EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Introduction to Organisation Management Service (OMS)

11 & 16 May 2023

EDQM Webinar

An agency of the European Union

OMS Introduction - Key Principles (1/4)

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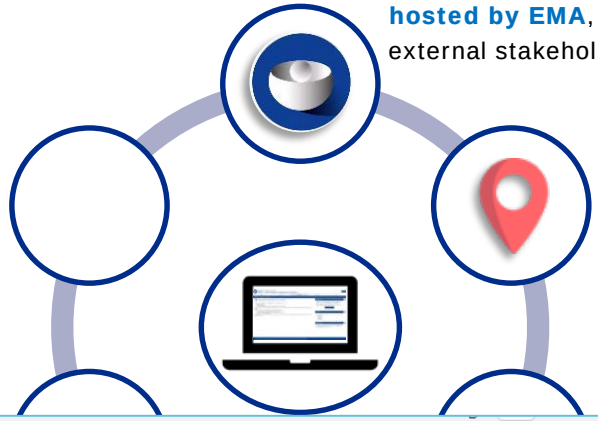
OMS Dictionary provides a central source of organisation data **hosted by EMA**, accessible to and used throughout EMA and by external stakeholders



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.

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OMS Introduction - Key Principles (2/4)

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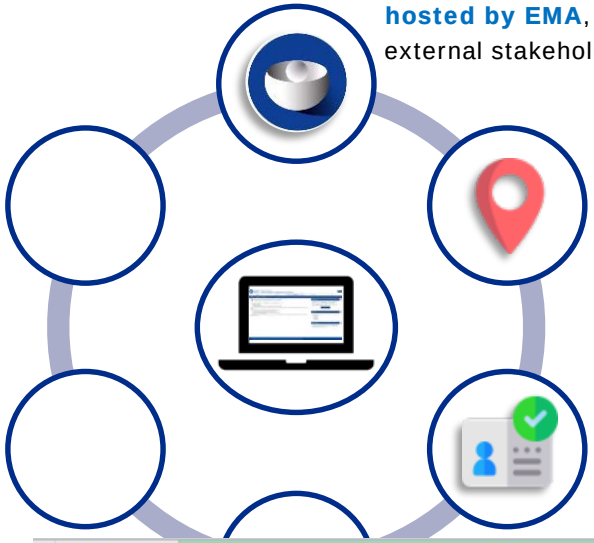

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Organisation data structured with unique IDs (**Organisation_ID** and **Location_ID**) and mapped to records loaded from source systems (e.g. EudraGMDP site reference code)

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 W	10-18	2201	Hagenbrunn	Österreich
6	Sandoz GmbH	- Außenlager Gebrüder Weiss GmbH	GA - aktiv	Läffiepweg	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

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OMS Introduction - Key Principles (3/4)

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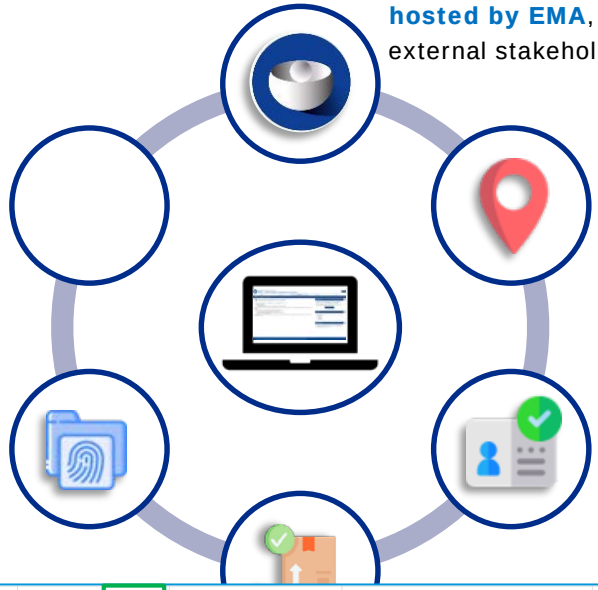

An **organisation**, as a legal entity, groups all its physical locations within a **country**

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

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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**

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

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)

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

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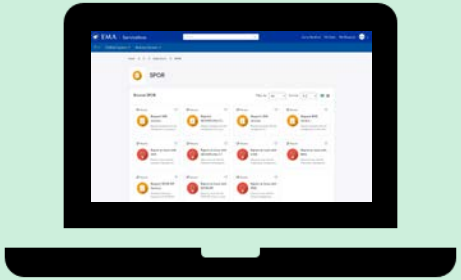
Where to find OMS?

OMS portal

- OMS Dictionary
- Change Request functionality to update/add organisation locations to OMS Dictionary
- OMS guidance and requirements

OMS Web UI (europa.eu)



ServiceNow

- Questions (data or system related, follow-up on Change request)
- Report an Incident

Employee Topic - Employee Center (europa.eu)

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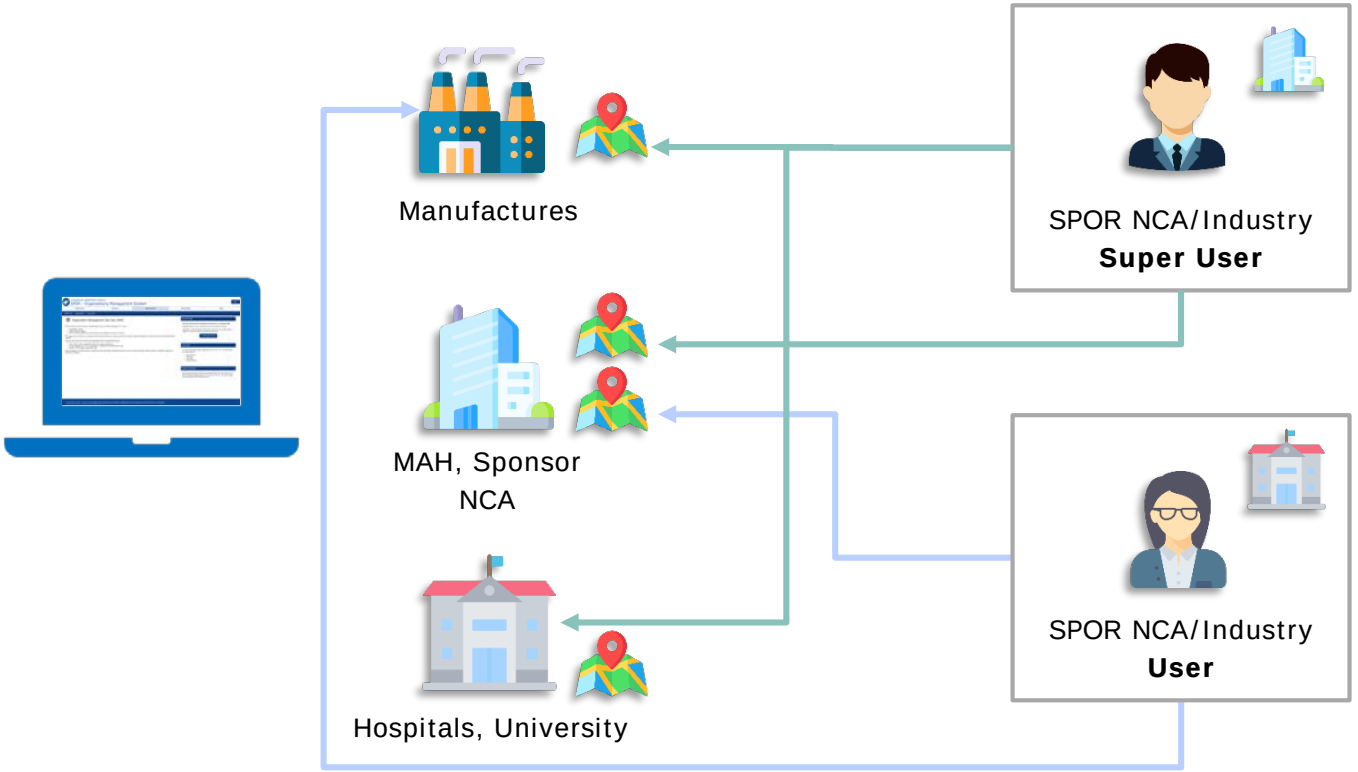
Who can change OMS data?



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

*Further information on requirements can be found on the OMS portal under document *E – Change request*

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OMS Change Request process at a glance

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Submission

Requestor

Submit OMS CR with **supporting document**

Validation / Standardisation

EMA Data Stewards

Guidance / references & tools

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

Approval / Rejection

EMA Data Stewards

EMA is OMS Data Owner

- 5-10 WD SLA
- CR **Approved** or **Rejected** user always receives email acknowledgment with the outcome
- If disagreement, raise ticket in Service Desk, indicating CR number

Organisation data owner

EMA

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Data vs Reference Sources

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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

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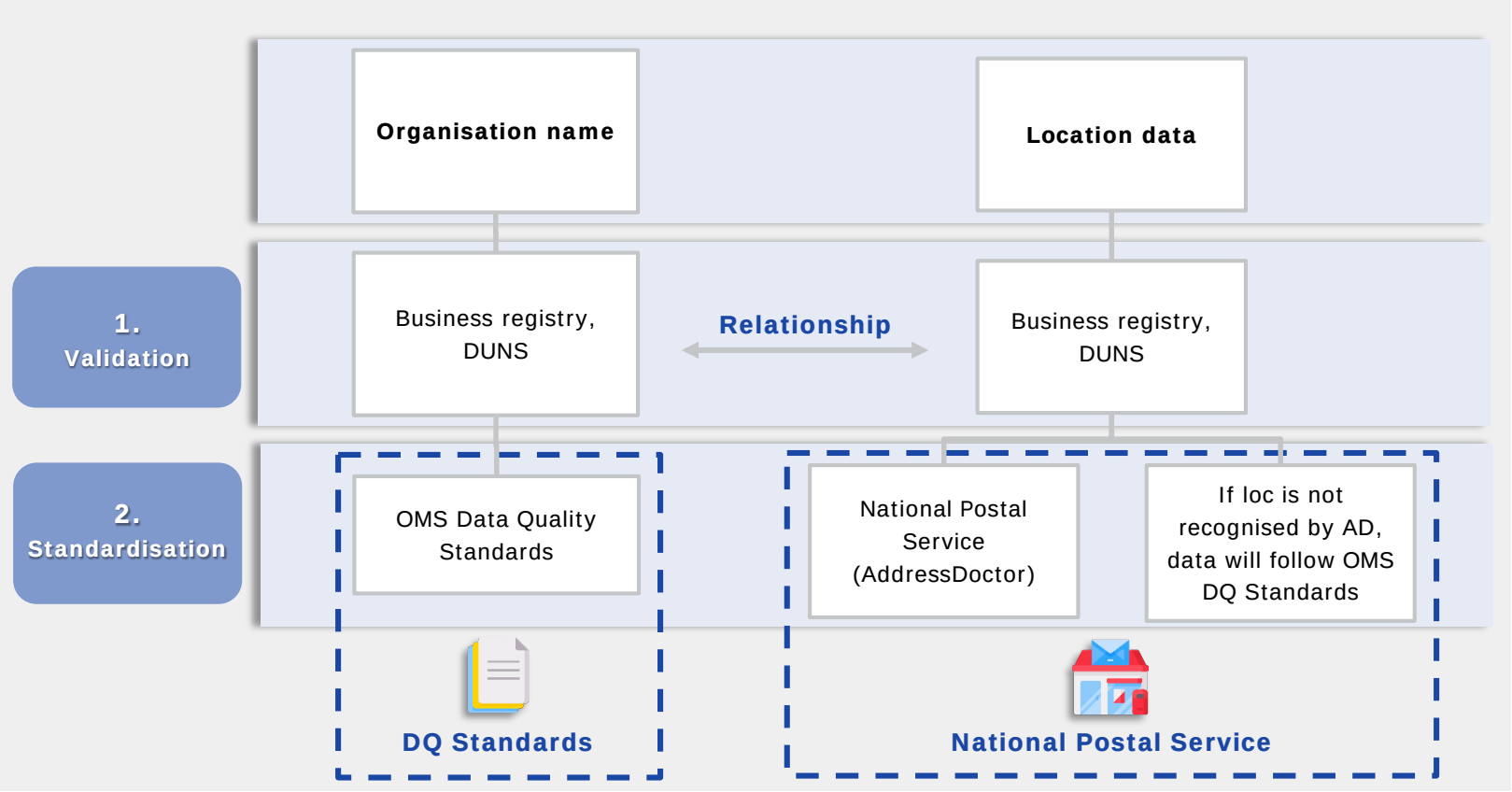
Data & Data Management Process



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What is AddressDoctor?

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AddressDoctor is an **address library** used for address validation, correction and standardisation

World-wide & Certified

- AddressDoctor's validation service is delivered in combination with **reference data for more than 240 countries and territories**
- The service combines in one engine **postal certifications** from **all five global postal organisations**

Standardised

- Addresses are **formatted according to local postal standards**
- Validation service can parse, analyse, verify, correct and format addresses according to local postal standards - ensuring that correct elements appear in the appropriate hierarchical alignment

Enriched

- AddressDoctor's validation service allows to **enrich address data with geocodes**

Character set & transliteration

- Address Verification supports **40 different character sets** and **transliterates addresses into Latin characters** from six different writing systems
- When available in the reference files addresses can be automatically transliterated – address localised will be generated

Up-to-date

- The reference database is **updated throughout the year**

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OMS IDD - Change Request Process Organisation validation & standardisation

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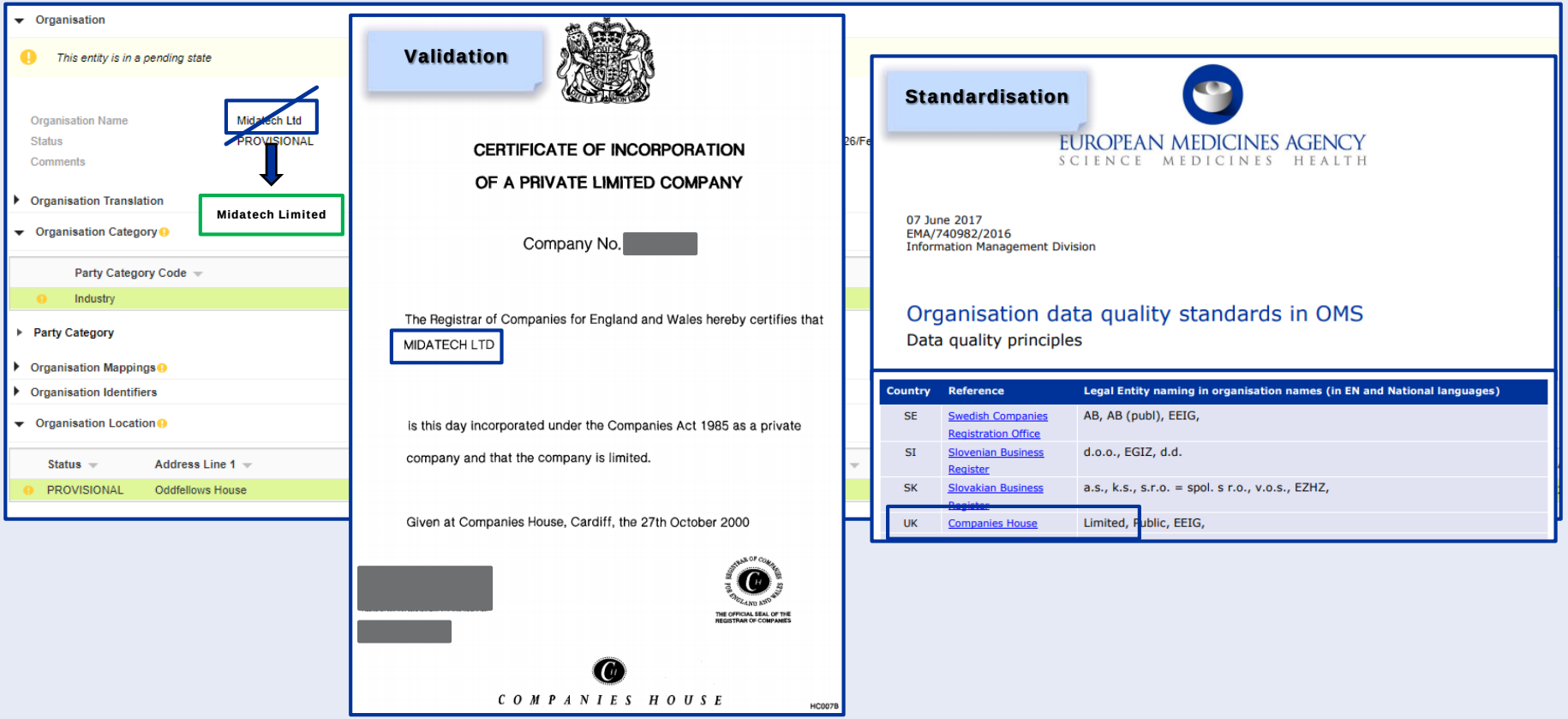

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OMS IDD - Change Request Process Location validation & standardisation

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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

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Any questions on the webinar?

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Further information

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

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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

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