceutical Ingredient registration that includes the full company name and address, or
3. DUNS or GS1 number, or similar facility identifier providers documentation (TBC: letter/email/scanned printout, *etc*.) stating the identifier number along with the full company name and address, or
4. If none of the above exists, a letter-headed document signed by the organisation that the user represents, stating full company name and address for which registration is required.

All documents to be dated.

Requesting New Organisation/Location

For an organisation <u>outside</u> the EEA:

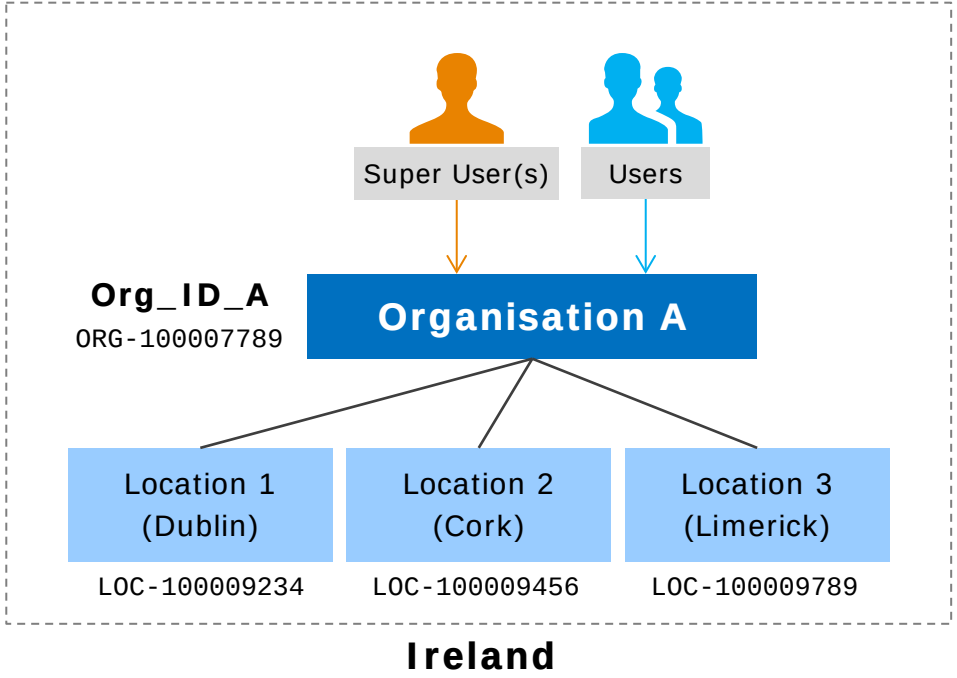
1. DUNS or GS1 number, or similar facility identifier providers documentation (letter/email/scanned printout, *etc*.) stating the identifier number along with the full company name and address, or
2. A trade register document that includes the full company name and address, or
3. The EudraGMDP reference number or document for the GxP certificate that includes the full company name and address, or
4. If none of the above exists, a letter-headed document signed by the organisation that the user represents, stating full company name and address for which registration is required.

All documents to be dated.

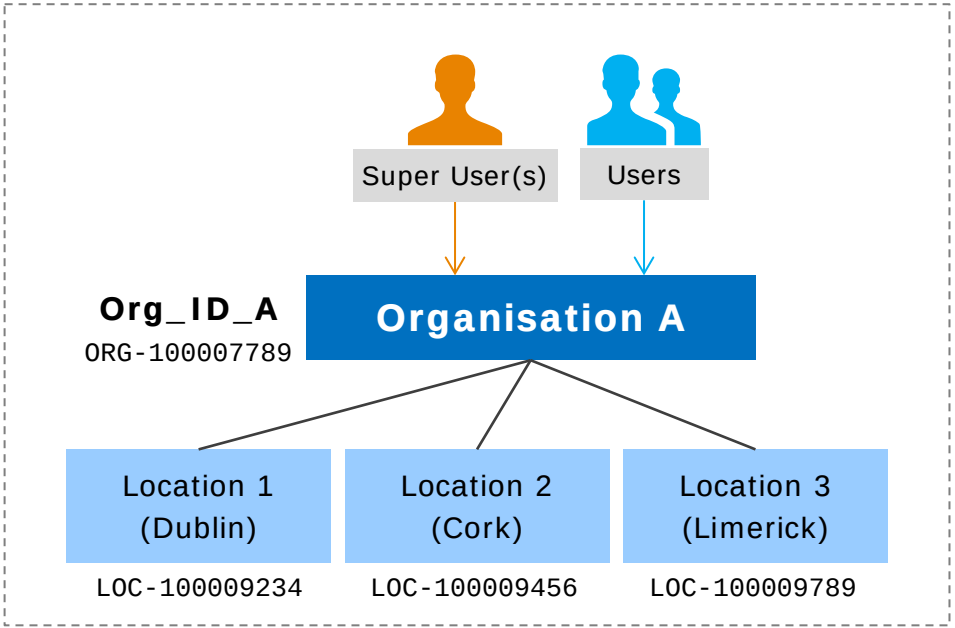
Super User Registration Scenarios

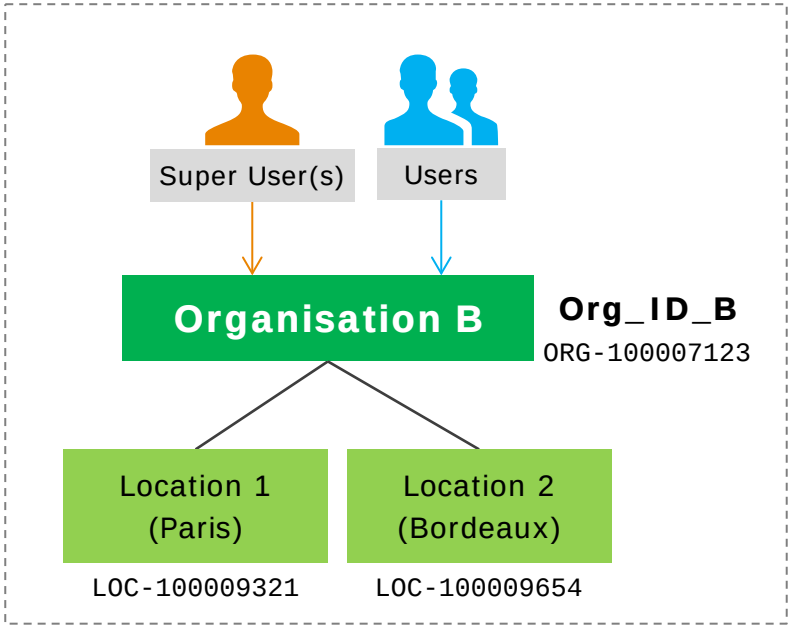
1. **Simple scenario**. Industry Super User and Industry User are both associated with a single organisation (via Organisation_ID) that is established in a single country; organisation is associated with one or more locations (via Location_ID).
2. **Simple international scenario**. Organisation A and Organisation B are established in different countries but perhaps have the same name as they are part of the same group of companies. Industry Super User and Industry User roles are associated with a single organisation in each country, but have no affiliation with the other organisations in other countries. Remember that OMS does not model group structures or company hierarchies.
3. **Shared access international scenario**. The same Industry Super User and Industry User may be registered for SPOR access with multiple organisations (via Organisation_ID). This allows the same Users/Super Users to submit change requests in OMS on behalf of more than one organisation.
4. **Third party service provider scenario**. Industry Super User and Industry User accounts are associated with many organisations in many locations in different countries. This allows for consultancy or service providers to submit SPOR data change requests on behalf of multiple clients.

Super User Registration Scenario #1



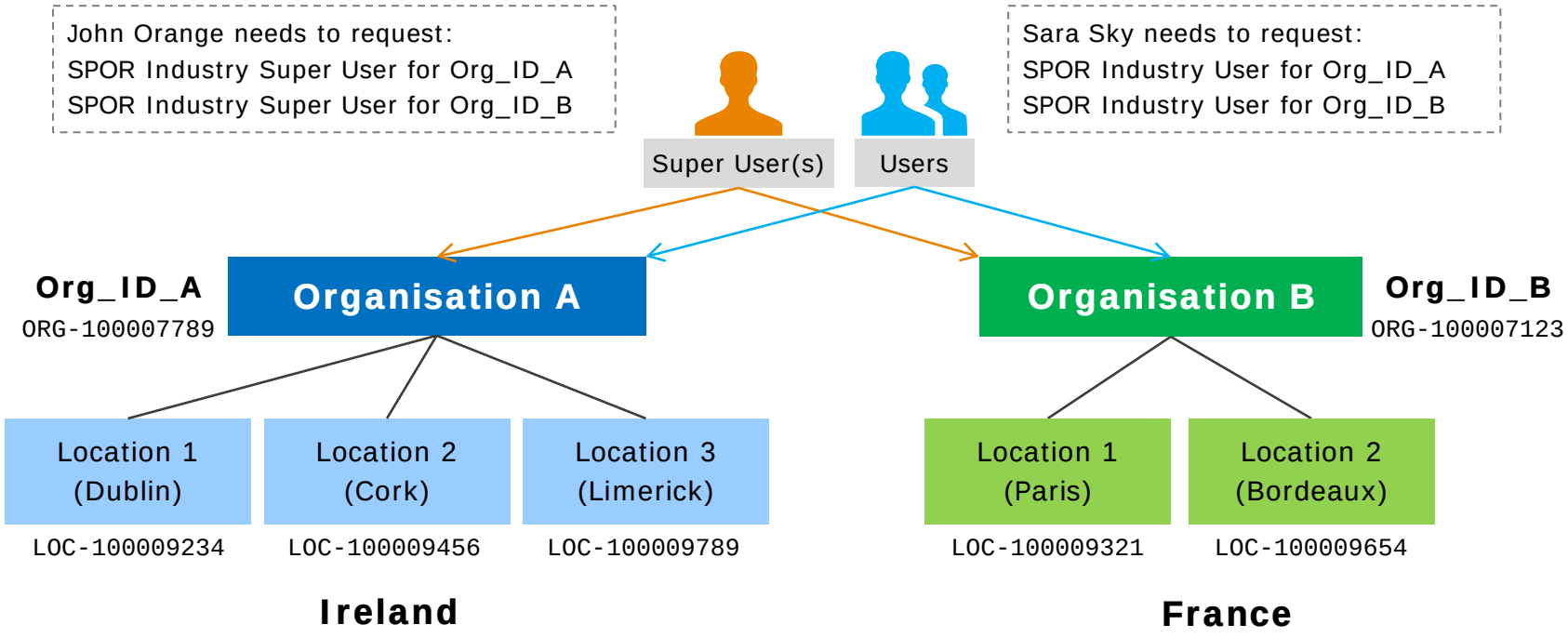
Super User Registration Scenario #2





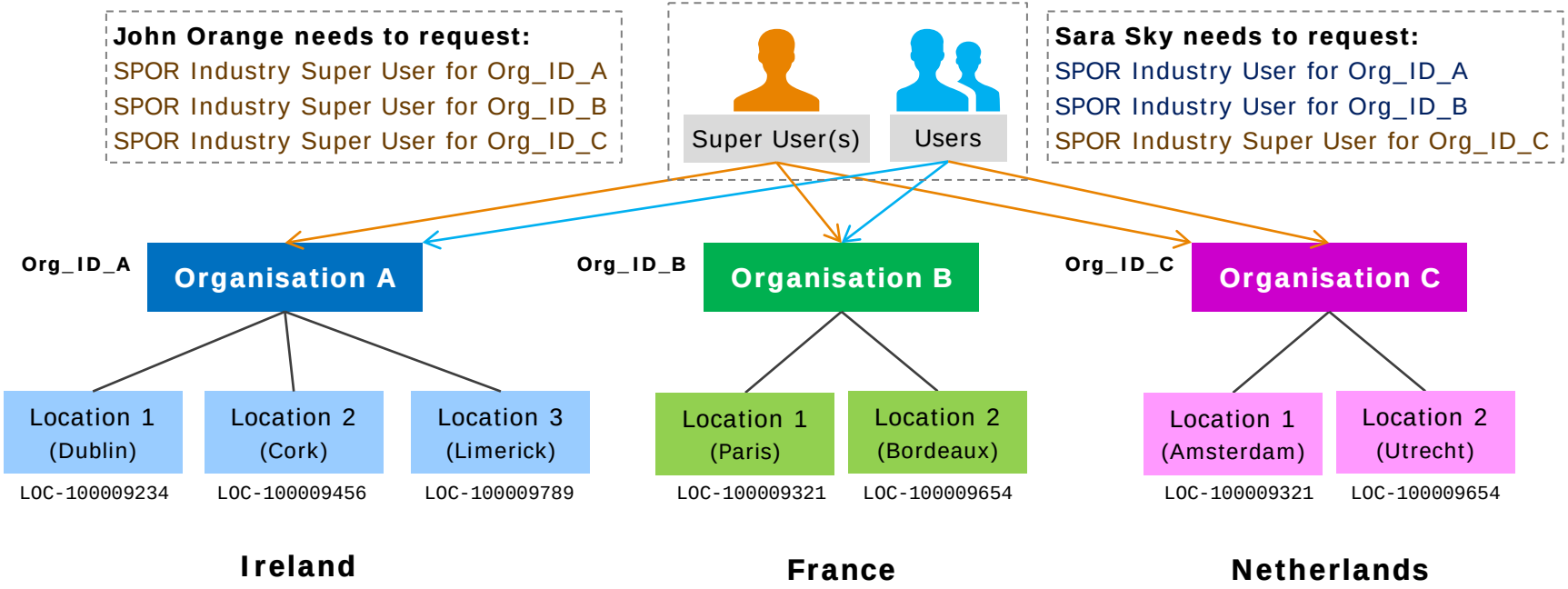
Note: the name of Organisation A can be the same as the name of Organisation B

Super User Registration Scenario #3



Note: the name of Organisation A can be the same as the name of Organisation B

Super User Registration Scenario #4



Note: the name of Organisation A can be the same as the name of Organisation B and Organisation C

Summary of Key Milestones

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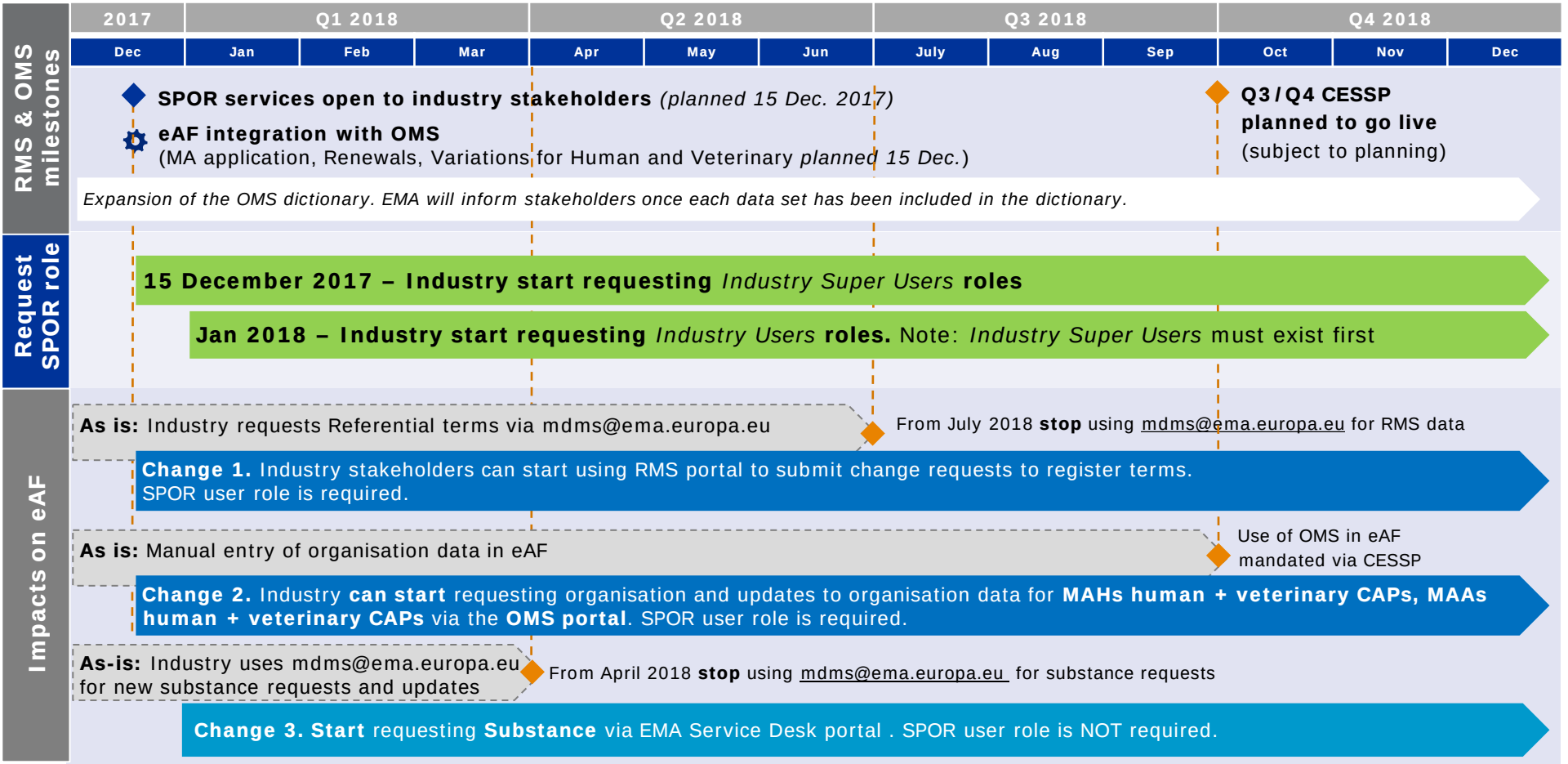

Open questions session

Q&A – Onboarding users to SPOR data services

1. When is the deadline to complete registration of industry users for SPOR?
Registration of SPOR users is predominantly driven by the business process which uses SPOR data. RMS and OMS are already supplying master data to eAF. For example if an organisation address requires updating (before the application form is submitted to a regulatory authority) a user can request such changes by submitting a change request via the OMS portal. To do that a user needs to be registered as a SPOR user.

There may also be other parts of business operations which will benefit from access to full SPOR services.

2. Who manages access to SPOR and how?
Access to SPOR is managed via the EMA Account Management portal. There are different types of SPOR roles (Super User, User) that NCA and industry stakeholders can request. EMA will approve the first Super User for an organisation. The first Super User can then approve subsequent Users for a given organisation.

3. How many Industry Super Users should an organisation register for SPOR?
EMA recommends that each organisation should have at least two registered Industry Super Users. These users will be responsible for approving subsequent Users. They are also responsible for revoking access in case the User leaves the organisation.

Note: EMA approves only the first Industry Super User.

Q&A – Onboarding users to SPOR data services

4. How many Industry Users should an organisation register for SPOR?
An organisation can have multiple SPOR Industry Users. The population of users is driven predominantly by the business process that uses the SPOR data. eAF is the first application using Referentials and Organisation master data. The organisation in question must decide, depending on their circumstances (e.g. number of SPOR users needed, organisational structures, etc.), how many users they should register in SPOR.

5. Does the SPOR Industry Super User also need to request a SPOR User Role for the same organisation (e.g. for ORG_ID 100001234)?
If you have requested the SPOR Industry Super User role for an organisation "ORG_ID 100001234", the same person does not need to request the SPOR User Role for the same organisation "ORG_ID 100001234". In terms of access to functionality in the SPOR portal, Industry Super User and Industry User have the same access rights in RMS and OMS. The difference between these two roles is that a Super User is accountable on behalf of their organisation for approving roles/revoking access for other users via the Account management system.

	Industry Super User	***Industry User***
View public data in SPOR portal	Yes	Yes
Search data in SPOR portal	Yes	Yes
Download data from SPOR portal	Yes	Yes
Submit Change Requests (CR) in SPOR portal	Yes	Yes
Permission to authorise Users in the EMA Account Management portal	Can authorise Industry Users	No

Q&A – Onboarding users to SPOR data services

6. I would like to register for SPOR but by organisation is not in the OMS dictionary.
Login to the EMA Account Management Portal and request a SPOR Unaffiliated User role. It will be approved instantly by the system. The next day, log in to the OMS portal and request to add your organisation to the OMS dictionary by submitting an OMS change request. Wait for the change request to be validated by the OMS data steward – you will receive a confirmation e-mail. The organisation is added to the OMS dictionary automatically. After your organisation is added to the OMS dictionary, login to the EMA Account Management Portal and create another request, but this time for the SPOR Industry Super User role. Relevant guidance is published on the OMS web portal under the 'Documents' menu option.

7. I don't know if my organisation has appointed SPOR Industry Super User(s).
If I request an Industry User role will EMA approve it?
If your organisation is in the OMS dictionary e.g. "ORG_ID 100001234" you will be able to submit a request for the Industry User role for that organisation via the Account Management Portal. If your organisation does not yet have an assigned Industry Super User, your request will remain on hold, pending approval. EMA only approves the first Industry Super User. You should ensure that your organisation appoints a Super User and that they request the Industry Super User role via the EMA Account Management portal. Since this will be the first Super User for the organisation, EMA will approve the request. Any subsequent request are approved or rejected by the Super User(s) of that organisation.

Q&A – Onboarding users to SPOR data services

8. Who should sign the User Affiliation Template letter?
The person/signatory should be someone who works for the organisation to which the User will be affiliated. They should also be recognised as having sufficient authority within their organisation to sign the letter.

The signature of a person would be admissible if they hold a managerial role and have the requisite authority within the organisation to approve the affiliation request. If the first Super User fulfils such requirements then they can also sign the letter.

9. Can anyone in an Industry organisation become the first Industry Super User?
Any Industry user can submit a request to become the first SPOR Industry Super User. However, the relevant supporting documentation (Affiliation Template letter) must accompany such an application. The request will be validated and processed by the EMA for an organisation's first Super User.

10. Do I have to send a company letter per affiliate organisation to become the first Industry Super User for all those organisations? Or could all requests be grouped together in a single letter that lists all required organisations and that includes supporting information?
You will need to submit a request via the EMA Account Management Portal for each affiliate organisation; then you can submit a Service Desk request with one letter that lists all the organisations for which you request the first Super User role and which includes all relevant information.

Q&A – Onboarding users to SPOR data services

11. We have multiple local operating companies within the EU, but would like to centralise control over Super User registration and SPOR access. Is this possible?
Yes – the same person can be an Industry Super User for multiple organisations. In addition, please note that any User or Super User can request creation/update/inactivation of any organisation in the OMS dictionary, not only their own (providing the relevant supporting documentation is provided). Therefore, it is not foreseen and not necessary for every organisation in OMS to have their own Super User. For example, in the future a MAH would request creation/update of organisation data for all manufacturers, CROs, control laboratories, etc. that would need to be included in their eAF.

12. How to affiliate to a company which does not have an Organisation_ID?
They are treated as any other company and can be added in OMS via a change request.

13. A Super User is mapped to an organisation_ID. In the initial registration process you are expecting us to specify each organisation_ID in the request as there is no hierarchy. If there is a new MAH that arises, how will you verify if the Super User is a valid user as the hierarchy does not exist?
Management of the users in the EMA Account Management portal is the responsibility of the Super Users. All organisations, whether they are Head Quarters or Affiliates, are treated equally. The Super Users have the facility to manage only the Users associated to the same organisation ID. If they want to manage Users for multiple organisations, they need to be Super Users for all those organisations.

Q&A – Onboarding users to SPOR data services

14. If an organisation (same organisation name) has operations at different locations in different countries, and therefore different organisation_IDs, do you allow for a Super User from Org_A managing the data for Org_B, Org_C, Org_D, *etc*?

Each organisation in OMS is identified by its Organisaton_ID which is unique to the legal entity in a given jurisdiction/country. OMS does not define corporate structures or group hierarchies. Therefore an organisation that has multiple headquarters and/or affiliated operating units in other countries can choose to register Super User(s) from Org_A to manage Users for Org_B, Org_C, Org_D, etc.

In addition, any User or Super User can request creation/update/inactivation of any organisation in OMS dictionary, not only their own (providing the relevant supporting documentation is provided). Therefore, it is not foreseen and may not be necessary for every organisation in OMS to have its own Super User.

Q&A – Organisations Management Services (OMS)

15. What is OMS (also referred to as OMS dictionary)?
OMS is the source of organisation master data. It consists of lists of organisations with associated physical locations that can be used as a reference and in support of EU regulatory activities. For example, OMS is already supplying data to eAF. In the future more business processes are expected to use OMS master data.

16. Does OMS define which role an organisation performs?
OMS does not define which role(s) an organisation performs since this depends on the context in which the data will be used, e.g. in theory an organisation can act as an MAH (Marketing Authorisation Holder) in the context of one medicinal product but as a sponsor or manufacturer for another medicinal product. In OMS there is also no differentiation between organisations created in the context of a human medicinal product versus a veterinary medicinal product.

17. Is OMS data regulatory data?
OMS is master data and not regulatory data. It manages and provides master data representing the current real-world information about organisations (as accurately as possible). For example, if the organisation name is changed then this can be updated in OMS, independently from any regulatory procedure. EMA does not wait for all the product information to be updated before the organisation/location data is updated in OMS.

18. How can Industry review data about their organisations that is held in OMS?
Go to the OMS Web Portal to browse the OMS dictionary of organisations. It is available freely and you do not need to log in. Industry stakeholders may therefore review at their convenience the information held in OMS about their organisation. If the user is logged in, they can also download the contents of the OMS dictionary as a CSV file. This will help them to map their own data against the OMS content.

Q&A – Organisations Management Services (OMS)

19. Where did the initial content of the OMS dictionary come from?
The initial content of the OMS dictionary originates from EU Telematics systems, i.e. xEVMPD – Article 57, EudraGMDP, and other EMA corporate systems. The data was taken from the above systems in Q4 2016, and since then a process has been applied of data cleansing, data consolidation, and data standardisation before being published in the OMS dictionary.

20. Since the initial OMS data was taken from the source systems in Q4 2016, there may have been changes that took place in xEVMPD – Art.57 after Q4 2016. What happens to the data in OMS?
In January 2018 EMA started updating OMS data based on the latest changes in xEVMPD – Art.57. This means that the relevant changes to the data in Art.57 will be reflected in the OMS. This has no impact on the users.

21. From where was the MAHs data for veterinary CAPs sourced?
MAHs for Veterinary CAPs were mainly sourced from an EMA corporate repository that is used for the management of centralised regulatory procedures. The data was not loaded from EudraPharm Vet; therefore users will not see the EV-VET code listed in OMS.

22. Will there be additional data included in the OMS dictionary?
Yes – additional Organisation data will be published in future. Prioritisation of its inclusion in the OMS dictionary will be defined at a later stage. EMA will communicate once additional data sets have been published.

23. Who can submit an OMS change request?
Any registered SPOR user can submit an OMS change request. Each request will require supporting documentation/information. These requests are validated and processed by EMA Data Stewards. The OMS portal would not prevent a registered SPOR User from submitting a request for their own organisation or any other organisation.

Q&A – Organisations Management Services (OMS)

24. In case an organisation has official records with slightly different addresses, how do we prevent 'address ping pong' in case we submit GMP certificate details in the initial request, and the trade registration details in an update request?
If there is a discrepancy between address details on various documents, the requester should ensure they reflect the true situation and have them updated if necessary. OMS, through the use of Informatica Address Doctor services, provides an address verification service. This service uses reference address data as provided by the main postal service in that country. This verification of the address by Address Doctor is also used to confirm the acceptability of the address data provided in the change request. In case of a disagreement between the EMA Data Steward and the requestor, this will be resolved on an ad hoc basis.

25. What are the data quality principles of which OMS users should be aware, e.g. use of capital letters, symbols?
OMS users may find it useful to consult guidance on OMS data quality standards when requesting additions and/or updates of organisations/locations in the OMS dictionary. This is available freely from the OMS web portal under the 'Documents' section.

26. Who is the business owner of entities within OMS?
EMA is the maintenance organisation for OMS and therefore they are the owners of its content. Any registered SPOR user can submit requests to update organisation data in OMS (providing relevant supporting documents/information). Validation and processing of these change requests is completed by EMA Data Stewards.

27. How will local addresses (non-English) be validated in OMS? Or by NCA Translators?
Functionality from the "Address Doctor" service provides the appropriate localised address(es) for a given location address. These localised addresses come from trusted sources, e.g. national postal services, from each country. Data stewards will manually check the localised address when creating and updating the location address.

Q&A – Organisations Management Services (OMS)

28. The manufacturing site "Pharma A", *10 Rue de la Chappelle 12345 Paris* was divested to another company in 2011 (Pharma B). Therefore this site under the name "Pharma A" is no longer valid but some of our MA files have not been updated yet to de-register this address as Drug Product Manufacturing or Batch Testing/Control or Packaging site. Our understanding is that it should be kept in OMS, even if no longer valid, but submit a request to change the status to INACTIVE? If this is the case, what is the trigger (legal basis) to change the status from ACTIVE to INACTIVE?

If the mentioned site has been sold to another legal entity and this site continues to operate, we would treat this as a split organisation. The Location at *26 Rue de la Chappelle* would be moved to either a new or existing organisation, *i.e.* Pharma B. If the location ceased to operate, or Pharma B does not need to be registered in OMS, then submit an "Update Location" change request with the request reason 'Deactivate Location'. This will change the status of the Location to INACTIVE.

In the event that the new company is needed in OMS, the following scenarios can occur.

a) If Pharma B does not exist in OMS: Submit a "New Organisation" change request with the required location details. In the 'Justification' free text section, explain in the change request that the given location (quote the Location_ID) has been transferred from Pharma A to the mentioned organisation. And provide the required documentation to prove this. This should be enough for EMA Data Stewards to split "Pharma A" in OMS by moving the location to the new Organisation. The Location_ID is kept the same.

b) If Pharma B exists in OMS: Submit an "Add Location" change request with the required location details. In the 'Justification' free text section, explain in the change request that the given location (quote the Location_ID) has been transferred from "Pharma A" to this organisation. And provide the required documentation to prove this. This should be enough for EMA Data Stewards to move the location from "Pharma A" to "Pharma B". The Location_ID is kept the same.

Q&A – eAF integration with RMS and OMS

29. Are there any software requirements to ensure the eAF v1.22 is usable for everyone, e.g. Adobe version limitation?
There are no specific software requirements to use eAF v1.22, but we always recommend using the latest version of Adobe Acrobat.

30. In the updated electronic application form (eAF v1.22) when entering specific organisation ID the search may return results for example in English and Spanish. Which language the user needs to select?
In the OMS dictionary the Organisation and Location details can be in English (as the main language) and other languages. The address can be in multiple languages, which is reflected by the 2 digit language code at the beginning of the drop down list of addresses. These are not duplicate addresses. The user will need to select the correct language.

31. Which version of the Organisation record (current, old) can be selected in the eAF?
Functionality in eAF v1.22 supports only the “current address” of an organisation. We foresee that applicants in future should be able to view previous versions of the same organisation/location data so that Variation applications are also supported.

32. What happens if the OMS address data is not up to date and the eAF data is included manually with the correct address? Will this cause validation issues?
If the user manually enters the correct address this should not have impact on the validation. However, we recommend that user submits an OMS change request to amend the address details.

33. Some manufactures are already in whereas MAHs are still missing. Can we use Manufacturers organisation data if the data are correct?
Yes. If the data you require is present and correct in OMS then please use it to identify organisations and locations in your regulatory submissions.

Q&A – eAF integration with RMS and OMS

34. Recently we came across a license for Kosovo. After checking the ISO standards for the two digit country code we realised that this country is not listed in the standards. It is not listed in the RMS list too. What should be selected as a country and country code?
The Country list in RMS did contain “Republic of Kosovo” (main term name) and “Kosovo” (short name) as a provisional term (RMS ID 100000110973). This term has been approved in the meantime so it should be selectable in the eAF.

35. Can we request some of the term descriptions be updated within RMS?
Registered SPOR users can submit change requests to update RMS data, including term descriptions, by selecting “New Term CR” and specifying the correct CR Type (“Update term”) . Any such change requests will be validated and processed by EMA Data Stewards.

36. Are we able to get a list of fields from the eAF that are actually being sourced from RMS?
RMS replaced EUTCT for referentials data in June 2017. Since this date, all controlled reference data terms used in eAF have been supplied by RMS, with the exception of substance-related lists (that still remain in EUTCT). No other sources of referentials are used.

The specific use of controlled terms and lists is dependent upon the requirements of each regulatory submission. The correspondence between the eAF forms, relevant sections/fields and RMS lists can be found below.

Q&A – eAF integration with RMS and OMS

Drop-down lists in the Electronic Forms	Electronic Forms and sections	RMS lists
Substance	MAA-Human Form - Administrative data; sections 2.1.2; 2.5.3; 2.6.1; 2.6.2 Variation Form - section 2 Renewal Form - sections 1; 3 MAA-Vet Form - Administrative data; sections 1.4; 2.1.2; 2.2.1; 2.5.3; 2.6.1	Terms can come from either of the following lists: • Substance - if used in Human medicinal products. • Veterinary Substance (Pilot) – if used in veterinary medicinal Products.
Container	MAA-Human Form - section 2.2.3 MAA-Vet Form - section 2.2.3	• Packaging (Container category = _Container)
Pharmaceutical Form	MAA-Human Form - Administrative data; section 2.2.1 Variation Form - section 2 Renewal Form - section 1 MAA-Vet Form - Administrative data; section 2.2.1	Terms can come from any of following lists: • Pharmaceutical Dose Form; • Combined pharmaceutical Dose Form; • Combination Package; • Combined Term; • Patient Friendly;

Q&A – eAF integration with RMS and OMS

Drop-down lists in the Electronic Forms	Electronic Forms and sections	RMS lists
Other Provisions	MAA-Vet Form - section 1.4	Maximum Residue Limit Provision (MRL Provision)
Animal Species	MAA-Vet Form - section 1.4	Maximum Residue Limit Species (MRL Species)
Quantity	MAA-Human Form - section 2.6.1 Renewal Form - section 3 MAA-Vet Form - section 2.6.1	Quantity Operator
Route of Administration	MAA-Human Form - section 2.2.2 Renewal Form - section 1 MAA-Vet Form - section 2.2.2	Route of Administration
Proposed Storage Conditions/Proposed Storage Conditions After First Opening	MAA-Human Form - section 2.2.3 MAA-Vet Form - section 2.2.3	Special Precaution for Storage
Species/Target Species	MAA-Vet Form - section 2.1.4; section 2.6.2	Target Species
Target Tissue	MAA-Vet Form - section 1.4	Tissue

Q&A – eAF integration with RMS and OMS

Drop-down lists in the Electronic Forms	Electronic Forms and sections	RMS lists
Unit	MAA-Human Form - section 2.6.1 Renewal Form - section 3 MAA-Vet Form - section 2.6.1	Units of Measurement
Administration device	MAA-Human Form - section 2.2.3 MAA-Vet Form - section 2.2.3	Packaging (Container category =_Administration device)
Closure	MAA-Human Form - section 2.2.3 MAA-Vet Form - section 2.2.3	Packaging (Container category =_Closure
Countries	MAA-Human Form MAA-VET Form Renewal Form Variation	Country
eeaCountries	MAA-Human Form MAA-VET Form Renewal Form Variation	Country (Country Grouping= =_EEA)

Q&A – eAF integration with RMS and OMS

Drop-down lists in the Electronic Forms	Electronic Forms and sections	RMS lists
nonEEACountries	MAA-Human Form MAA-VET Form Renewal Form Variation	Country (Country Grouping= =_Non-EEA)
euAndFreeTradeCountries	MAA-Human Form MAA-VET Form Renewal Form Variation	Country (Country Grouping= =_EFTA)
manufacturerControlTests,	MAA-Human Form - section 2.5.1.2 MAA-Vet Form - section 2.5.1.2	Manufacturing Activity
manufacturerFunctions,	MAA-Human Form - section 2.5.2 MAA-Vet Form - section 2.5.2	Manufacturing Activity,
manufacturerSteps	MAA-Human Form - section 2.5.3 MAA-Vet Form - section 2.5.3	Manufacturing Activity

Q&A – eAF integration with RMS and OMS

37. What happens if provisional terms are made available initially for use in procedures, but are subsequently rejected / not approved?

Provisional terms that are not subsequently approved i.e. are rejected are updated in RMS with the status nullified. Once a term is rejected the EMA Data Stewards will advise the requestor of the term on whether an already-existing alternative or a completely new term should be used instead.

The nullified terms are not deleted from RMS but they will no longer be visible in eAF.

Upcoming Webinar

Topic	Hands on – How to submit change requests for RMS & OMS
When	12 February 2018 at 1400h (UK)
Audience	SPOR Change Liaisons, eAF users, SPOR users.
Draft Agenda	1. Overview of data management and change request process. 2. How to submit change requests. 3. Basic rules of SPOR data quality. 4. Practical advice and best practice.

To register please e-mail spor-change-liaisons@ema.europa.eu

Places are limited; registration for this webinar is first come, first served.

Further information

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