Housekeeping notes – Personal data protection notice

*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.*

For Questions: www.slido.com code: #1314375

Housekeeping notes – Q&A

Join at
slido.com
#1314 375

- 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.

1 For Questions: www.slido.com code: #1314375

Webinar materials sharing

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

*If you would like to **receive recordings and presentations via email**, please register your e-mail address in Slido (www.slido.com) using the **event code #5864645.***

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Organisation Management Service (OMS)

4 October 2023, 10:00 – 12:00 Central European Summer Time (CEST)

Presented by Débora Martins Braga

SPOR Webinar Series – 2-12 October 2023

H2 2023 SPOR Webinars

EUROPEAN MEDICINES AGENCY

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 and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST

For Questions: www.slido.com code: #1314375

Goals of the session

Increase Awareness of OMS activities

Share planned activities

Show how OMS is addressing customer feedback

For Questions: www.slido.com code: #1314375

Agenda

EUROPEAN MEDICINES AGENCY

1. **Welcome**
   10:00 – 10:05
2. **Introduction to OMS**
3. **OMS processes: Data Stewardship**
4. **OMS Change request process**
5. **OMS Data Quality Management**
6. **OMS Statistics**
7. **OMS Documentation & Help**
8. **OMS in Projects/Systems**
9. **What's new in OMS** NEW
10. **Planned OMS Activities** NEW
11. **Key takeaways & Conclusions**
12. **Q&A Session**
    11:45 – 12:00

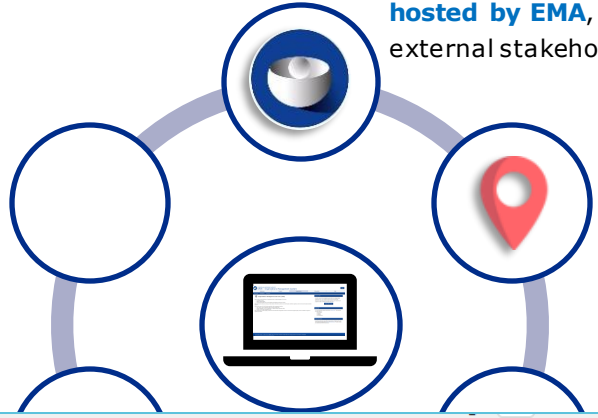
 For Questions: www.slido.com code: #1314375

Introduction to OMS

 For Questions: www.slido.com code: #1314375

OMS Introduction - Key Principles (1/4)

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

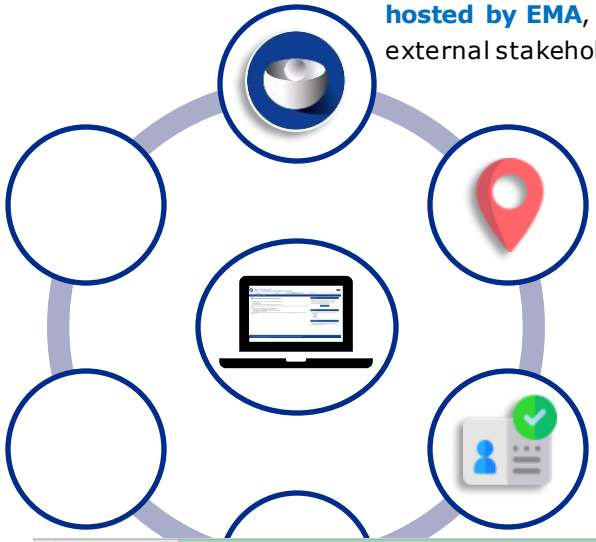
Organisation ID:	ORG-100032140
Organisation Name:	Opella Healthcare Belgium
Alternative Name:	EN - N.V. Opella Healthcare Belgium S.A. EN - Opella Healthcare Belgium Trading As Sanofi Belgium FR - Opella Healthcare Belgium S.A. NL - Opella Healthcare Belgium N.V.

For Questions: www.slido.com code: #1314375

OMS Introduction - Key Principles (2/4)

EUROPEAN MEDICINES AGENCY

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	Löffelweg	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 Schaftenau / 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

For Questions: www.slido.com code: #1314375

OMS Introduction - Key Principles (3/4)

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-100000789	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	

For Questions: www.slido.com code: #1314375

OMS Introduction - Key Principles (4/4)

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

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

An **organisation**, as a legal entity, groups all its physical locations within a **country**

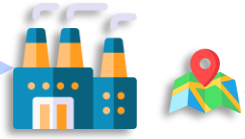
Roles (MAH vs Manufacture), **context** (H vs V) and details of **Departments are not managed in OMS**

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

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)

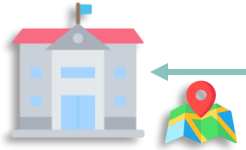
The **Location_ID** will be unique and will **not change**

Who can change OMS data?



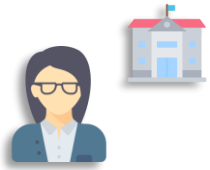
Manufactures

MAH, Sponsor
NCA



Hospitals, University

SPOR NCA/Industry
Super User



SPOR NCA/Industry
User

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 Introduction – Data vs Reference Sources

EUROPEAN MEDICINES AGENCY

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**:

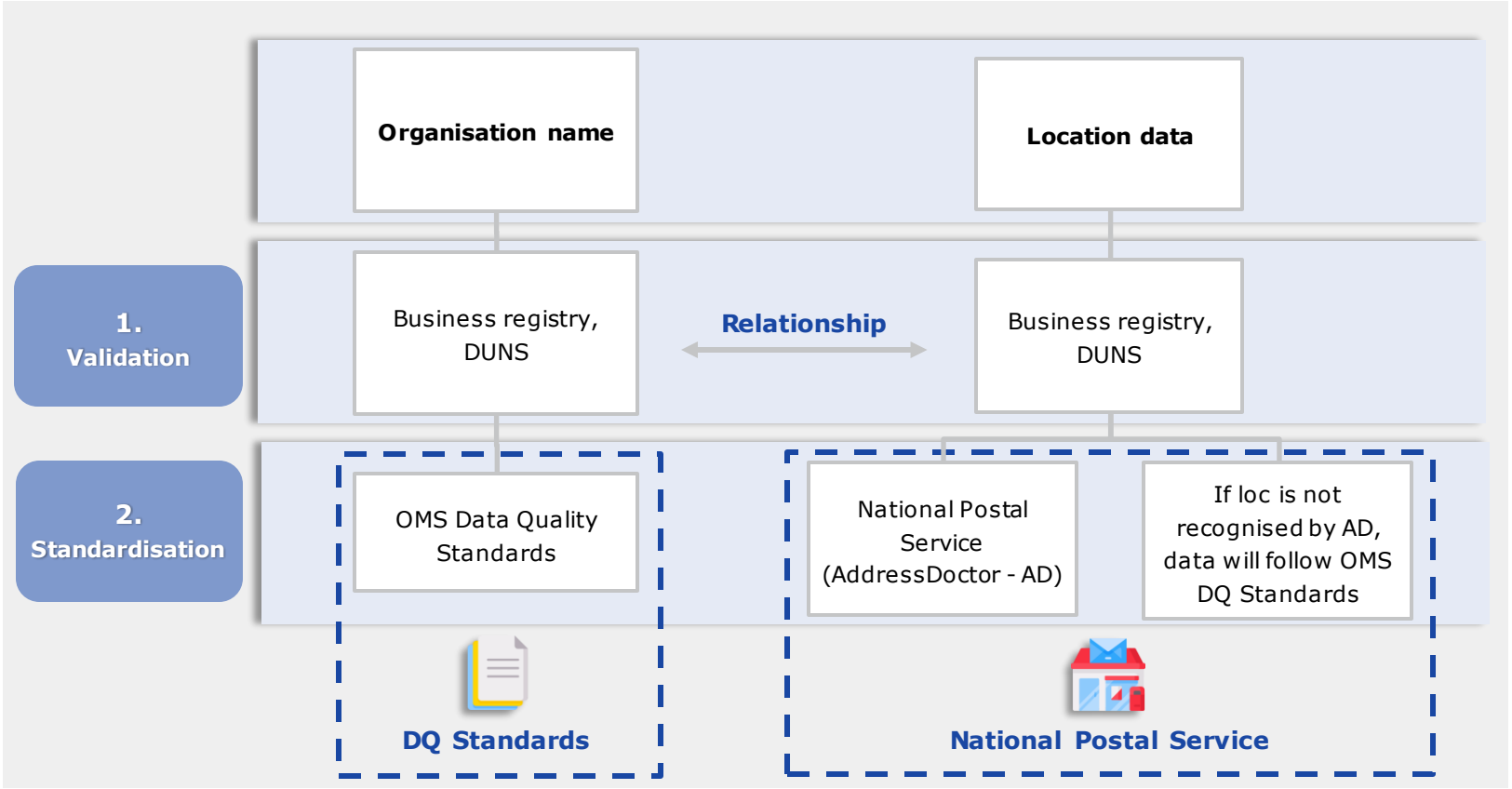
- correct organisation/ legal entity
- correct relationship with its address
- correct address

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 DQ rules

For Questions: www.slido.com code: #1314375

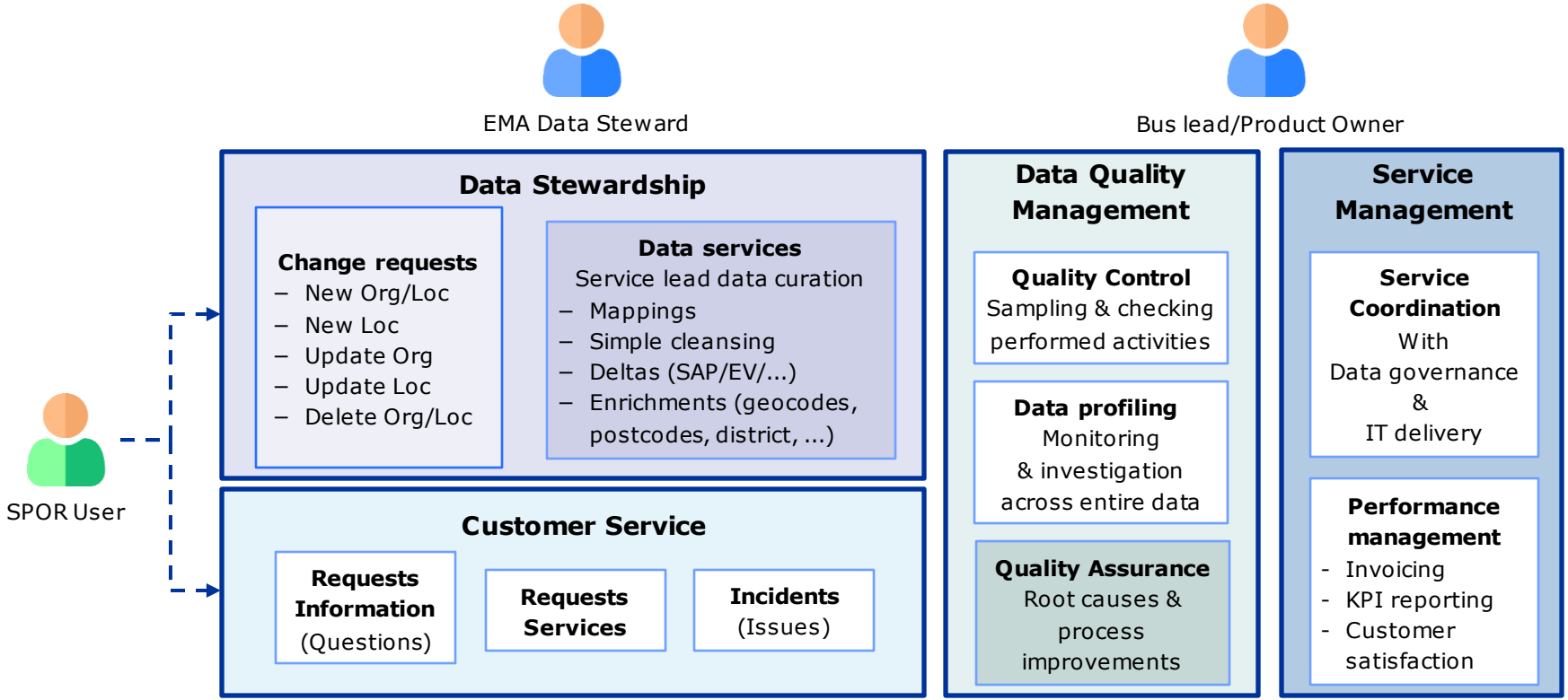
OMS Introduction – Data & Data Management Process



 For Questions: www.slido.com code: #1314375

OMS processes: Data Stewardship

SPOR Data Management Processes



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

For Questions: www.slido.com code: #1314375

OMS Change Request process

OMS Change Request process at a glance

EUROPEAN MEDICINES AGENCY

Submission → **Validation/ Standardisation** → **Approval/ Rejection**

Requestor

Submit OMS CR with **supporting document**

EMA Data Stewards

Guidance/ references & tools

Data Stewards validate all OMS CRs using guidance/ references & tools (OMS DQ standard, Business registry, AddressDoctor validation service)

EMA Data Stewards
EMA is OMS Data Owner

- 5-10 WD SLA
- CR **Approved** or **Rejected**
- If disagreement, raise ticket in Service Desk, indicating CR number

Organisation data owner
EMA

For Questions: www.slido.com code: #1314375

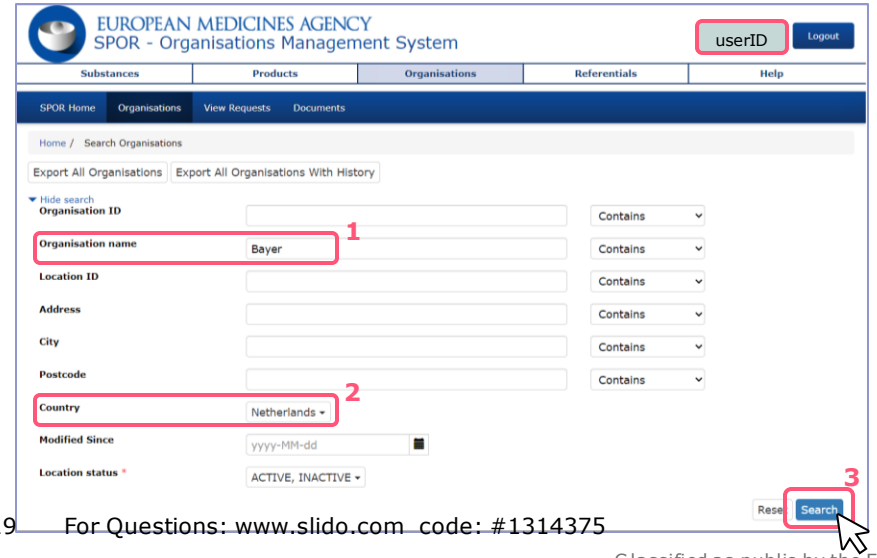
Change Requests Submission (1/4)

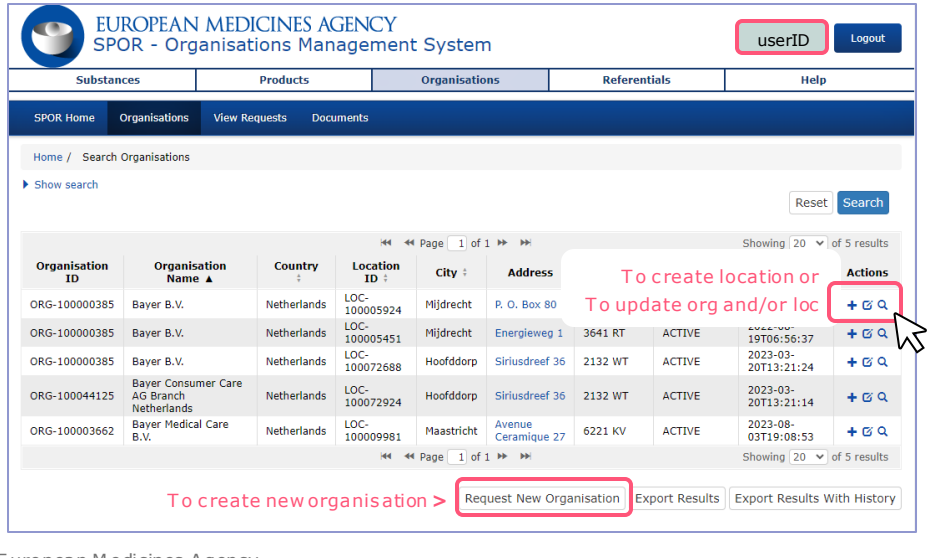
EUROPEAN MEDICINES AGENCY

Login

Requestor

Query OMS





For Questions: www.slido.com code: #1314375

Change Requests Submission (2/4)

EUROPEAN MEDICINES AGENCY

Create Organisation

Requestor

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

userID | Logout

Substances | Products | Organisations | Referentials | Help

SPOR Home | Organisations | View Requests | Documents

Home / Search Organisations / New Organisation Request

CR Information

CR Type: New Organisation

Request Reason*: Create a new organisation - as new legal entity

1. Select Create new organisation from the dropdown list

Justification

Requestor

Contact email*

Contact Phone

user information

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

Attachments: No documents found, click to add +

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

Audit trail

Date ▲	Status to	Comment
No data available in table		

Organisation Details

Organisation Name*: Bayer Netherlands B.V.

3. Organisation name as registered in the National Business Registry

Acronym

Organisation Type*: Industry

4. Select from the dropdown list the category type that best describe organisation main activity

Location Details

Address*: Siriusdreef 36

e.g. Canary Wharf

City*: Hoofddorp

Postcode: 2132 WT

County: e.g. London

Country*: Netherlands

5. Location details to be populated in the respective fields

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

Location Phone (1): Intl Code: e.g. +44 | e.g. 02036606000 | Ext:

6. Optional – communication details should NOT be private, use a company functional email and general phone number

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

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)

Cancel | Submit

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**

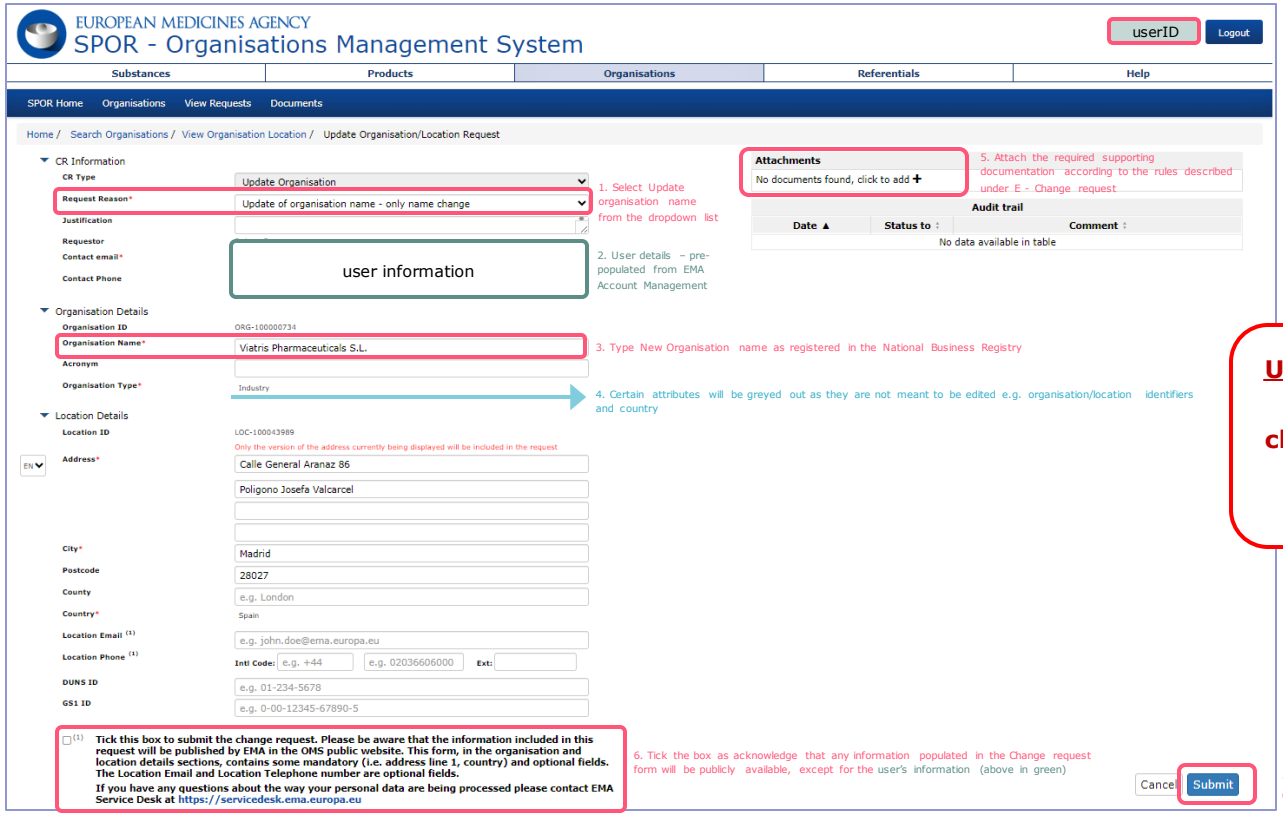
For Questions: www.slido.com code: #1314375

Change Requests Submission (3/4)

EUROPEAN MEDICINES AGENCY

Update Organisation name

Requestor



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

For Questions: www.slido.com code: #1314375

Change Requests Submission (4/4)

EUROPEAN MEDICINES AGENCY

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.

1. Select Deactivate Location from the dropdown list

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

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 to	Comment
No data available in table		

Requestor

Contact email*

Contact Phone

user information

Organisation Details

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

Organisation ID: ORG-100005535

Organisation Name*: GlaxoSmithKline Research & Development Limited

Acronym:

Organisation Type*: Industry

Location Details

Location ID: LOC-100002256

Only the version of the address currently being displayed will be included in the request

Address*: GSK House; 980 Great West Road

City*: Brentford

Postcode: TW8 9GS

County: Middlesex

Country*: United Kingdom

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

Location Phone (1): Intl Code: e.g. +44 | e.g. 02036606000 | Ext:

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

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

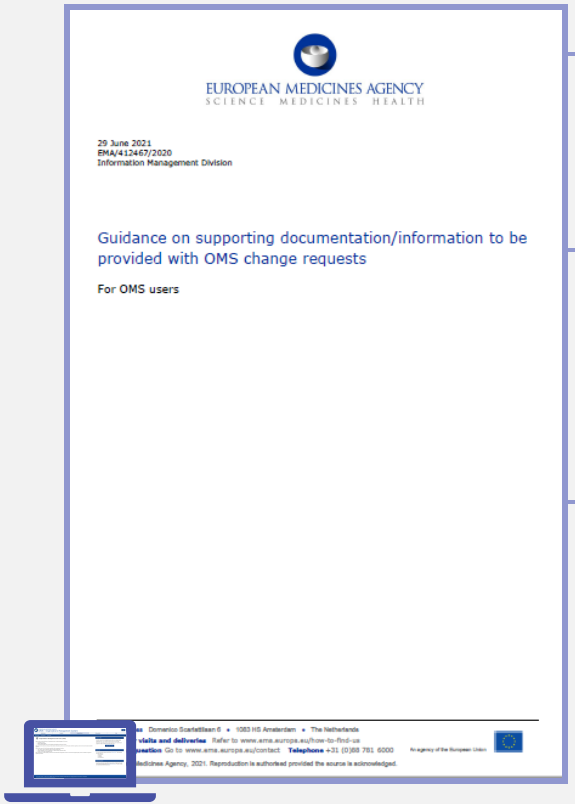
5. Click Submit, note that the information will not be made available immediately, Change request needs to be reviewed/validated by EMA Data Steward

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

For Questions: www.slido.com code: #1314375

Supporting documentation for Change Requests

EUROPEAN MEDICINES AGENCY


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 June 2021
EMA/412467/2020
Information Management Division

Guidance on supporting documentation/information to be provided with OMS change requests

For OMS users

EEA organisation

1. Extract from the National Business Registry

Hospital, University & Public entities

1. Headed letter with organisation and location details – signed and dated
2. GMP certificates until January 28th 2022 – hereafter EudraGMDP will use OMS data

Non-EEA organisation

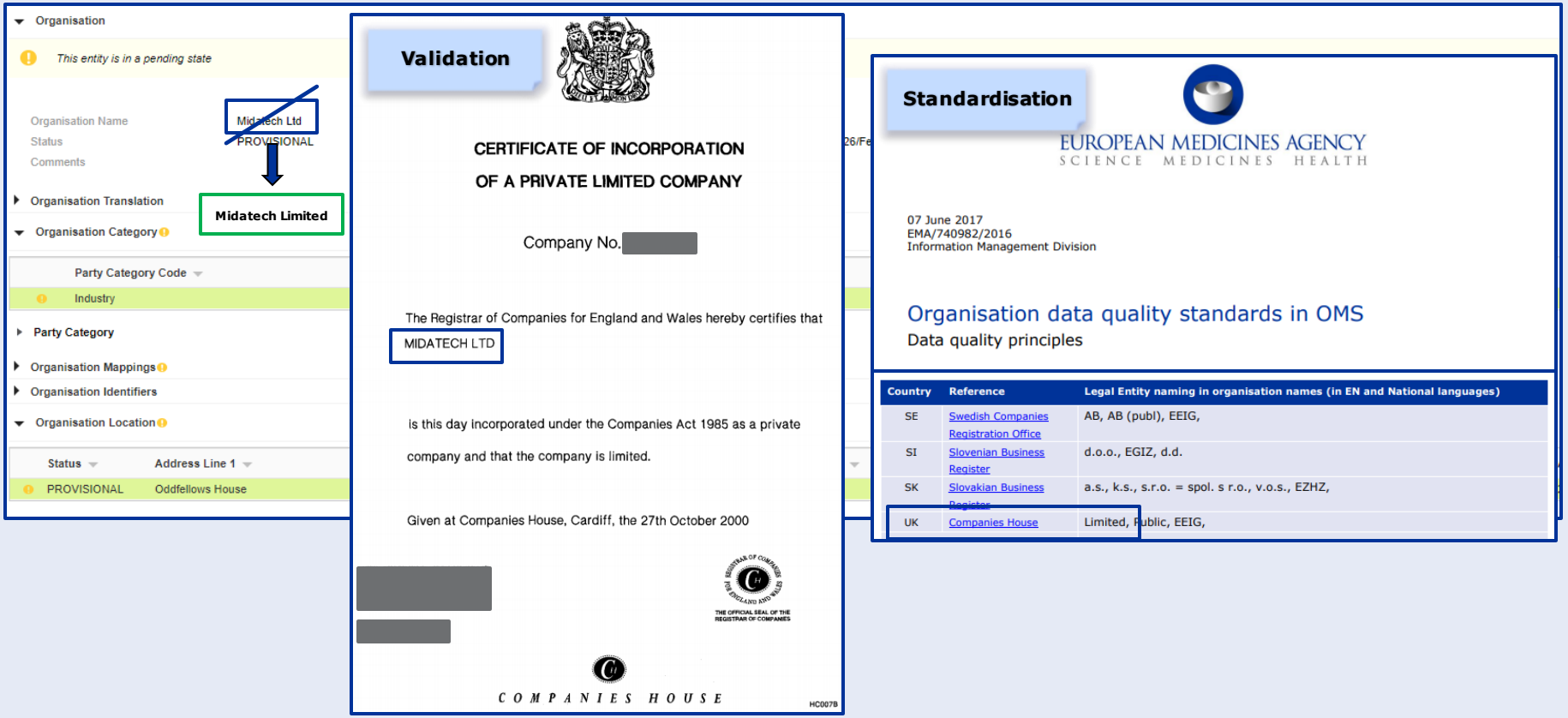
1. Document stating the DUNS or GS1 identifier number
2. Extract from the National Business Registry
3. GMP certificates until January 28th 2022 – hereafter EudraGMDP will use OMS data
4. Headed letter with organisation and location details – signed and dated

*The numbering indicates the order of documentation preference for each organisation/jurisdiction

For Questions: www.slido.com code: #1314375

OMS IDD - Change Request Process Organisation validation & standardisation

EUROPEAN MEDICINES AGENCY



 For Questions: www.slido.com code: #1314375

OMS IDD - Change Request Process Location validation & standardisation

EUROPEAN MEDICINES AGENCY

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

Validation

Brønnøysundregistrene — Firmaattest

Organisasjonsnummer: [redacted]
Organisasjonsform: [redacted] Under avvikling
Stiftelsesdato: [redacted]
Registrert i Foretaksregisteret: [redacted]
Foretaksnavn: [redacted]
Forretningsadresse: c/o TheVIT AS
Gunnar Randers' vei 24
2007 KJELLER
3030 LILLESTRØM
Norge
Kommune:
Land:

Standardisation

Organisation Location

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

For Questions: www.slido.com code: #1314375

OMS IDD - Change Request Process

Rejected change requests:

- *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

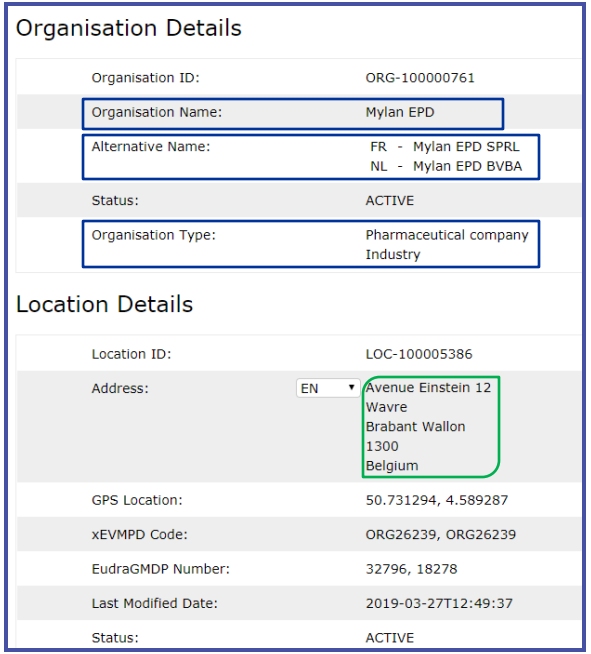
OMS IDD - Change Request Process

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/#/

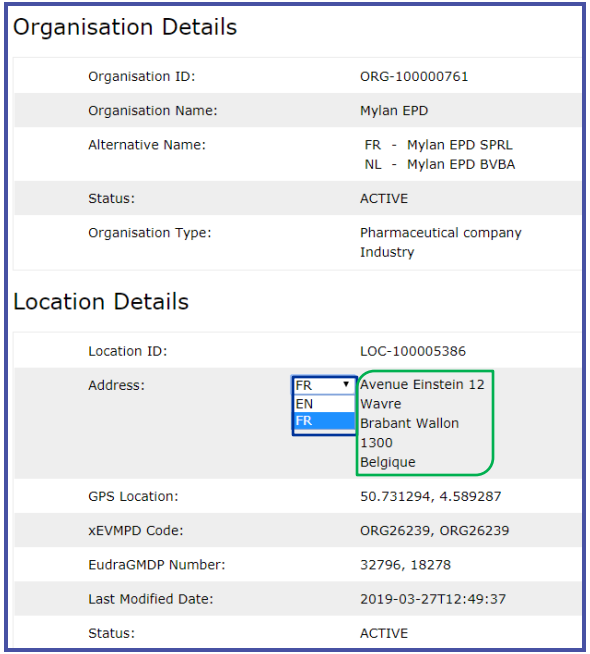


Organisation Details

Organisation ID:	ORG-100000761
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-100000761
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 EN 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 Data Quality Management

 For Questions: www.slido.com code: #1314375

SPOR Data Quality Management at a glance

EUROPEAN MEDICINES AGENCY

Data services
Identified defects/errors are corrected in OMS

Proactive

Quality Assurance

- Root causes are analysed and where possible preventive actions are identified/ implemented
- Process improvements

Activity Monitoring

Data mgmt Task

Quality Control

- Tasks are routinely sampled (~20%) and inspected to detect errors
- Sampled tasks are re-inspected by EMA to calibrate QC results

Data Monitoring

Data

Data Profiling

- Profiles are built to identify data not meeting the DQ rules
- KPIs are developed

Reactive

Customer Services

DQ Defects

- Defects/errors are classified into **Major/Minor**

Issues

- Issues reported to Service Desk on DQ of Orgs/Locs

Data Quality is ACCEPTABLE if:

<5% major errors (duplicates, incorrect approval/rejection incorrect merges)

AND

<10% minor errors (inconsistent details)

For Questions: www.slido.com code: #1314375

OMS Data Quality Management

EUROPEAN MEDICINES AGENCY

Data Based monitoring

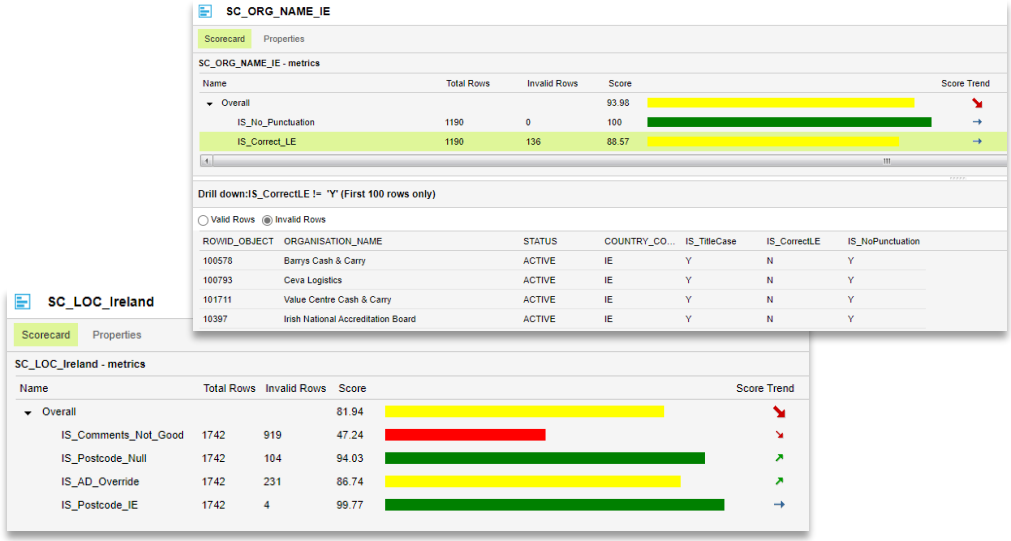
Data → **Data Profiling** → **DQ Defects** → **SPOR KUG**

New DQ standards published and new profiles to assure we maintain a good quality

Discussions with KUG, possible new business rules

- Profiles are built (data vs business rules) to identify data that does not follow the DQ requirements
- Constant monitoring and development
- Priority given following color indicators and type of error (major vs minor):

1. **Red** – outside acceptable thresholds
2. **Yellow**
3. **Green** – close to acceptable threshold, non-100% scores



 For Questions: www.slido.com code: #1314375

OMS Data Quality Management

OMS_ORGANISATION_DQ

Scorecard | Properties

OMS_ORGANISATION_DQ - metrics

Name	T..	I...	Score	Score Trend
Accuracy			-	-
Duplications			99.99	→
Conformity			90.12	↘
Consistency			100	→
Completeness			-	-

OMS_LOCATION_DQ

Scorecard | Properties

OMS_LOCATION_DQ - metrics

Name	T..	I...	Score	Score Trend
Accuracy			90.29	↘
Duplications			99.99	→
Conformity			98.5	→
Consistency			-	-
Completeness			99.39	→

Data Quality attributes

Accuracy
Reflects reality?

Uniqueness
Only instance?

Conformity
Data standardised?

Consistency
Conflicting information?

Completeness
Details missing?

For Questions: www.slido.com code: #1314375

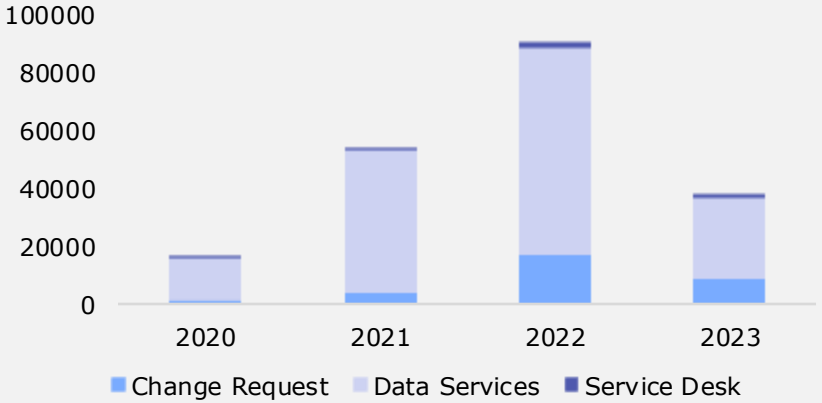
OMS Statistics

OMS Statistics

Change requests and Service desk are on a **slight increasing** trend in 2023

Despite the increase in change requests and data processing, **Service Desk SLA compliance has improved**

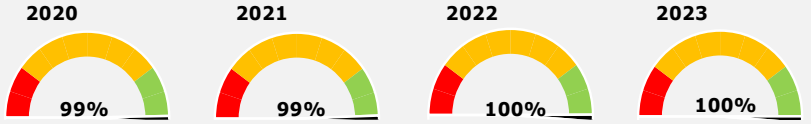
OMS Activities



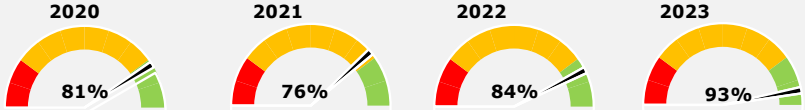
**2023 up to Q2 cumulative*

Overall Compliance

Change Request



Service Desk



AVERAGE SLA COMPLIANCE - 75%

For Questions: www.slido.com code: #1314375

OMS Documentation & help

For Questions: www.slido.com code: #1314375

OMS Documentation & Help (I)

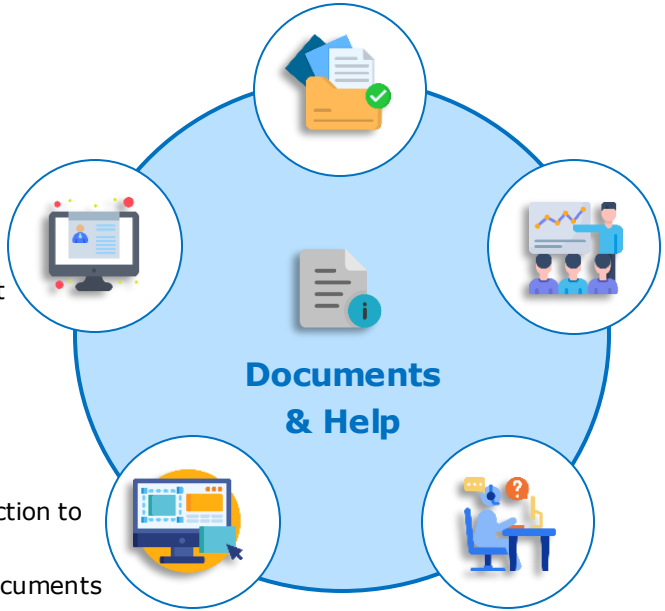
EUROPEAN MEDICINES AGENCY

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



Training opportunities

- @emainfo channel contains Videos of SPOR webinars with tips/tricks and questions raised from users

EMA corporate website

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

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

For Questions: www.slido.com code: #1314375

OMS Documentation & Help (II)

EUROPEAN MEDICINES AGENCY

[OMS Web UI (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	Published Date
A - About OMS	General - Legal disclaimer, copyright and other policies of using Organisation and Location data.	2017-06-26
A1 - OMS Introduction - Webinar 21 October 2021	Webinar - OMS Key principles, services and activities - 21 October 2021	2021-02-04
A2 - Quick initiation process flow	Guidance - Quick reference guidance for first time users: introduction, access and add/update records	2022-02-03
A3 - OMS FAQs	Guidance - OMS Frequently Asked Questions	2023-02-13
A4 - OMS Introduction - Webinar 10 March 2022	Webinar - OMS services, activities and statistics - 10 March 2022	2022-03-14
A5 - OMS News Items	NEWS - Recent changes implemented, open discussions, future discussions and upcoming functionalities	2023-02-23
A6 - OMS Introduction - Webinar 15 September 2022	Webinar - OMS services, activities and statistics - 15 September 2022	2022-09-20
B - OMS Operating Model	Policy - Range of services available for stakeholders to use and/or request new/updated data, including stakeholder interactions and roles.	2018-05-25
C - OMS Data Quality standards	Guidance - Data quality standards applied in OMS	2023-03-09
C1 - OMS DQ - Webinar 25 September 2018	Webinar - Key principles and rules covered in OMS Data Quality standards - 25 September 2018	2018-11-19
C2 - OMS DQ - Webinar 26 February 2019	Webinar - OMS Data Quality Issues - 26 February 2019	2019-08-16
C3 - OMS Guidance on Assessing Organisation Names and Location Data	Guidance - When minor differences between organisation names and location data are acceptable	2021-02-16
C4 - OMS Mapping Guidance	Guidance – Process for mapping and when to create an OMS change request	2021-06-02
D - OMS Controlled Vocabularies	Guidance - Controlled vocabularies used in OMS	2017-06-16
E - OMS Change Requests	Guidance - Rules and Supporting documentation required by change request type	2023-01-23
F - OMS Web User Manual	Manual - How to search, view, export data and request a new/updated data in OMS web Portal.	2018-04-17
G - Using OMS data in eAF - Webinar 27 June 2018	Webinar - OMS landscape and its use in eAF and in CESP in the future - 27 June 2018	2018-06-27
G1 - Q&A on eAF Mandatory use of OMS	Process - OMS mandatory for CAPs from November 1st onwards - Questions and Answers	2021-10-06
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.	2018-12-18
I - Impacts of OMS merge on EMA systems	Guidance – Validation of OMS consuming system data after the merge takes place in OMS	2021-04-28
J - CT registration Headed letter template	Template - For requesting the creation of sponsors and/or clinical trial sites	2023-01-23
U - About SPOR	General - Legal disclaimer, copyright and other policies of using SPOR data.	2017-06-26
V - SPOR Questions & Answers	General - Compiled questions on a variety of topics, including user registration, Industry on-boarding, and eAF integration.	2018-02-12
V1 - RDM Customer Satisfaction Survey 2021	SPOR Customer Satisfaction Survey November 2021	2022-01-31
V2 - RDM Customer Satisfaction Survey 2022	SPOR Customer Satisfaction Survey October 2022	2023-02-13
X - SPOR SLAs	General - Service Level Agreement (SLAs) for the SPOR data services.	2021-02-17
Z - SPOR User Registration Manual	Manual - How to register for EMA systems and request SPOR user roles.	2023-02-14
Z1 - SPOR User Registration - Webinar 5 October 2017	Webinar - How to register for EMA systems and request SPOR user roles - 5 October 2017	2020-07-15
Z2 - SPOR Super User Affiliation Template Letter	Template - For requesting the organisation's first SPOR Super User role.	2020-09-20
Z3 - SPOR API Access - Q&A	Process - How to request access to SPOR API - Questions and Answers	2017-12-06
Z4 - SPOR API Access - Webinar 10 November 2021	SPOR API Access - Webinar 10 November 2021	2021-11-11
Z5 - EMA - API General Terms of Service - Terms of Use	EMA - API General Terms of Service - Terms of Use	2021-06-29
Z6 - SPOR API Access Request Form	SPOR API Access Request Form	2021-11-08
Z7 - SPOR API Access and Usage - Webinar 18 March 2022	Webinar - API Registration process and OMS/RMS API usage demo and tips	2022-04-04

For Questions: www.slido.com code: #1314375

OMS Documentation & Help (III)

OMS Web UI (europa.eu)

A5 - OMS News Items

Before start

- A2 - Quick initiation process flow
- C3 - OMS Guidance on Assessing Organisation Names and Location Data
- A3 - OMS FAQs

Access

- Z - SPOR User Registration Manual
- Z2 - SPOR Super User Affiliation Template Letter
- F - OMS Web User Manual

Data Quality

- C - OMS Data Quality standards
- A1 - OMS Introduction - Webinar 21 October 2021

Change request process

- F - OMS Web User Manual
- E - OMS Change Requests
- C - OMS Data Quality standards
- X - SPOR SLAs

For Questions: www.slido.com code: #1314375

OMS in Projects/Systems

 For Questions: www.slido.com code: #1314375

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 & DADI*	**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

For Questions: www.slido.com code: #1314375

The following organisations are available in eAF:

- Status = Active

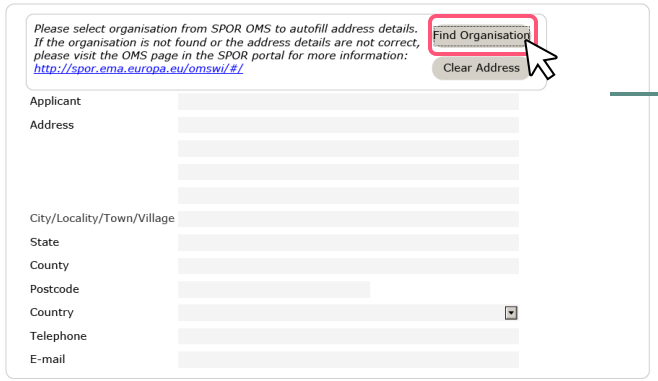
The following OMS data fields are available in eAF:

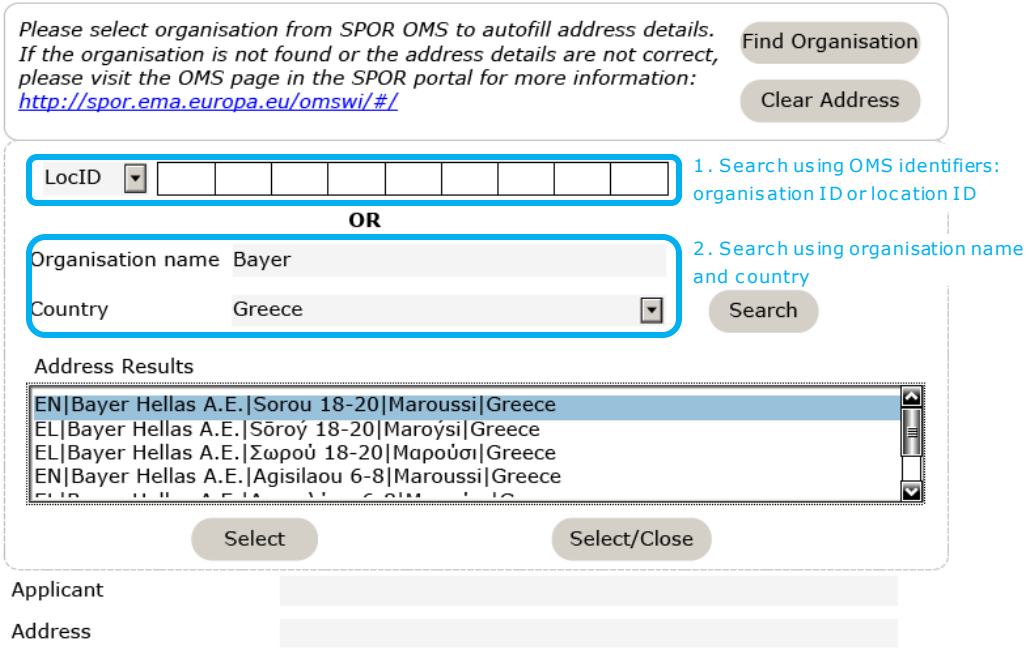
Data field name in eAF	Data field name in OMS
OrgID/LocID	Organisation ID/Location ID
Applicant/Company name	Organisation name
Address	Address
City/Locality/Town/Village	City
Country	Country

OMS in Projects/Systems - eAF

EUROPEAN MEDICINES AGENCY

eSubmission





 For Questions: www.slido.com code: #1314375

OMS in Projects/Systems – SAP information in IRIS

EUROPEAN MEDICINES AGENCY

Information flow – from SAP to IRIS

2. SAP (manual)
Deltas daily

EUROPEAN MEDICINES AGENCY
IRIS

1. Financial process

A. User submits form to SAP account management
B. SAP account management automatically creates/updates SAP customer ID and its details

Notes:
- *SAP is still not consuming from OMS*
- *Users always need to submit changes to SAP account management to create/update organisation and location details*

3. OMS team

A. Validates and standardised Organisation
B. Standardises address
C. Collects/consolidates the SAP customer ID - restricted information in OMS

Notes:
- *Location deactivation need to be submitted directly to OMS*
- *User can submit other changes to OMS - changes not submitted to OMS will be picked up from the Deltas*
- *Users should not request SAP changes via OMS change request*

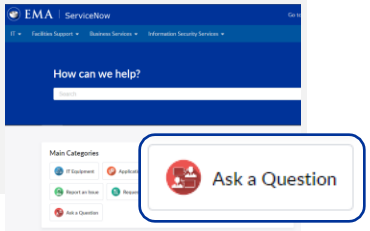
4. Procedures in IRIS

Data in IRIS is available as per OMS dictionary

- Organisation & location data
- SAP customer ID, applicable to procedures involving a fee

Troubleshooting – If **SAP customer ID not available or information is displayed incorrectly in IRIS**:

1. Submit a **ticket (*Ask a Question*) in EMA Service Desk** to:
   - Service: SPOR
   - Service offering: OMS
2. OMS team will **investigate** the full synchronisation between SAP/OMS/IRIS and **assign the ticket to the correct team**



For Questions: www.slido.com code: #1314375

What's new in OMS

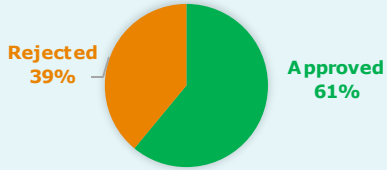
 For Questions: www.slido.com code: #1314375

OMS registration process improvement

WHY

- Number of **Rejected OMS Change requests** continues **high (39%)**
- **28%** of rejected Change requests in Q4 2022 with reason "**Organisation/Location already existed**"
- **20%** with **2/more consecutive change request** submitted

2022 OMS Change Requests



HOW

- To **reduce the number of consecutive rejected change requests,** OMS team will **open a ServiceNow ticket** on behalf of the user to enable the discussion of any **outstanding questions** about OMS registration processes

IMPACT to users

- **Improve customer experience and overall process efficiency** by reducing number of rejected changes requests
- To ensure you will be notified when OMS team opens the ServiceNow ticket please verify you have a **functional and frequently monitored email address** linked to your EMA Account (under EMA Account Management)

For Questions: www.slido.com code: #1314375

OMS ServiceNow knowledge articles

WHY

Simplify user experience when basic **OMS support** is required

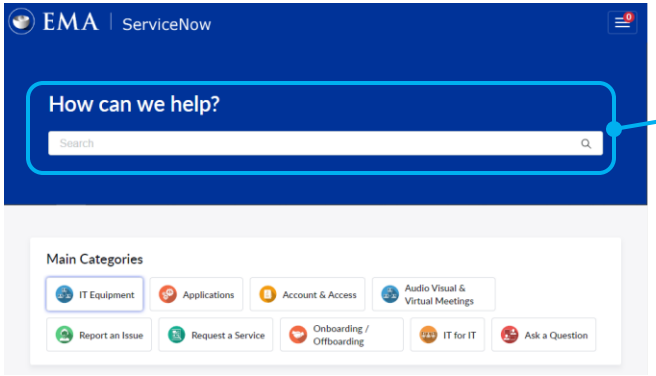
HOW

OMS imported all our **Frequently Asked Questions into ServiceNow**

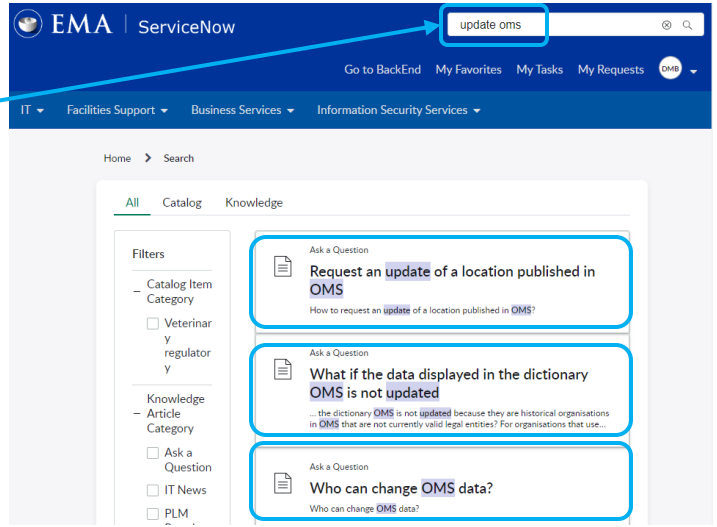
IMPACT to users

Improve customer experience by:

- Reducing the waiting time, since the **question is instantly answered**
- **No need to find/open docs** and look for relevant Q&A



ServiceNow



For Questions: www.slido.com code: #1314375

OMS becomes mandatory in CEP certificates (EDQM)

EUROPEAN MEDICINES AGENCY

CEP 2.0

EMA SPOR/OMS ORG_ID and LOC_ID mandatory

MORE INFORMATION

As of **1 June 2023** CEP holders and applicants must provide the EMA SPOR/OMS ORG_ID and LOC_ID for all companies involved in CEP dossiers.

Consult here the **CEP 2.0 – Webinar for CEP holders and CEP users** - *European Directorate for the Quality of Medicines & HealthCare (edqm.eu)*

Certification of Substances Department

Certificate of suitability

No. CEP-2023-836-Rev-00

Name of the substance:
CHOCOLATE

Name of holder:
ABRACADABRA Ltd
13 Magic Street
Wonderland-987654 Sugar town
ORG_ID 998877665
LOC_ID 112233456

Site(s) of production:
SEE ANNEX 1

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **CHOCOLATE** NO. XXXX of the European Pharmacopoeia, current edition including supplements, and any additional test(s) and analytical procedure(s) in line with the approved specification given in **ANNEX 2.**

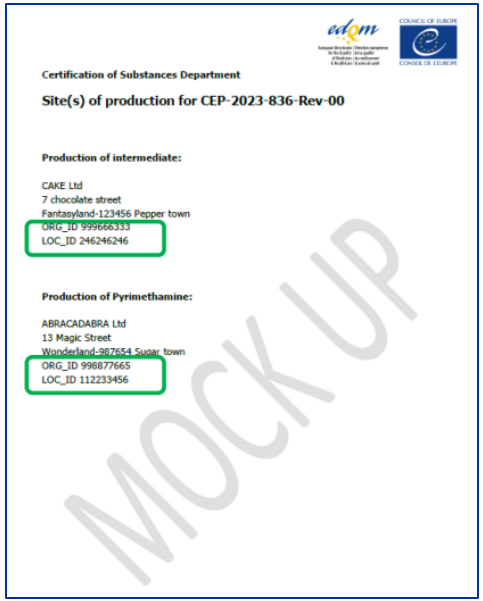
In the last steps of the synthesis purified water is used as solvent.

No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of the substance.

The re-test period of the substance is 12 months if stored in double polyethylene bags in a triple laminated bag.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance

MOCK UP



Certification of Substances Department

Site(s) of production for CEP-2023-836-Rev-00

Production of intermediate:

CAKE Ltd
7 chocolate street
Fantasyland-123456 Pepper town
ORG_ID 999666333
LOC_ID 246246246

Production of Pyrimethamine:

ABRACADABRA Ltd
13 Magic Street
Wonderland-987654 Sugar town
ORG_ID 998877665
LOC_ID 112233456

MOCK UP

For Questions: www.slido.com code: #1314375

Planned OMS activities

 For Questions: www.slido.com code: #1314375

Planned OMS Activities

EUROPEAN MEDICINES AGENCY

Activities for 2024 to be adjusted based on Customer Satisfaction Survey's results

	Q3 2023	Q4 2023	Q1 2024	Q2 2024
Deliver efficient and effective regulatory data services	**OMS – Customer Services**			
	Increase QC/QA			
	Review Serv Desk Q&A			
	OMS - Data Management (Change requests & Data services)			
	1 OMS Data Protection Notice			
	Process improvement – SAP (Manual) Deltas			
	2 Implementation – EV Deltas to OMS			
	OMS – Data Quality			
	Enrichments • DUNS? • Notified Bodies + EudamedID			
	3 Enrichment National Business Registry number (NBRn)			
	New/updated DQ profiles			
	4 Process improvement – Category review			
	EV Currency check- MAH	Currency check		
Improve customer satisfaction and success	**OMS – Documentation**			
	Review & condense OMS docs	(New) How to read our docs		
	ServiceNow experience > collect user histories and how can we improve based on the same			
	OMS in CP – eCPP and others extension			
	OMS – Awareness & visibility			
	SPOR webinars	SPOR Customer Satisfaction survey		SPOR webinars
Modernise Data & Information Management	Information Management Modernisation initiatives			
	OMS planned improvements – Bug fixes, Return CR functionality, New flag to identify HQ locations, Display NBRn in WebUI/OMS portal and allow its maintenance through CR			
	Prioritised Epics (eAF, IRIS, ePI, shortages, NFR and other)			

For Questions: www.slido.com code: #1314375

Planned Service Process Improvements 2023 (I)

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT to users:	
OMS Data Protection Notice	OMS collects personal information through change request process and ticket management according to Regulation (EU) 2018/1725	• **Q3/Q4 2023** – Development • **Q4 2023** - Publication	Provides **clear information** on: - purpose of collection of personal information and how long is kept - what type of data is collected - who controls/process it - how we ensure security of the data - how users can exercise their rights in this matter	1
EV Deltas to OMS	Ensure all EV Marketing Authorisation Holders are corrrectly synchronised into OMS	Enrich OMS Dictionary with: • Standardised Organisation name • Standardised Location details • EV MAH codes **Q4 2023** - Go-live	Ensures smooth transition/migration into PMS Minimises access issues by ensuring Users will see all their products	2

For Questions: www.slido.com code: #1314375

Planned Service Process Improvements 2023 (II)

EUROPEAN MEDICINES AGENCY

	WHY	HOW & WHEN	IMPACT to users:	
Enrichment National Business Registry number (NBRn)	• Facilitate identification of potential duplicates – same Number, old name vs new name • Facilitates identification of legal address	• **Ongoing -** By enriching the legal address location with National Business Registry number	Provides clear identification of official legal address of a certain organisation/legal entity	3
Category review	Improve data profiling	• Review current categories available and possible expansion to accommodate new requirements and/or recent system integrations • **Q4 2023/Q1 2024** - Assessment	Clearer categorisation of OMS records facilitates filtering/usage of data	4

 For Questions: www.slido.com code: #1314375

Key takeaways and conclusions

For Questions: www.slido.com code: #1314375

Takeaways & Conclusions

EUROPEAN MEDICINES AGENCY

Increase Awareness of OMS activities

- *Provided background information: introduction to OMS, OMS processes (CR, DQ)*
- *Provided key updates: revised statistics, integration in business processes*

Share recent and planned activities

- *Service desk improvements: Knowledge base articles and point of contact to users*
- *News: OMS becomes mandatory in CEP certificates (EDQM)*
- *Planned: Enrichment of National Business Registry number (NBRn), Review of OMS categories*

Show how OMS is addressing customer feedback

- *Continue to improve OMS Documentation – review and condense*
- *OMS registration process improvement – reduce rejection of Add organisation CR*
- *OMS ServiceNow knowledge articles – simplify user experience*

For Questions: www.slido.com code: #1314375

Quiz Time

For Questions: www.slido.com code: #1314375

Any questions on the webinar?

For Questions: www.slido.com code: #1314375

H2 2023 SPOR Webinars

EUROPEAN MEDICINES AGENCY

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 and XEVMPD Data Governance	2 October 2023	10:00-12:00 CEST
Referentials Management Service (RMS)	3 October 2023	10:00-12:00 CEST
Organisation Management Service (OMS)	4 October 2023	10:00-12:00 CEST
Substance Management Service (SMS)	5 October 2023	10:00-12:00 CEST
Product Management Service (XEVMPD)	6 October 2023	10:00-12:00 CEST
Service Desk for SPOR and XEVMPD	10 October 2023	10:00-12:00 CEST
EMA Account Management	11 October 2023	10:00-12:00 CEST
SPOR application programming interface (API) - SPOR API	12 October 2023	10:00-12:00 CEST

For Questions: www.slido.com code: #1314375

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

Glossary (1/4)

EUROPEAN MEDICINES AGENCY

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	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. Business epics are large initiatives that deliver Solutions needed by the business/customers Enabler epics are pieces of work that extend the architectural infrastructure of the solution under development or improve the performance of the value stream

Glossary (2/4)

EUROPEAN MEDICINES AGENCY

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

Glossary (3/4)

EUROPEAN MEDICINES AGENCY

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

Glossary (4/4)

EUROPEAN MEDICINES AGENCY

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