



Please note that **this session is being recorded and will be made available** through **EMA Corporate Website and YouTube channel.**



Throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the [EMA Data Privacy Statement for Slido](#).

Updated Slido Codes in the Footer, if you are copying slides please make sure footers are all the same

Join at
slido.com
#SWOCT924



- Join via **QR code** or **slido.com** - *please provide your questions and comments in Slido only*
- **Send or upvote the questions** you want to hear answered – *before raising a question check whether its has been raised already and vote for it*



Q&A Management

- Questions will be shown on the screen and managed live in the Q&A session
- EMA colleagues will attempt to **address questions in writing throughout the session**
- EMA colleagues will **verbally address (unanswered) top voted questions** at the end in the live Q&A session



Unanswered questions

- This can be due to high volume of questions or assistance of a specific colleague not available today is required
- Unanswered questions will be reviewed, and the **most relevant ones may be addressed** in other webinars or in a FAQ document
- We may request that you ask **Questions on specific issues/cases** in Service Desk to be tracked, investigated and adequately assigned



Presentations will be* available at:

- SPOR Portal Documents section
- EMA Events Web Page

*1st version of presentation already published,
to be updated with final version (if necessary)



Recordings will be available at:

- EMA YouTube Channel
- EMA Events Web Page



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Organisation Management Service (OMS)


9 October 2024, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Débora Martins Braga

SPOR Webinar Series – 4-14 October 2024



During **SPOR webinars**, EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST



Increase Awareness of OMS activities



Share **current and planned activities**



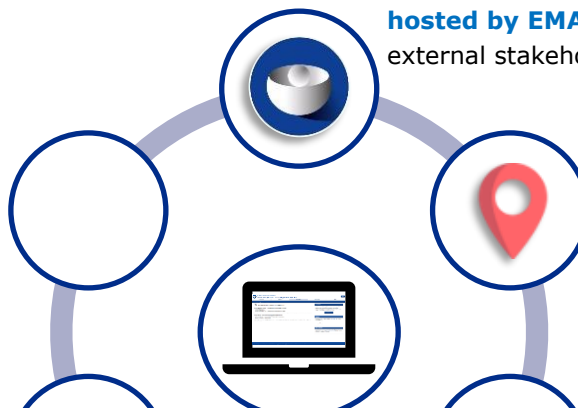
Show how OMS is addressing **customer feedback**



Introduction to OMS



OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders



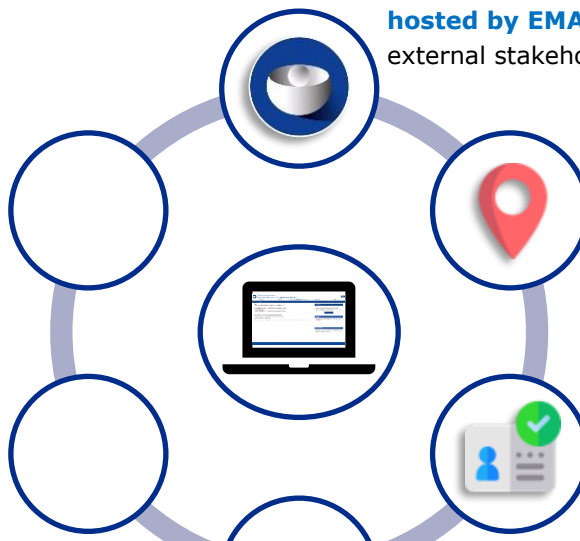
An **organisation**, as a legal entity, groups all its physical locations within a **country** **Roles** (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

Organisation ID	Organisation Name ▲	Country †	Location ID †	City †	Address	Postcode †	Location status
ORG-100013412	European Medicines Agency	Netherlands	LOC-100020264	Amsterdam	Domenico Scarlattilaan 6	1083 HS	ACTIVE
ORG-100013412	European Medicines Agency	Netherlands	LOC-100020260	Amsterdam	P.O. Box 71010	1008 BA	ACTIVE
ORG-100013412	European Medicines Agency	Netherlands	LOC-100018793	Amsterdam	Orlyplein 24	1043 DP	INACTIVE
ORG-100006175	European Medicines Agency	United Kingdom	LOC-100010800	London	30 Churchill Place	E14 5EU	INACTIVE

Organisation ID:	ORG-100032140
Organisation Name:	Opella Healthcare Belgium
Alternative Name:	EN - N.V. Opella Healthcare Belgium S.A. EN - Opella Healthcare Belgium Trading As Sanofi Belgium FR - Opella Healthcare Belgium S.A. NL - Opella Healthcare Belgium N.V.



OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders



An **organisation**, as a legal entity, groups all its physical locations within a **country Roles** (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)

Organisation Details

Organisation ID:	ORG-100000546
Organisation Name:	Sandoz GmbH
Status:	ACTIVE
Organisation Type:	Industry Pharmaceutical company

Location Details

Location ID:	LOC-100000450
Address:	Biochemiestrasse 10 Kundl Tirol 6250 Austria
xEVMPD Code:	ORG1431
EudraGMDP Number:	6236, 6506, 6513, 6536, 6618, 7357, 5296, 5298, 9027, 9400, 9530, 16284, 18205
Last Modified Date:	2021-05-20T15:58:30
Status:	ACTIVE

	A	B	D	F	G	H	I	J
1	Name	missing information in OMS and needed for certificates	Status	Straße	Hausnummer	PLZ	Ort	Staat
2	Sandoz GmbH	/ Site ComOps Wien	GA - aktiv	Stella-Klein-Löw-W	17	1020	Wien	Österreich
3	Sandoz GmbH		GA - aktiv	Jakov-Lind-Straße	5.Top 3.05	1020	Wien	Österreich
4	Sandoz GmbH	/ Site ComOps Wien - Außenlager SCHACHINGER pharmalogistik GmbH	GA - aktiv	Schemmerlstraße	72	1110	Wien	Österreich
5	Sandoz GmbH	/ Site ComOps Wien - Außenlager SCHACHINGER pharmalogistik GmbH	GA - aktiv	Logistikzentrum Wi	10-18	2201	Hagenbrunn	Österreich
6	Sandoz GmbH	- Außenlager Gebrüder Weiss GmbH	GA - aktiv	Löfflweg	35	6060	Hall	Österreich
7	Sandoz GmbH	- Organisationseinheit LOG	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
8	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Anti Infectives & Chemical Operations FDF Kundl (AICO FDF Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
9	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Sandoz Development Center Kundl (SDC Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
10	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Anti-Infectives & Chemical Operations API Kundl (AICO API Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
11	Sandoz GmbH		GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
12	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Aseptics Drug Product Schafstenu / Kundl (Aseptics DPS Kundl)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
13	Sandoz GmbH	- Betriebsstätte / Manufacturing Site Drug Substance Kundl (DSK)	GA - aktiv	Biochemiestrasse	10	6250	Kundl	Österreich
14	Sandoz GmbH	, Außenlager Gebrüder Weiss GmbH	GA - aktiv	Gewerbepark	9	6300	Wörgl	Österreich
15	Sandoz GmbH	, Außenlager Schenker & Co AG	GA - aktiv	Gewerbepark	2	6300	Wörgl	Österreich
16	Sandoz GmbH	- Außenlager Schenker & Co AG	GA - aktiv	Gewerbepark Süd	8	6330	Kufstein	Österreich



OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders



An **organisation**, as a legal entity, groups all its physical locations within a **country**
Roles (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)

The **Location_ID** will be unique and will **not change**

ORG-10000789	Sanofi-Aventis Groupe	France	LOC-100001368	Paris	54 Rue La Boetie	75008	ACTIVE	2019-08-28T17:37:51	+ 🔗 🔍
ORG-100026749	Sanofi	France	LOC-100014428	Paris	54 Rue La Boetie	75008	ACTIVE	2020-08-21T14:56:22	+ 🔗 🔍
ORG-100010027	Sanofi Pharma Bristol-Myers Squibb SNC	France	LOC-100014368	Paris	54 Rue La Boetie	75008	INACTIVE	2020-03-03T14:09:38	+ 🔗 🔍
ORG-100001962	Sanofi Clir S.N.C.	France	LOC-100005474	Paris	54 Rue La Boetie	75008	ACTIVE	2020-09-11T11:57:00	+ 🔗 🔍
ORG-100014407	Sanofi Mature Ip	France	LOC-100020362	Paris	54 Rue La Boetie	75008	ACTIVE	2020-09-03T15:28:54	+ 🔗 🔍

OMS **does not have individuals**. If individuals are required in a certain regulatory procedure, this needs to be dealt directly by each system

OMS publish the **latest information** available and maintain all **versions** in a date format (version timestamp)



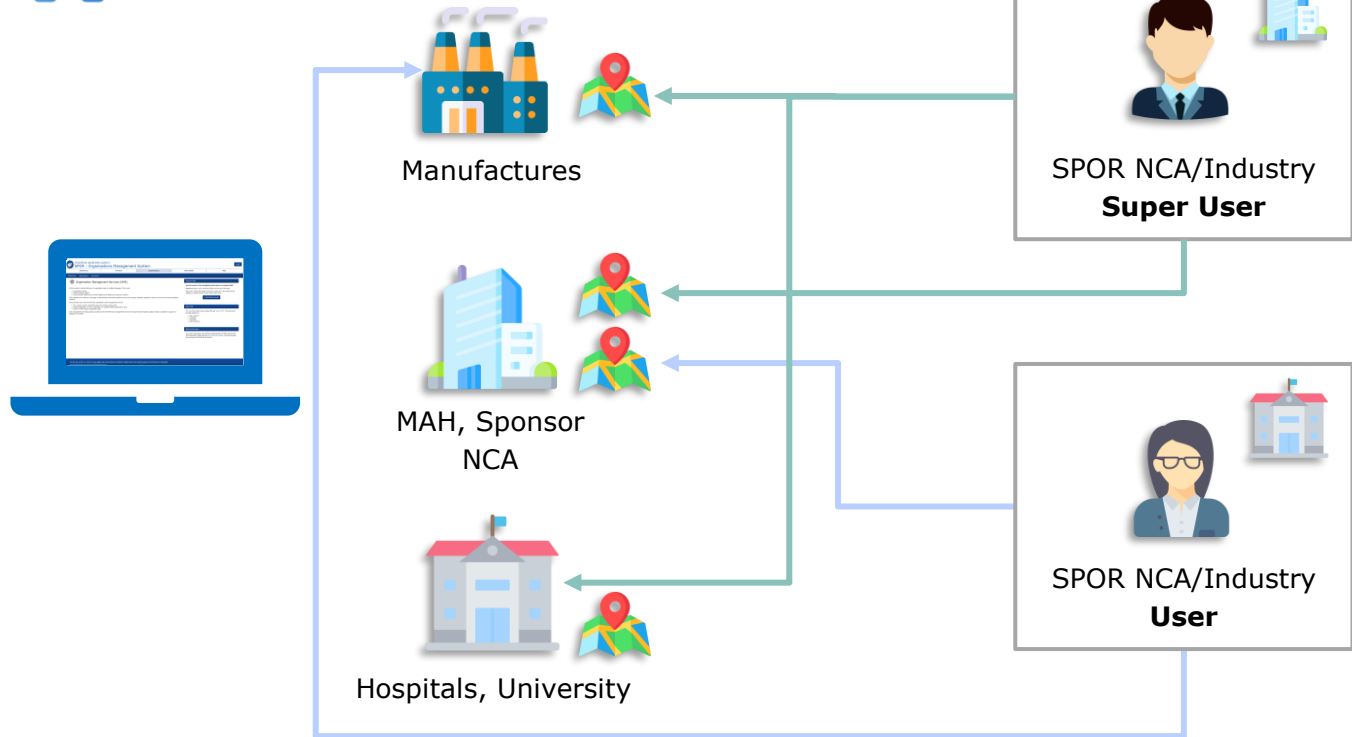
OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders

An **organisation**, as a legal entity, groups all its physical locations within a **country Roles** (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)

The **Location_ID** will be unique and will **not change**

Who can change OMS data?



Anyone can submit a Change Request to **any organisation and/or location** published in the OMS Dictionary, as long as they submit supporting documentation

Validation of data as per date of the Change Request

OMS is a standardised list of Organisations/Locations



OMS uses **Reference sources of information** (Trade registry, DUNS, other documents/sources) to ensure **data correctness/accuracy**



OMS data **reflects reality**:

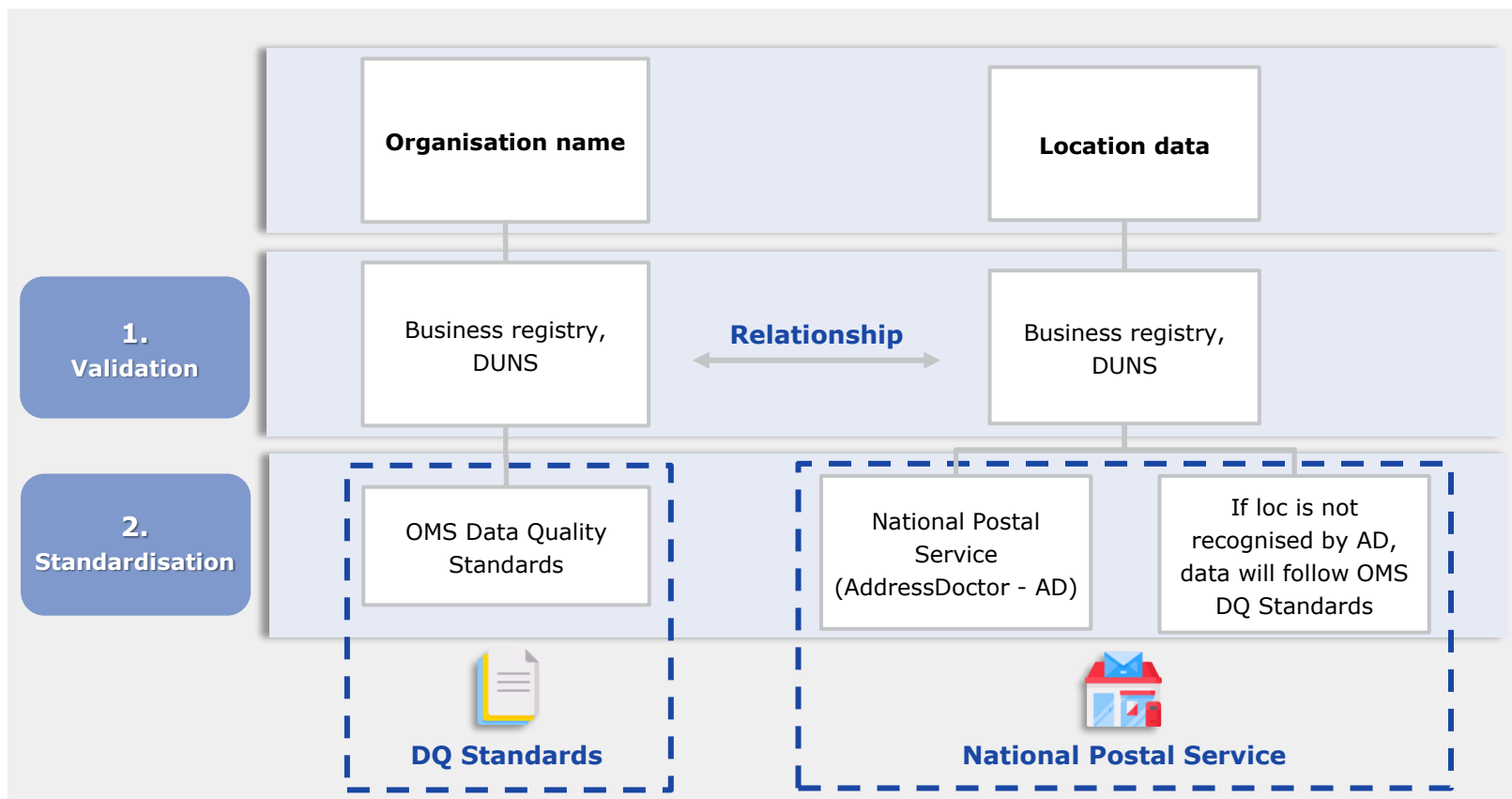
- correct organisation/legal entity
- correct relationship with its address
- correct address



OMS reflects **equivalent** information as the **Trade registry** (or other documents/sources) but it is **not meant to be** the same/ **“copy”** of Trade registry (or other documents/sources)

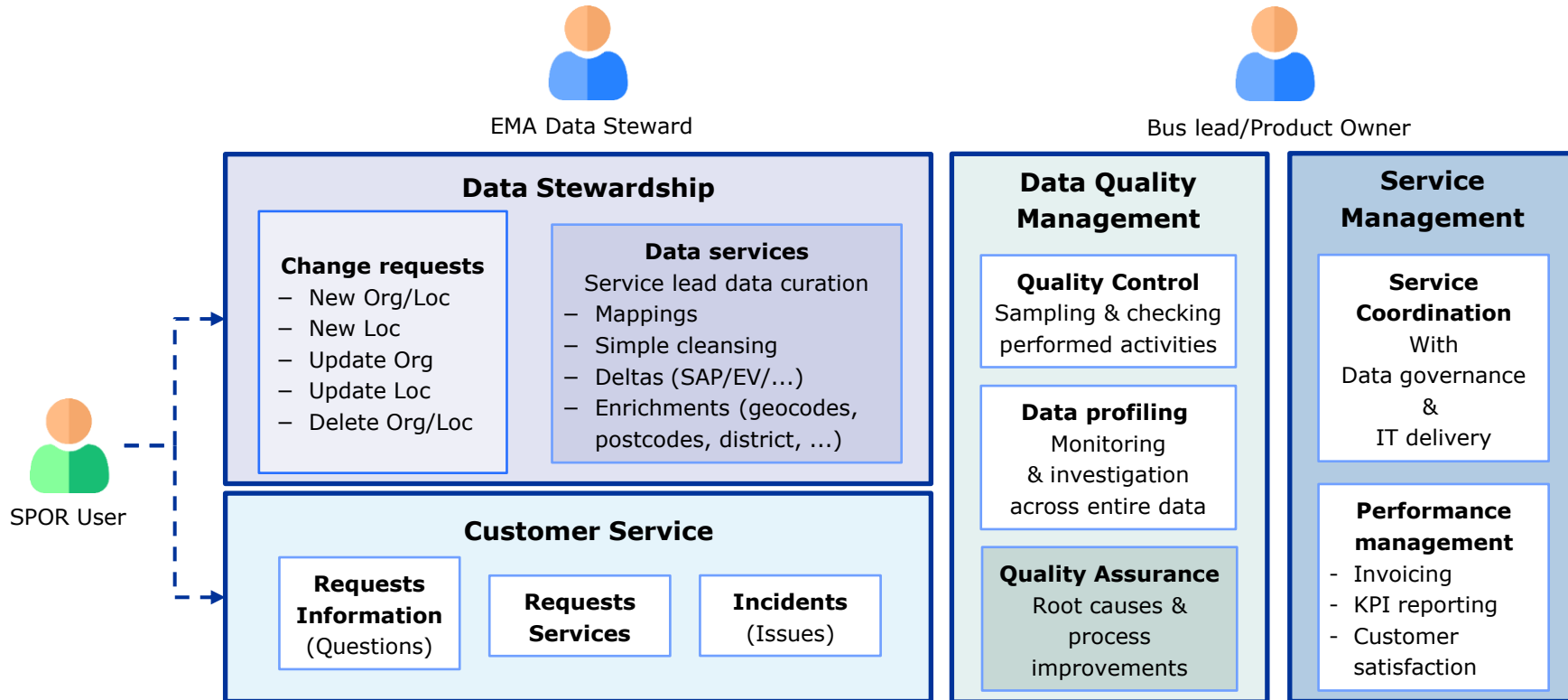


OMS reflects **consistent information** i.e. OMS will apply/standardise the organisation/address information according to the agreed Data Quality rules





OMS processes



Data management processes are defined, operational and are monitored/reported on



OMS Data Services

EV to OMS deltas

XEVMPD

Organisation missing in XEVMPD?



Insert/update organisation via **XEVPRM**
As per OMS -> reference LOC ID

Organisation created/updated in XEVMPD



Reference Organisation in XEVMPD product entry

- Organisation/Location data still needs to be created/updated in XEVMPD
- OMS organisation/location details should be used

Product **should** be updated in XEVMPD by reflecting organisation details as used in OMS and **referencing LOC ID**



Request organisation create/update via **OMS portal: OMS Change Request**



Organisation created/updated in OMS



XEVMPD to OMS deltas
(Import XEVMPD codes and details into OMS)

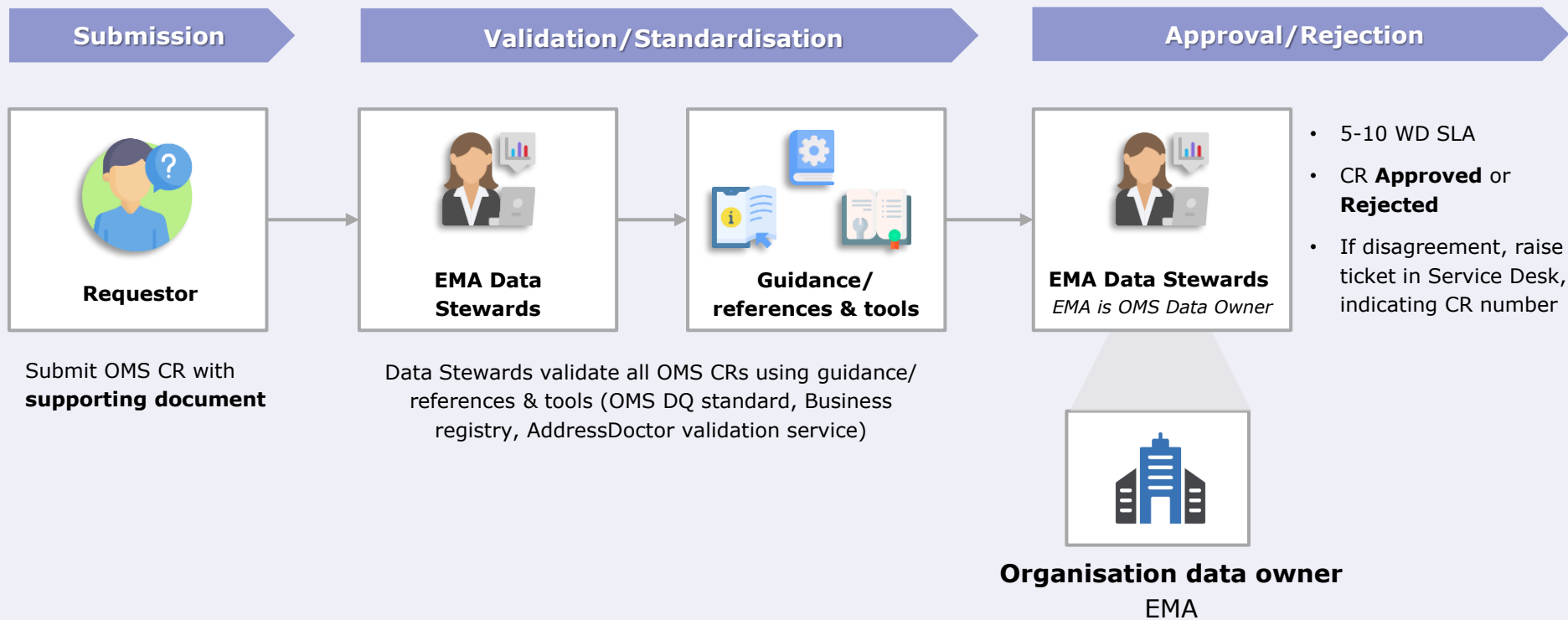
- Change Requests should be submitted to OMS first as data can be required for IAM/user registration, eAF etc.
- Organisation/Location data is created and standardised based in Change Requests and supporting documentation

- EMA/OMS team processes deltas/updates from XEVMPD
- EMA/OMS team focuses on EV-OMS mappings, other Organisation/Location details normally follow what was requested via Change Request (as required by eAF and other use cases before XEVMPD submission)

OMS



OMS Change Request process



Login

Requestor



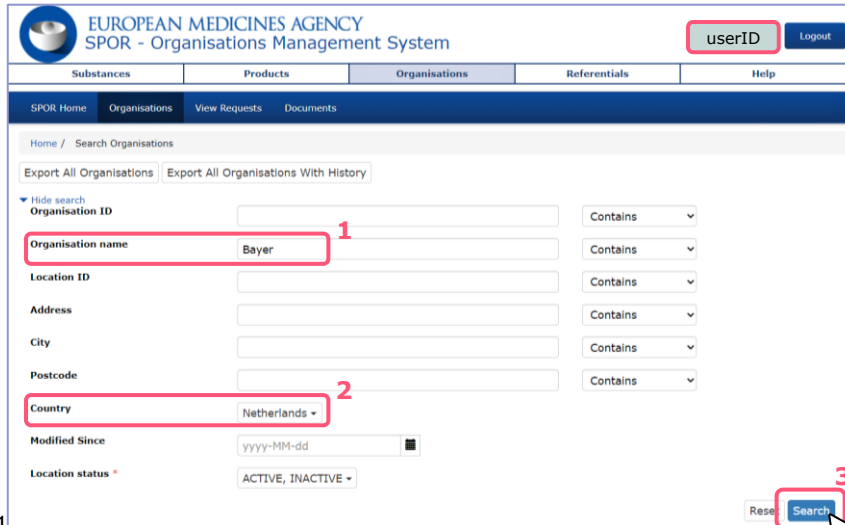
EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances Products Organisations Referentials Help

SPOR Home Organisations Documents

Login

Query OMS



EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

userID Logout

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations

Export All Organisations | Export All Organisations With History

Hide search

Organisation ID Contains

Organisation name Contains **1**

Location ID Contains

Address Contains

City Contains

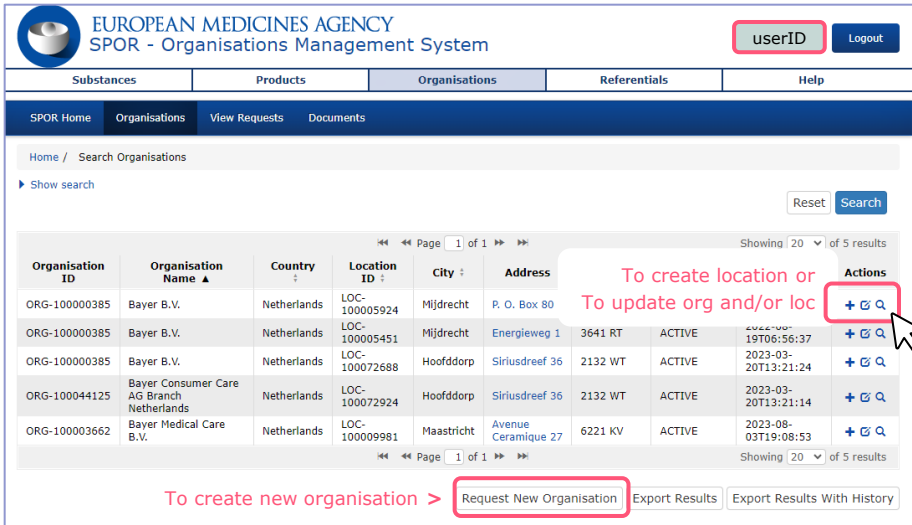
Postcode Contains

Country **2**

Modified Since

Location status

Search **3**



EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

userID Logout

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations

Show search

Reset Search

Showing 20 of 5 results

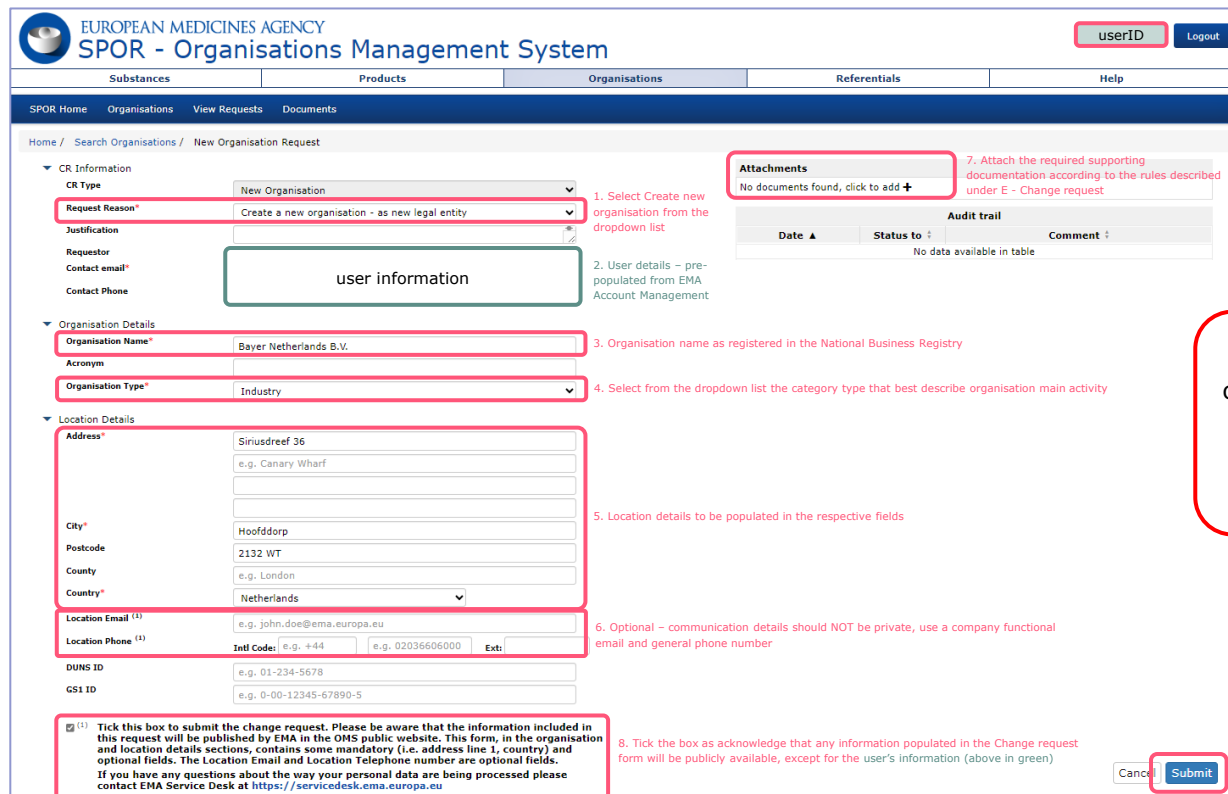
Organisation ID	Organisation Name	Country	Location ID	City	Address	Actions
ORG-100000385	Bayer B.V.	Netherlands	LOC-100005924	Mijdrecht	P. O. Box 80	+ @ Q
ORG-100000385	Bayer B.V.	Netherlands	LOC-100005451	Mijdrecht	Energieweg 1	+ @ Q
ORG-100000385	Bayer B.V.	Netherlands	LOC-100072688	Hoofddorp	Siriusdreef 36	+ @ Q
ORG-100044125	Bayer Consumer Care AG Branch Netherlands	Netherlands	LOC-100072924	Hoofddorp	Siriusdreef 36	+ @ Q
ORG-100003662	Bayer Medical Care B.V.	Netherlands	LOC-100009981	Maastricht	Avenue Ceramique 27	+ @ Q

To create location or To update org and/or loc

To create new organisation > Request New Organisation | Export Results | Export Results With History

Create Organisation

Requestor



The screenshot shows the 'New Organisation Request' form in the SPOR system. The form is divided into several sections: CR Information, Organisation Details, and Location Details. The 'Request Reason' is set to 'Create a new organisation - as new legal entity'. The 'Organisation Name' is 'Bayer Netherlands B.V.' and the 'Organisation Type' is 'Industry'. The 'Location Details' section includes fields for Address, City, Postcode, County, and Country. The 'Location Email' and 'Location Phone' fields are optional. A 'Submit' button is visible at the bottom right.

Annotations:

- 1. Select Create new organisation from the dropdown list
- 2. User details – pre-populated from EMA Account Management
- 3. Organisation name as registered in the National Business Registry
- 4. Select from the dropdown list the category type that best describe organisation main activity
- 5. Location details to be populated in the respective fields
- 6. Optional – communication details should NOT be private, use a company functional email and general phone number
- 7. Attach the required supporting documentation according to the rules described under E - Change request
- 8. Tick the box as acknowledge that any information populated in the Change request form will be publicly available, except for the user's information (above in green)
- 9. Click Submit, note that the information will not be made available immediately, Change request needs to be reviewed/validated by EMA Data Steward

Create new organisation
only when a new **company is registered as new legal entity in the National Business Registry**



Update Organisation name

Requestor



EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

userID Logout

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations / View Organisation Location / Update Organisation/Location Request

CR Information

CR Type: Update Organisation

Request Reason*: Update of organisation name - only name change

Justification: Update of organisation name - only name change

Requester: [Redacted]

Contact email*: [Redacted]

Contact Phone: [Redacted]

Attachments

No documents found, click to add +

Audit trail

Date ▲	Status to :	Comment :
No data available in table		

Organisation Details

Organisation ID: ORG-10000734

Organisation Name*: Viartis Pharmaceuticals S.L.

Acronym: [Redacted]

Organisation Type*: Industry

Location Details

Location ID: LOC-100043989

Address*: Calle General Aranz 86
Poligono Josefa Valcarcel

City*: Madrid

Postcode: 28027

Country: e.g. London
Spain

Location Email (1): e.g. john.doe@ema.europa.eu

Location Phone (1): Int'l Code: e.g. +44 e.g. 02036606000 Ext: [Redacted]

DUNS ID: e.g. 01-234-5678

GS1 ID: e.g. 0-00-12345-67890-5

⁽¹⁾ Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields. If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>

6. Tick the box as acknowledge that any information populated in the Change request form will be publicly available, except for the user's information (above in green)

Cancel Submit

1. Select Update organisation name from the dropdown list

2. User details – pre-populated from EMA Account Management

3. Type New Organisation name as registered in the National Business Registry

4. Certain attributes will be greyed out as they are not meant to be edited e.g. organisation/location identifiers and country

5. Attach the required supporting documentation according to the rules described under E - Change request.

Update organisation name
only when the **company** changes the legal name in the **National Business Registry**

7. Click Submit, note that the information will not be made available immediately, Change request needs to be reviewed/validated by EMA Data Steward

Deactivate Location

Requestor



EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

userID Logout

Substances Products Organisations Referentials Help

SPOR Home Organisations View Requests Documents

Home / Search Organisations / View Organisation Location / Update Organisation/Location Request

CR Information

CR Type: Update Organisation and Location

Request Reason*: Deactivate location

Justification: This location is no longer being used by Glaxo and company moved to another location which has already been created on OMS.

Requestor: user information

Contact email*: [redacted]

Contact Phone: [redacted]

Attachments

No documents found, click to add +

2b. Attach the required supporting documentation according to the rules described under E - Change request.

Audit trail

Date	Status	Comment
No data available in table		

1. Select Deactivate Location from the dropdown list

2a. **Mandatory** - clear statement/justification that the organisation is **NO LONGER doing business in this address**

3. User details - pre-populated from EMA Account Management

Organisation Details

Organisation ID: ORIG-100005535

Organisation Name*: GlaxoSmithKline Research & Development Limited

Acronym: [redacted]

Organisation Type*: Industry

Location Details

Location ID: LOC-100002256

Address*: GSK House, 980 Great West Road, Brentford, TW8 9GS, Middlesex, United Kingdom

City*: Brentford

Postcode: TW8 9GS

Country: Middlesex

Country*: United Kingdom

Location Email (1): e.g. john.doe@ema.europa.eu

Location Phone (1): Int'l Code: e.g. +44, e.g. 02036606000, Ext: [redacted]

DUNS ID: e.g. 01-234-5678

OSI ID: e.g. 0-00-12345-67890-5

(1) Tick this box to submit the change request. Please be aware that the information included in this request will be published by EMA in the OMS public website. This form, in the organisation and location details sections, contains some mandatory (i.e. address line 1, country) and optional fields. The Location Email and Location Telephone number are optional fields. If you have any questions about the way your personal data are being processed please contact EMA Service Desk at <https://servicedesk.ema.europa.eu>

4. Tick the box as acknowledge that any information populated in the Change request form will be publicly available, except for the user's information (above in green)

Cancel Submit



Location Deactivation
only when the **company** is **no longer operating/doing business in a certain location**

Organisation

! This entity is in a pending state

Organisation Name: **Midatech Ltd** (PROVISIONAL)

Status: **PROVISIONAL**

Comments:

Organisation Translation: **Midatech Limited**

Organisation Category:

Party Category Code:

Industry

Party Category:

Organisation Mappings:


Organisation Identifiers:

Organisation Location:

Status: **PROVISIONAL**

Address Line 1: **Oddfellows House**

Validation




**CERTIFICATE OF INCORPORATION
OF A PRIVATE LIMITED COMPANY**

Company No. [REDACTED]

The Registrar of Companies for England and Wales hereby certifies that **MIDATECH LTD**

is this day incorporated under the Companies Act 1985 as a private company and that the company is limited.

Given at Companies House, Cardiff, the 27th October 2000



COMPANIES HOUSE

HC0078

Standardisation



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 June 2017
EMA/740982/2016
Information Management Division

Organisation data quality standards in OMS
Data quality principles

Country	Reference	Legal Entity naming in organisation names (in EN and National languages)
SE	Swedish Companies Registration Office	AB, AB (publ), EEIG,
SI	Slovenian Business Register	d.o.o., EGIZ, d.d.
SK	Slovakian Business Register	a.s., k.s., s.r.o. = spol. s r.o., v.o.s., EZHZ,
UK	Companies House	Limited, Public, EEIG,

Organisation Location

This entity is in a pending state

Address Line 1	c/o TheVIT AS	Address Line 2	Gunnar Randers' vei 24	Address Line 3	
Address Line 4		Street Number		Postal code	2007
Po Box		City	Kjeller	State	
County		Country	Norway	GPS Latitude	
GPS Longitude		Is Headquarter		Active Start Date	27/Feb/2020
Active End Date		Is Mastered		Hierarchy Class Code	LCTN
Hierarchy Code	ORG_HIERARCHY	Relationship Type Code	ORG-LCTN	Status	PROVISIONAL
Active Request	true	Ignore Address Doctor		To Date	
Comments					

Record 4 of 4

Brønnøysundregistrene

Validation Firmaattest

Organisasjonsnummer:

Organisasjonsform: Under avvikling

Stiftelsesdato:

Registrert i Foretaksregisteret:

Foretaksnavn:

Forretningsadresse:

Kommune:

Land:

Organisation Location

Standardisation

This entity is in a pending state

Address Line 1	Gunnar Randers' Vei 24	Address Line 2		Address Line 3	
Address Line 4		Street Number	24	Postal code	2007
Po Box		City	Kjeller	State	
County		Country	Norway	GPS Latitude	59.974546
GPS Longitude	11.047364	Is Headquarter		Active Start Date	27/Feb/2020
Active End Date		Is Mastered		Hierarchy Class Code	LCTN
Hierarchy Code	ORG_HIERARCHY	Relationship Type Code	ORG-LCTN	Status	PROVISIONAL
Active Request	true	Ignore Address Doctor	No	To Date	
Comments	3-Good/ Local Address -> Line1:Gunnar Randers' Vei 24 City:Kjeller Country:Norge Lang:NO				

Record 4 of 4



National Postal Service



Rejected change requests:

- *Requester receives an email acknowledgement containing:*
 - *Reject Reason code*
 - *Comment providing the user with justification and further guidance*



OMS does not have change request return option:

If the user did not **submit supporting documentation** or **forgot to update the relevant data**, a **new change request** needs to be created in the system

- For new ORG/LOC – create new change request
- For updates – 1 change at a time – the first change request needs to be rejected, only after the user will be able to submit the new change request



**EMA
Data Steward**

Approves change request



Ensures the data is available
on SPOR and is showing the
correct information



Check the organisation and location
record on the OMS web portal -
<https://spor.ema.europa.eu/omswi/#/>



Requestor

Receives an approval message, with respective
OMS identifier

Organisation Details

Organisation ID:	ORG-10000761
Organisation Name:	Mylan EPD
Alternative Name:	FR - Mylan EPD SPRL NL - Mylan EPD BVBA
Status:	ACTIVE
Organisation Type:	Pharmaceutical company Industry

Location Details

Location ID:	LOC-100005386
Address:	EN Avenue Einstein 12 Wavre Brabant Wallon 1300 Belgium
GPS Location:	50.731294, 4.589287
xEVMPD Code:	ORG26239, ORG26239
EudraGMDP Number:	32796, 18278
Last Modified Date:	2019-03-27T12:49:37
Status:	ACTIVE

Organisation Details

Organisation ID:	ORG-10000761
Organisation Name:	Mylan EPD
Alternative Name:	FR - Mylan EPD SPRL NL - Mylan EPD BVBA
Status:	ACTIVE
Organisation Type:	Pharmaceutical company Industry

Location Details

Location ID:	LOC-100005386
Address:	FR Avenue Einstein 12 Wavre Brabant Wallon 1300 Belgique
GPS Location:	50.731294, 4.589287
xEVMPD Code:	ORG26239, ORG26239
EudraGMDP Number:	32796, 18278
Last Modified Date:	2019-03-27T12:49:37
Status:	ACTIVE



OMS Statistics

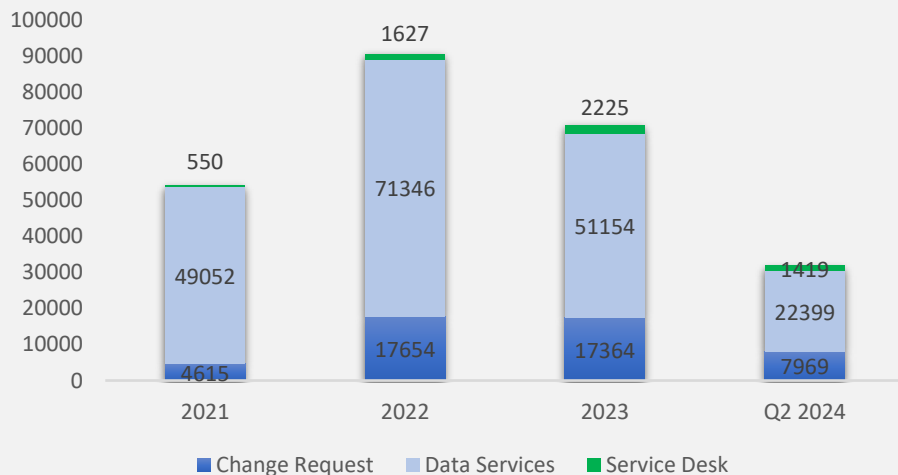


Service desk with a **slight increase** trend in 2024



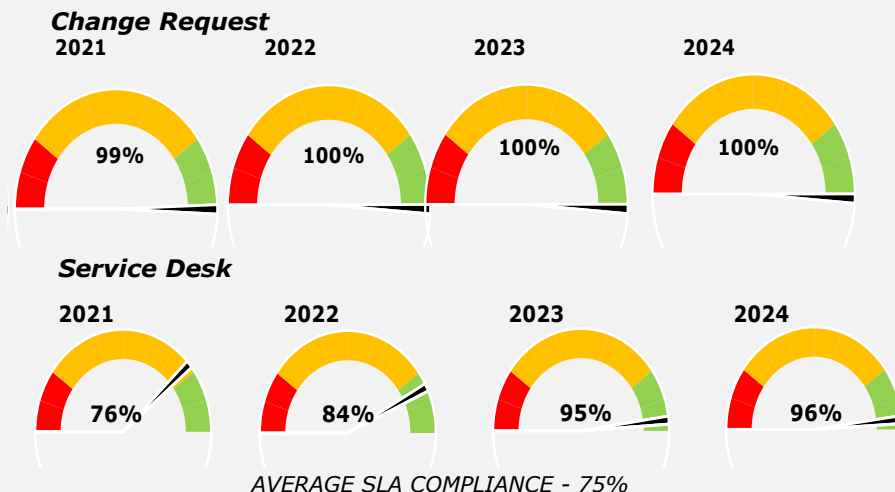
Despite the increase in **Service Desk**, **SLA compliance has improved**

OMS Activities



*up to Q2 2024 cumulative

Overall Compliance





OMS Documentation & help

SPOR portal

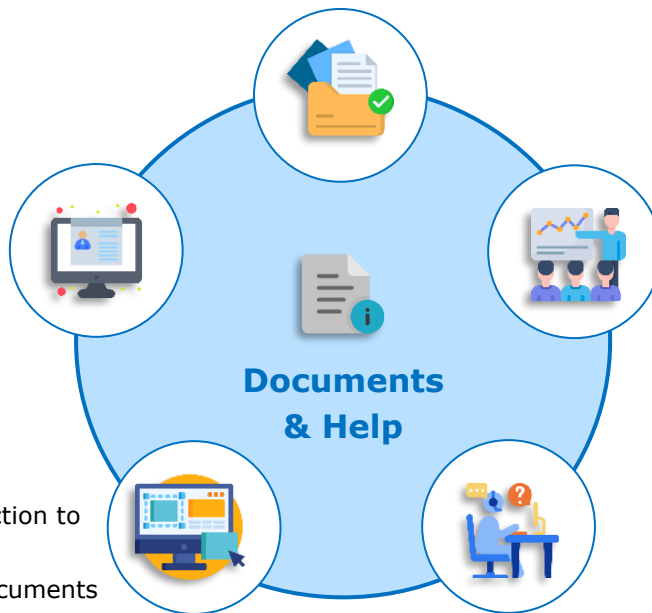
- OMS web user manual – guidance on SPOR services, e.g. searching, exporting data, requesting CRs
- SPOR user registration manual (how to register for SPOR)
- SPOR affiliation template (to register the first industry super user)
- Change Request Validation in OMS
- Organisation data quality standards in OMS
- SPOR SLAs (SLA are indicative and will be reviewed in future)
- OMS FAQs

EMA Account Management Portal

- Guidance on to obtain access to EMA systems (including SPOR)
- Create a new EMA account and request SPOR user role

EMA corporate website

- SPOR vision and general introduction to SPOR projects
- SPOR related information and documents



Training opportunities

- [@emainfo channel](#) contains Videos of SPOR webinars with tips/tricks and questions raised from users

EMA Service Desk

- For any help needed and not found in docs e.g
- Service requests, issues, requests for technical support can be submitted through the [ServiceNow Portal](#)



[OMS Web UI \(europa.eu\)](https://europa.eu)

OMS portal Documents:

- Link access to export the document
- Short description of document content
- Last update date

OMS service & Statistics & quick initiation guidance

Process guidance:
Operating Model; DQ standards used, system/ CR guidance

OMS in consuming systems

Performance: customer satisfaction surveys & SLAs

Registration process & templates

API access

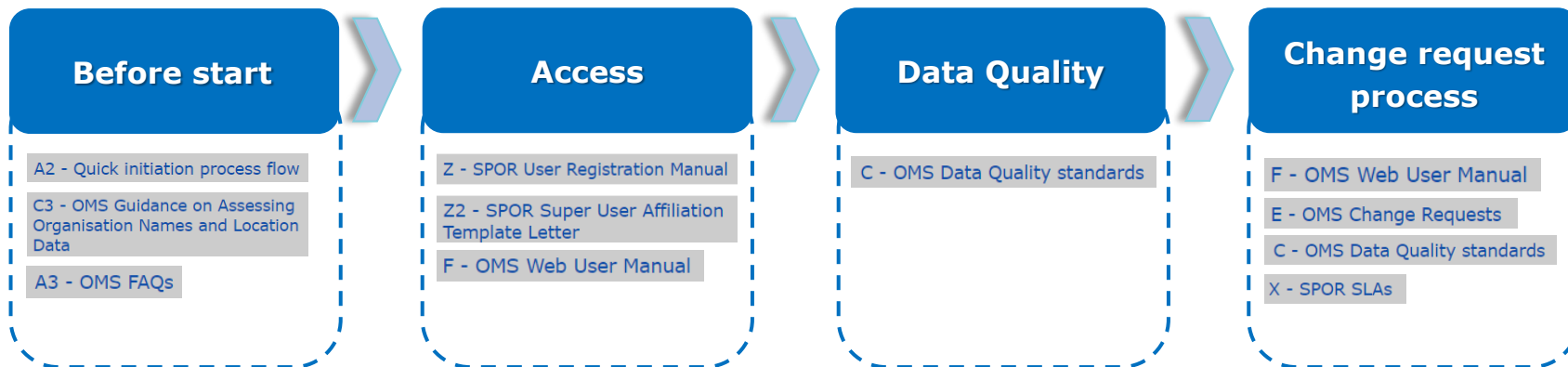
General	Technical
Document Name ▲	Document Description :
A - About OMS	General - Legal disclaimer, copyright and other policies of using Organisation and Location data.
A10 - SPOR Data Governance – SPOR Week 2 October 2023	Webinar - SPOR Data Governance
A11 – SPOR & XEVMPD Status Update 10 April 2024	Webinar - Recent & planned changes and impacts to users
A12 – SPOR & XEVMPD Status Update 10 July 2024	Webinar - Recent & planned changes and impacts to users
A2 - Quick initiation process flow	Guidance - Quick reference guidance for first time users: introduction, access and add/update records
A3 - OMS FAQs	Guidance - OMS Frequently Asked Questions
A5 - OMS News Items	NEWS - Recent changes implemented, open discussions, future discussions and upcoming functionalities
A9 - OMS Webinar – SPOR Week 4 October 2023	Webinar - OMS services, activities and statistics
B - OMS Operating Model	Policy - Range of services available for stakeholders to use and/or request new/updated data, including stakeholder interactions and roles.
C - OMS Data Quality standards	Guidance - Data quality standards applied in OMS
C3 - OMS Guidance on Assessing Organisation Names and Location Data	Guidance - When minor differences between organisation names and location data are acceptable
C4 - OMS Mapping Guidance	Guidance - Process for mapping and when to create an OMS change request
D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS
E - OMS Change Requests	Guidance - Rules and Supporting documentation required by change request type
F - OMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in OMS web Portal.
G1 - Q&A on eAF Mandatory use of OMS	Process - OMS mandatory for CAPs from November 1st onwards - Questions and Answers
H - Manufacturer organisations in the OMS dictionary	Process - Manufacturer organisation data lifecycle in the context of regulatory activities and who is responsible for registration/updating organisation data about manufacturers in the OMS.
I - Impacts of OMS merge on EMA systems	Guidance - Validation of OMS consuming system data after the merge takes place in OMS
J - CT registration Headed letter template	Template - For requesting the creation of sponsors
K - Individual registration Headed letter template	Template - For requesting the creation of Entrepreneurs
T - OMS Data Protection Notice	General - Explains essential details of the processing of personal data by OMS
U - About SPOR	General - Legal disclaimer, copyright and other policies of using SPOR data.
V - SPOR Questions & Answers	General - Compiled questions on a variety of topics, including user registration, industry on-boarding, and eAF integration.
V3 - RDM Customer Satisfaction Survey 2023	SPOR Customer Satisfaction Survey November 2023
X - SPOR SLAs	General - Service Level Agreement (SLAs) for the SPOR data services.
Z - SPOR User Registration Manual	Manual - How to register for EMA systems and request SPOR user roles.
Z2 - SPOR Super User Affiliation Template Letter	Template - For requesting the organisation's first SPOR Super User role.
Z3 - SPOR API Access - Q&A	Process - How to request access to SPOR API - Questions and Answers
Z4 - SPOR API Access - Webinar 10 November 2021	SPOR API Access - Webinar 10 November 2021
Z5 - EMA - API General Terms of Service - Terms of Use	EMA - API General Terms of Service - Terms of Use
Z6 - SPOR API Access Request Form	SPOR API Access Request Form
Z7 - SPOR API Access and Usage - Webinar 18 March 2022	Webinar - API Registration process and OMS/RMS API usage demo and tips
Z8 - Access to SPOR API – SPOR Week 20 April 2023	Webinar - API Registration process and OMS/RMS API usage demo and tips



[OMS Web UI \(europa.eu\)](http://europa.eu)



A5 - OMS News Items



Let's have a short break!





OMS in Projects/Systems



Legend

- Implemented
- Planned
- Not planned yet

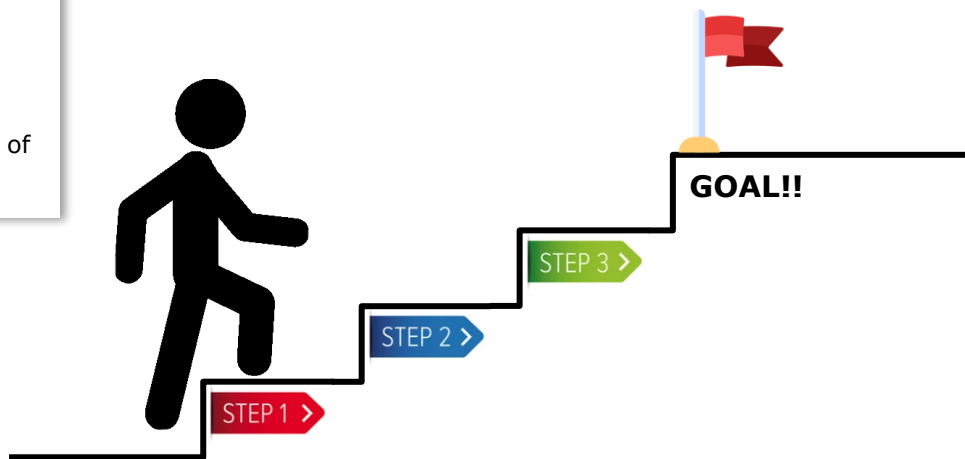
System	Domain	Process
EMA Account Management & EV registration	H&V	User registration, identity and access management
EudraCT & CTIS	H	Phase 1-4 Trials
IRIS	H&V – CAPs only	Scientific Advice + Orphan Designation + ITF + Marketing Status + Inspections + Parallel Distribution + Shortage (iSPOC) + PRIME
EAF (PDF) & eAF webform & PML Portal & PMS (just H)	H&V	Submission MAA, Variations, Renewal
SIAMED via ECD	H&V – CAPs only	Review, Approval
UPD	V	Approval
EudraGMDP	H&V	Inspections + Manufacturing Import Authorisation + Wholesale Distribution Authorisation
XEVMPD & EV vet	H&V	Safety reporting

1

Organisation ID	Organisation Name ▲	Country †	Location ID †	City †	Address	Postcode †	Location status †
ORG-100000375	Rosemont Pharmaceuticals Limited	United Kingdom	LOC-100000383	Leeds	Rosemont House	LS11 9XE	ACTIVE

Ensure (MAH) **organisation and location** details are **available** and **Active in OMS**

details are created in OMS as per OMS Data quality standards i.e. details may not be a copy of supporting documentation nor XEVMPD data



If **organisation and locations** details are **NOT** available in OMS:

- access to many EU systems such as PLM Portal and **PMS cannot be requested**
- **eAF** (webform) **cannot be submitted**

2

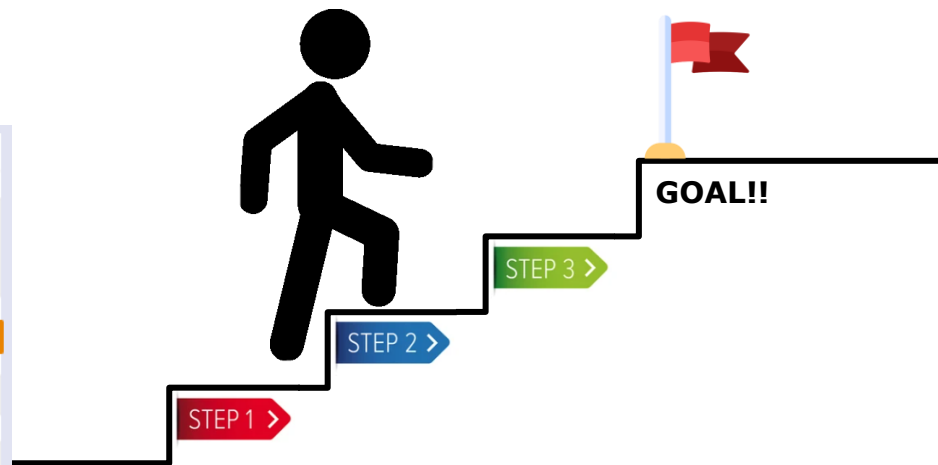
Ensure XEVMPD-OMS data **mappings are correct in OMS**

Any **Valid** XEVMPD code needs to be available under the correct Loc ID.

XEVMPD code will only be deleted from OMS when it has been Nullified in XEVMPD

XEVMPD	
MAHs	<ul style="list-style-type: none">ORG42369 - ROSEMONT PHARMACEUTICALS LIMITEDORG1689 - ROSEMONT PHARMACEUTICALS LTDORG14923 - ROSEMONT PHARMACEUTICALS LTDORG14928 - ROSEMONT PHARMACEUTICALS LIMITED
Sponsors	<ul style="list-style-type: none">ORG3147 - ROSEMONT PHARMACEUTICALSORG1690 - ROSEMONT PHARMACEUTICALS LTD

Location Details		OMS
Location ID:	LOC-100000383	
Address:	Rosemont House Yorkdale Industrial Park Braithwaite Street Leeds LS11 9XE United Kingdom	
GPS Location:	53.788549, -1.562502	
xEVMPD Code:	ORG3147, ORG42369, ORG1689, ORG1690, ORG14923, ORG14928	
EudraGMDP Number:	6723, 6846	
National Business Registry number:	00924648	
Last Modified Date:	2024-02-06T10:34:22	
Status:	ACTIVE	



If **mapping doesn't exist** in OMS, **products will not be visible in PMS!**

- Any mapping issue, report through OMS Service Desk [question](#) (with Service: SPOR + Service Offering: OMS)
- If mappings are correct and you still experience issues accessing product data in PLM, please submit a '[Report an Issue](#)' (with Service: PLM Portal + Service Offering: PMS Product Data)

3

When requesting any role in **EMA Account Management** ensure the **same LOC ID**, with XEVMPD-OMS mapping, is used

01 Search Criteria | 02 Select Organisations | 03 Select Roles | 04 Additional Info | 05 Request Submitted

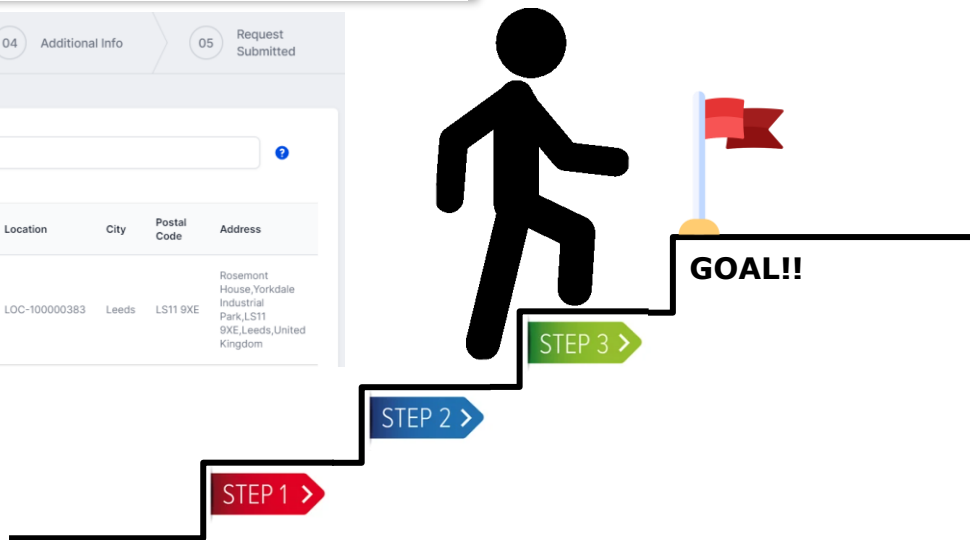
Selected Organisations

Organisations

Search

1 results

Id	Name	Country	Location	City	Postal Code	Address
<input type="checkbox"/> ORG-100000375	Rosemont Pharmaceuticals Limited	United Kingdom	LOC-100000383	Leeds	LS11 9XE	Rosemont House, Yorkdale Industrial Park, LS11 9XE, Leeds, United Kingdom



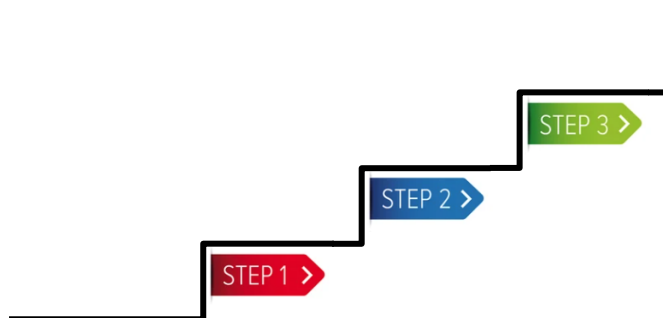
If **different Loc ID** is used when requesting the **EMA Account Management** role, **products** will not be visible in eAF/PML portal & PMS



Access to PLM Portal and PMS product(s) is managed by **EV code mapping in OMS**



GOAL!!



IMPORTANT!

OMS Loc ID = MAH EV code in the mapping under OMS Loc ID = OMS Loc ID used in IAM

LOC-100000383

ORG42369,

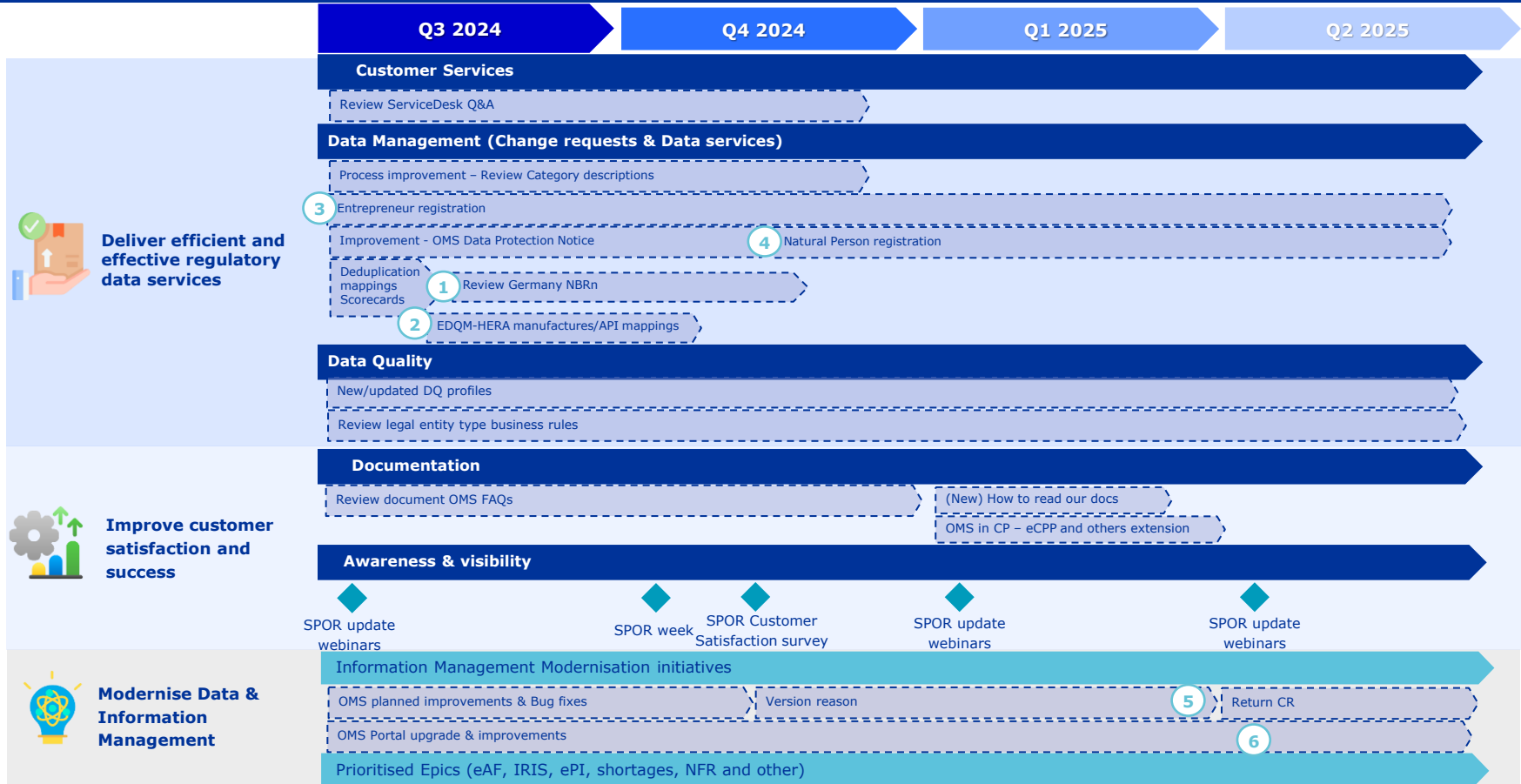
LOC-100000383

LOC-100000383

MAH EV code must correspond to the same OMS Loc ID that users are affiliated to - if not, users will have issues to access PLM portal and seeing relevant products!!



OMS Status update



Work ongoing or completed – Highlights of what has been started in the last quarter



EUROPEAN MEDICINES AGENCY



WHY



HOW & WHEN



IMPACT/ BENEFITS to users

Review Germany NBRn

- 1 "False duplicates" found with the recently created Scorecard for Mapping Deduplication i.e. different district courts/registration offices can use the same National Business Registry number

Need to **enrich** National Business Registry number, captured in OMS, for Germany companies **with place of district court/registration offices** registered in, i.e.

Name	Mapping Code
Sirio Pharma Germany GmbH	HRB 11869 Neuruppin
SKW Stickstoffwerke Piesteritz GmbH	HRB 11869 Stendal

- Q3 – enrichment of "false duplicates"
- Q3/Q4 – enrichment of all German legal addresses, total ~5130 records

Ensure clear identification of official legal address of a certain organisation/legal entity

EDQM-HERA manufactures/API mappings

- 2 HMA Post marketing Risk assessment tool to be enriched with OMS Loc Identifier to expedite communication of surveillance results with Network members that use OMS on a mandatory bases

OMS to map API and finished product manufacturers that are currently in MRP/DCP/API database

- Q3 – manufactures mapping
- Q3/Q4 – API mapping

All API and finished product manufacturers are mapped across OMS and HMA database and available in OMS for use in regulatory procedures

Entrepreneur registration

- 3 Whilst a long-term solution is under assessment, certain **registered Entrepreneurs** need to be added to OMS to be able to proceed with veterinary procedures in UPD, EudraGMDP certificates and EV MAH obligations

- OMS will register **Individuals/Entrepreneurs** not registered with official National Business Registry but **registered in the publicly available official Entrepreneur database*** of each country
- The sources* used are published in the OMS Data Quality Standards, other possible sources should be requested/reported via ServiceNow
- **Individuals/Entrepreneurs** will be registered in OMS with two categories:
 - Industry/Pharmaceutical company – to ensure downstream systems can use them
 - Individual/Entrepreneur (NEW)

Organisation Type:	Industry
	Pharmaceutical company
	Individual
	Entrepreneur

We don't expect more users/Entrepreneurs to register in OMS!

This leads to less CR rejections -> requests for UPD/EudraGMDP/EV MAH



WHY



HOW & WHEN



IMPACT/ BENEFITS to users

4

Natural Person registration

Whilst a long-term solution is under assessment, **certain Natural Persons need to be added to OMS** to be able to proceed with veterinary procedures in UPD, EudraGMDP certificates and EV MAH obligations

- OMS will register **Individuals/Natural Persons** for which there is a **legal justification** and are **not registered with National Business Registry**
- OMS Data Protection Notice (OMS DPN) provides **clear information** on:
 - Justification for inclusion in OMS
 - How data will be processed
- **Individuals/Natural Persons** will be registered in OMS with two categories:
 - Industry/Pharmaceutical company – to ensure downstream systems can use them
 - Individual/Natural Person (NEW)

We don't expect more users/Entrepreneurs to register in OMS!

This leads to less CR rejections -> requests for UPD/EudraGMDP/EV MAH

5

Version reason

Transparency on OMS changes and the reason for new versions of organisations/locations

For each new version OMS will maintain 2 fields:

- **Version type** – standard RMS terms eg **Location standardisation or business merge**
- **Version comment** – further details on reason/outcome eg what changed or which ID will prevail in the merge

- Possibility to query OMS API to determine complex data changes eg merges
- **Clearer reason for creation of new version**, e.g.
 - Version type: Location standardisation + Comment: what changed
 - Version type: Business merge + Comments: which ID will become the master/prevail

6

OMS Portal upgrade & improvements

OMS Portal technology (AngularJS) support is ending

- Refactoring the OMS Portal/WebUI from **AngularJS** to the latest **Angular version**
- Q3 – Implementation in UAT
 - Q4/Q1 – Implementation in Production

- Improve user experience
- Increase security and performance by using the latest technical version available

Whenever OMS records change, each version/timestamp will have written reason

Version code ¹

- RMS term identifier

Version type ²

- Standardised RMS term*
 - High level action i.e. Add vs Update
 - Applicable changes i.e. Change at mapping level

Version comment ³

- Free text with relevant details
 - Origin of change i.e. ETL vs CR
 - Applicable changes i.e. Add EV code

	A	C	D	P	Q	U	V ¹	W ²	X ³
	Organisation ID	Version Timestamp From	Version Timestamp To	Status	Name	Location ID	Organisation Version Type Code	Organisation Version Type Name	Organisation Version Comment
1	ORG-100002468	2025-10-11T04:42:33.896+01:00		ACTIVE	Viatris UK Healthcare Limited	LOC-100008397;LCC	20000104400615	Validation check	Organisation valid as off time stamp date
3	ORG-100002468	2023-09-25T13:48:27+02:00	2025-10-11T04:42:34+01:00	ACTIVE	Viatris UK Healthcare Limited	LOC-100008397;LCC	20000104400609	Standardisation update	Organisation name standardisation – CR process
4	ORG-100002468	2022-04-06T11:25:00+02:00	2023-03-31T11:13:14+02:00	ACTIVE	VIATRIS UK Healthcare Limited	LOC-100008397;LCC	20000104400602	Name change	Name change in NBR - ETL process
5	ORG-100002468	2018-12-01T07:20:18+01:00	2022-04-06T11:25:00+02:00	ACTIVE	Mylan UK Healthcare Limited	LOC-100008397;LCC	20000104400602	Name change	Name change in NBR - CR process
6	ORG-100002468	2017-02-05T11:44:17+01:00	2018-12-01T07:20:18+01:00	ACTIVE	BGP Products Limited	LOC-100008397;LCC	20000104400601	New organisation	New organisation - ETL process

	A	B	C	D	G	Q	V ¹	W ²	X ³
	Organisation ID	Current Version	Version Timestamp From	Version Timestamp To	Identifier Code	Name	Organisation Version Type Code	Organisation Version Type Name	Organisation Version Comment
1	ORG-100002342	Y	2024-10-01T12:28:38.523+02:00		ORG-100005743; ORG-100008904; ORG-100002342	Orifarm Generics A/S	20000104400620	Business merge	Orifarm acquired Copyfarm A/S, main Org ID is ORG-100002342
3	ORG-100002342	N	2024-03-06T06:28:38+01:00	2024-10-01T12:28:39+02:00	ORG-100005743; ORG-100008904;	Orifarm Generics A/S	20000104400621	Deduplication	Main Org ID is ORG-100005743
4	ORG-100002342	N	2017-11-29T15:48:48+01:00	2024-03-06T06:28:38+01:00	ORG-100005743;ORG-	Orifarm Generics A/S			
5	ORG-100002342	N	2017-11-29T15:45:46+01:00	2017-11-29T15:48:48+01:00	ORG-100005743;ORG-	Orifarm Generics A/S			

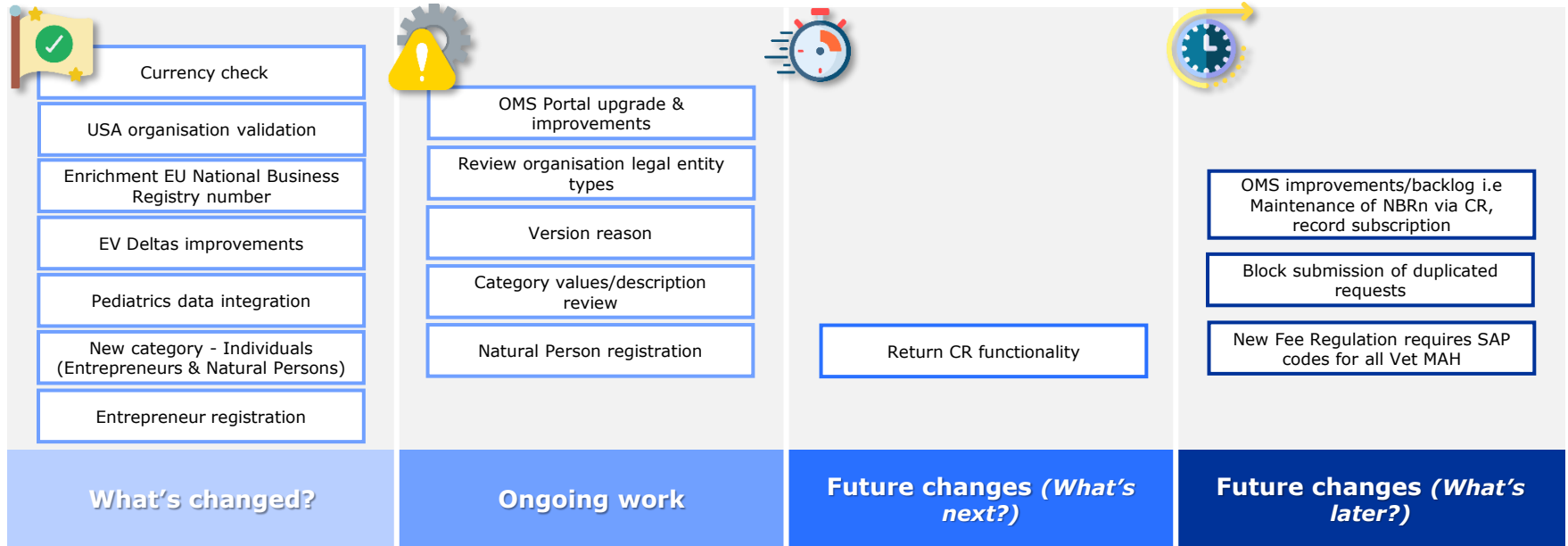
*Standardise list currently being developed in consultation with KUG and internal systems

Versioning information is visible via **OMS export** and **OMS API** - currently in UAT

Old versions will not have version reason!!
OMS team will **include version** information to any record added/updated **after implementation**

Transparency and to **support** with **complex data changes** (merges)

Improvements are planned on **OMS export** and **OMS API** to ensure all previous versions are available and clear for non-surviving records after merge



Acronyms

EV: EudraVigilance

CR: Change Request

NBRn: National Business Registries number

SAP: Statutory Accounting Principles

MAH: Marketing Authorisation Holder



Key takeaways and conclusions



Increase Awareness of OMS activities

- *Provided background information: introduction to OMS, OMS processes*
- *Provided key updates: revised statistics, integration in PMS*



Share **recent and planned activities**

- *News: **EV Deltas improvements**, **Entrepreneurs registration***
- *Planned: **Natural person registration**, **Version reason**, **OMS Portal upgrade & improvements***



Show how OMS is addressing **customer feedback**

- *Continue to improve **OMS Data Quality** – **review of OMS categories***
- *OMS **registration process** improvement – allow **Entrepreneurs registration***
- *OMS **ServiceNow** knowledge articles review – **simplify user experience***





Any questions on the webinar?



During **SPOR webinars**, EMA's Regulatory Data Management Service team talks about all aspects of regulatory data management and how it works today.

 Webinar title	 Date	 Time
SPOR Data Governance	4 October 2024	10:00-12:00 CEST
Referentials Management Service (RMS)	7 October 2024	10:00-12:00 CEST
Substance Management Service (SMS)	8 October 2024	10:00-12:00 CEST
Organisation Management Service (OMS)	9 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for MAH	10 October 2024	10:00-12:00 CEST
Product Management Service (XEVMPD) for Sponsors	11 October 2024	10:00-12:00 CEST
Substance, product, organisation and referential (SPOR) application programming interface (API) - SPOR API	14 October 2024	10:00-12:00 CEST



Further information

Contact us through ServiceNow @ <https://support.ema.europa.eu/>

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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

Follow us on  **@EMA_News**



Glossary



Acronym	Name
API	Application Programming Interface
Art. 57	Article 57 of Regulation (EU) 726/2004, which requires marketing authorisation holders to electronically submit to the Agency information on all medicinal products for human use authorised in the EU
CAP	Centrally Authorised Product
CR	Change request
CTIS	Clinical Trials Information System
DADI	Digital Application Dataset Integration
DMP	Development Medicinal Product
DCP	De-centralised Procedure
DQ	Data Quality
eAF	Electronic Application Form
ePI	Electronic Product Information
eCTD	Common Technical Document in electronic format
EMA DB	European Medicines Agency Data Board
EMRN	European Medicines Regulatory Network
Epic	<p>An epic is a container with one common objective, for a development initiative large enough to require analysis, definition of a minimal viable product (MVP) and financial approval before implementation. An epic usually takes more than one Programme Increment to complete and is broken into multiple Features.</p> <p>Business epics are large initiatives that deliver Solutions needed by the business/customers</p> <p>Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream</p>



Acronym	Name
ESMP	European Medicines Shortages Monitoring Platform
ESMDP	European Medicinal Devices Shortages Monitoring Platform
EURS	European Review System for eCTDs
EU-SRS	European Substance Reference System
EUTCT	European Union Telematics Controlled Terms
FHIR	Fast Healthcare Interoperability Resources
HMA	Heads of Medicines Agencies
IAM	Identity and Access Management
ICSR	Individual Case Safety Report
IDMP	The ISO IDMP standards specify the use of standardised definitions for the identification and description of medicinal products for human use
INN	International Nonproprietary Names
IRIS	A secure online platform for handling product-related scientific and regulatory procedures with EMA (iris.ema.europa.eu)
KUG	Key User Group
KPI	Key Performance Indicator
MAA	Marketing Authorisation Application
MAH	Marketing Authorisation Holder
Mon	Monitoring Value Stream



Acronym	Name
MRP	Mutual Recognition Procedure
NAP	Nationally Authorised Product
NCA	National Competent Authority
NDB	Network Data Board
NICTAC	Network ICT Advisory Committee represents the network IT community
NPAG	Network Portfolio Advisory Group represents the Management Board and HMAs
OD	Orphan Designation
OMS	Organisation Management Service
PB	Portfolio Board
PI	Programme Increment, a three month period of work
PI Planning ceremony	A quarterly event to plan work for the entire Value Stream in the next quarter, ensuring that teams and stakeholders have a shared mission and vision
PIP	Paediatric Investigation Plan
PLM	Product Lifecycle Management Value Stream
PMS	Product (Data) Management Service
PO	Product Owner (PO) is the Agile team member primarily responsible for maximizing the value delivered by the team by ensuring that the team backlog is aligned with customer and stakeholder needs.
RMS	Referential Management Service
R&D	Research and Development Value Stream



Acronym	Name
SAFe	Scaled Agile Framework
SIAMED	An Information System for the management of regulatory procedure for centrally authorised products
SLA	Service Level Agreement
SPOR	Substance, Product, Organisation and Referential
SmPC	Summary of product characteristics
SMS	Substance Management Service
SQI	Service Quality Indicator (metric)
SVG	Substance Validation Group
UNII	Unique Ingredient Identifier
USAN	United States Adopted Names
Value Stream	Value Streams represent the series of steps that an organization uses to implement Solutions that provide a continuous flow of value to the Business/Customer
VSM	EMA Value Stream Manager (VSM) is a "Servant Leader and Coach" for the Value Stream teams
VSO	EMA Value Stream Owner (VSO) has the primary responsibility for the business outcomes, including the delivery of business outcomes, in their Value Stream
XEVMPD	eXtended EudraVigilance Medicinal Product Dictionary