



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quick guide

How to use the Organisation Management Service (OMS)

CTIS Training Programme – Module 03

Version 1.1 – April 2022

Learning Objectives

- Understand how to search for an organisation in the Organisation Management Service (OMS).
- Understand the process of submitting a Change Request for a new organisation in OMS.
- Understand the process of submitting a Change Request to update the information of an existing organisation in OMS.

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Introduction

CTIS interacts with five main databases and systems. These allow to register users, search for information on organisations and medicinal products, and store data and documents provided to CTIS. All these databases and systems are managed by EMA.

One of these databases, the Organisation Management Service (OMS) provides a single source of validated organisation data for CTIS, such as organisation names and location addresses. Additionally, the [OMS Portal](#) includes several guidance documents, maintained by EMA, and accessible through Google Chrome or the Microsoft Edge browser.

In the OMS Portal, users can click on the '[Documents](#)' sub-tab to access all the documentation on the use of OMS. To view the documents, users can select the 'View document' icon  on the right side of each document.



Document Name	Document Description	Published Date	Actions
A - About OMS	General - Legal disclaimer, copyright and other notices of using Organisation and Location data.	2017-08-28	
B1 - OMS Introduction - Webinar 21 November 2017	Webinar - OMS use principles, services and activities - 21 October 2017	2017-02-04	
B - OMS Operating Model	Policy - Range of services available for stakeholders to use and/or request recapitulated data, including stakeholder interactions and roles.	2018-05-25	
C - OMS Data Quality standards	Guidance - Data quality standards applied in OMS	2017-08-28	
C1 - OMS DQ - Webinar 28 November 2018	Webinar - Key principles and roles covered in OMS Data Quality standards - 28 September 2018	2018-11-18	
C2 - OMS DQ - Webinar 28 February 2019	Webinar - OMS Data Quality Issues - 28 February 2019	2019-03-18	
C3 - OMS Guidance on Answering Change Requests - Names and Location	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	2020-06-02	
D - OMS Controlled Medicines	Guidance - Controlled medicines used in OMS	2017-08-28	
E - OMS Change Requests	Guidance - Rules and Supporting documentation required for change request form	2018-08-08	
F - OMS User Manual	Manual - How to search, view, export data and request a recapitulated data in OMS web Portal	2018-08-17	
G - OMS Data Quality	Webinar - OMS Guidance and its use in AMF and in CDSP in the future - 27 June 2018	2018-06-27	
H - OMS AMF Feedback on use of OMS	Process - OMS readiness for CAPs from November 2017 onwards - Questions and Answers	2017-09-04	
I - Manufacturer organisations in the OMS database	Process - Manufacturer organisations data flow in the context of regulatory activities and data is responsible for registration/labelling organisation data about manufacturers in the OMS.	2018-12-18	
J - Importers of OMS merge on EMA Location	Guidance - Validation of OMS containing address data after the merge takes place in OMS	2021-04-28	
K - About SPOR	General - Legal disclaimer, copyright and other notices of using SPOR data.	2017-08-28	

On this page, important documents can be found, such as C (OMS standards used for maintaining a record); C3 and C4 (guidance on how data is standardised); E (required documentation per type of change request); F (full manual); Z (SPOR user registration manual). It is not necessary to log into the OMS portal with an EMA account to access the guidance documents.

If users need to create a new organisation or to update the details of an existing one, they need to submit a Change Request. Users will need to log in to the [OMS portal](#) with their EMA account. Every user with an EMA account is assigned automatically the 'Unaffiliated user' role of the Substances, Products, Organisations, and Referentials (SPOR) and therefore, the user can request the creation of a new organisation (*see section Change Request for a new organisation*). By having that role, users are not affiliated/associated with any organisation that exists in OMS.

If users need to submit a Change Request to update the details of an existing organisation or to add a new location, users will need first to affiliate themselves with their organisation (users don't need to be affiliated with a certain organisation to update its details). Users need to obtain the role of SPOR National Competent Authority or Industry user (depending on whether they are authority users or sponsor users, including Pharmaceutical companies, CROs, Academia) for their organisation via the EMA Account Management. Only after the access is approved will users be considered affiliated with the organisation and be able to request changes to any of the records published.

For more information on the various SPOR roles, users may refer to document 'Z - SPOR User Registration Manual', stored in the '[Documents](#)' section of the OMS portal.



Document Name	Document Description	Published Date	Actions
Y - SPOR Questions & Answers	General - Compiled questions on a variety of topics, including user registration,		
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.		
Z1 - SPOR User Registration - Webinar 5 October 2017	Webinar - How to register for EMA systems and request SPOR user roles - 5 Oct		

Sections of this quick guide

This quick guide is structured in three sections:



Search an organisation

This section outlines the steps that users can follow to search for an organisation in OMS.



Create a new organisation

This section outlines the steps that users can follow to submit a Change Request to create a new organisation.



Update an existing organisation

This section outlines the steps that users can follow to submit a Change Request to update information of an existing organisation.

Search an organisation



Users can submit Change Requests to request the creation of a new organisation in OMS, or to update the data of an existing organisation. Before submitting any request to the OMS, the user must search the organisation in the available records.



If users face any issues with accessing the OMS portal, it is suggested to **clean the cache memory or history**. If the issue persists, it is suggested to use the browser in **Incognito/Private mode**.

If users need to create a new organisation or to update the details of an existing one, users must submit a **Change Request**. First, users must **search if their organisation** exists in the [OMS Portal](#). These steps are applicable for all types of organisations (sponsor, CRO, investigational site, authorities' organisation, etc.).

To do that, **users must log in to the OMS portal** with the user's EMA account credentials. Once in the OMS Portal, the user can click on the '**Organisations**' sub-tab, found on the 'Organisations' tab of the OMS home interface.

EUROPEAN MEDICINES AGENCY
SPOR - Organisations Management System

Substances | Products | **Organisations**

SPOR Home | **Organisations** | View Requests | Documents

Organisation Management Services (OMS)

OMS provides a central dictionary of organisation data in multiple languages. This covers:

- organisation names;
- location address details;
- communication details such as email address and telephone number per location.

OMS supports the continuous exchange of data between information systems across the European medicines regulatory network and across the pharmaceutical industry.

OMS provides users with the following organisation data management services:

- view, search, export organisation data and change request data;
- request registration of a new organisation or update existing organisation data;
- access to multi-lingual organisation data.

Data management and data quality processes drive the SPOR data management services to ensure that the highest quality of data is available to support EU regulatory processes.

Users can then use the search fields to **retrieve their organisation**. Only the 'location status' field is mandatory, which by default is set in 'ACTIVE, INACTIVE'. If multiple search fields are used, the system will narrow down the search. Users can use the drop-down list on the right side of each field to indicate whether the details of the results begin with, or contain the keyword(s), used in the search fields.

SPOR Home | Organisations | View Requests | Documents

Home / Search Organisations

Export All Organisations | Export All Organisations With History

Hide search

Organisation ID: Contains

Organisation name: Begins with

Location ID: Contains

Address: Contains

City: Contains

Postcode: Contains

Country: 0 Selected -

Modified Since: yyyy-MM-dd

Location status: ACTIVE, INACTIVE

Reset Search

Once the user has populated the search fields, the user can click on the '**Search**' button.

Create a new organisation



If the user is not able to find the requested organisation, they can request creation of a new organisation.

If **no results are retrieved from the search**, a relevant message appears on the top part of the search fields, indicating that no results matching the search criteria have been found.



At the same time, a **new button** appears at the **bottom-right corner** of the search fields. Users can click on the **'Request new organisation'** button, which will redirect them to the **registration form**.



Users can then fill in the fields of the registration form accordingly. By default, the email is automatically populated coinciding with the email of the EMA user account of the creator of the organisation. The field can be edited, and the user may populate a different email for further communication during validation.

Home / Search Organisations / New Organisation Request

CR Information

CR Type: New Organisation

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

Justification: for test reasons, please ignore request

Requestor: First Last

Contact email*: flast@email.com

Contact Phone: 1111111111

Organisation Details

Organisation Name*: Test Organisation

Acronym:

Organisation Type*: Industry

Location Details

Address*: Promitheos Street 16
e.g. Canary Wharf

City: Athens

Postcode: 11146

Country: Attiki

Country*: Greece

Location Email (1): info@test-organisation.com

Location Phone (1): Int'l Code: +30 1111111111 Ext:

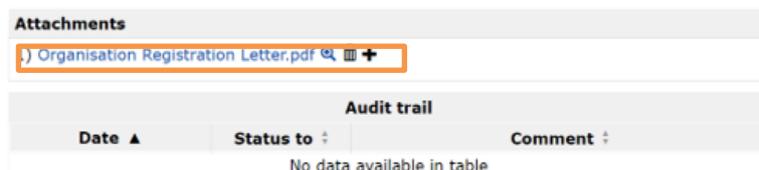
DUNS ID: e.g. 01-234-5678

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



Please consult the document **'E - OMS Change Requests'**, stored in the **'Documents'** section of OMS portal to be make sure the appropriate documentation is attached to the request.

After populating all the information, users are expected to **upload the appropriate documentation in the 'Attachments' placeholders**, next to the populated information, by selecting the **'+'** button. If the documentation attached to the request is not compliant with OMS's requirements, it may lead to the rejection of the request.



Create a new organisation

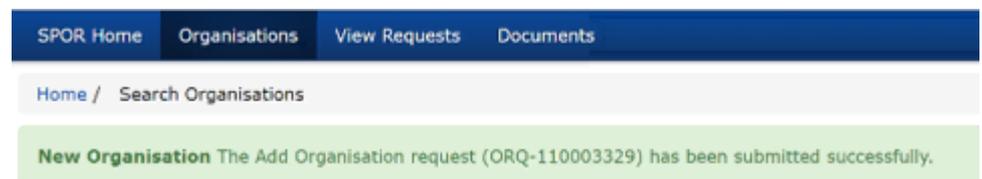


Once submitted, the requests cannot be edited, only viewed. Through the 'View Requests' sub-tab. Only the user who sends the request is able to view it.

Once users have populated all the information about the new organisation and attached the appropriate documentation, users select the **checkbox** under the information fields, acknowledging that they are aware that the information included in the request **will be published** by EMA on the OMS public website.

⁽³⁾ 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>

After clicking the checkbox, users can select the 'Submit' button in the **bottom right corner**. This will redirect the users back to the 'Search Organisations' page, in which a **message** above the search fields will appear, informing the user that the request has been submitted successfully and displaying a **Change Request ID**.



Users can **track** the **status** of their requests by accessing the 'View Request' sub-tab which will be active once a request has been submitted. Users cannot retrieve a Change Request ID in the search functionality. Therefore, these can only be tracked through the 'View Request' sub-tab.



In the 'View Requests' sub-tab, users can **view the information of their submitted requests** including: the Change Request ID, the Change Request type, the name of the requestor, the Change Request date, the organisation name, the address, the status, and the status date.

CR ID	CR Type	Requestor	CR Date	Organisation Name	Address	Status	Status Date	Actions
ORQ-110003329	ADD-ORGANISATION	First Last	2021-11-23T13:51:21	Test Organisation	Promitheos Street 16, Athens	SUBMITTED	2021-11-23T13:51:21	



The ID provided after a request is submitted is not the final Organisation ID. Any ID starting with ORQ refers to the Change Request ID.

Update an existing organisation



The user can request an update to an organisation or location details, after searching the organisation and only if the user has a SPOR (Super) user role.

In case users need to update the details of an existing organisation, users will need to submit a Change Request. To do that, users can **search** their organisation, and **click on the spyglass icon** next to the organisation on the results page.

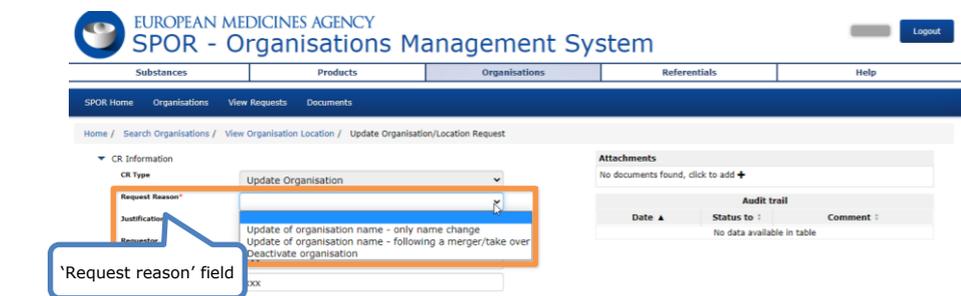
Organisation ID	Organisation Name ▲	Country ▼	Location ID ▼	City :	Address	Postcode ▼	Location status ▼	Modified :	Actions
ORG-100002154	Panp Test Organisation rance		LOC-100001011	Beignon	Parc Rue royale 12 Du C	5380	ACTIVE	2021-08-12T09:26:59	

This will redirect users to the organisations' page in which the information is displayed. Once on the organisation's page, users can select the button '**Request change**'. For users to be able to request a change to an existing organisation or to add a new location, users need to be affiliated to an organisation available in OMS (not necessarily to this particular organisation for which they are updating the details). Anyone can submit a change regardless of the organisation they are affiliated with; they need at least one affiliation to be able to submit modification requests of existing organisation details. Nonetheless, the requirement remains that valid supporting documentation should be provided to support the change request in OMS.

Users can obtain the role of SPOR NCA or Industry (Super) user for their organisation (depending on whether the user corresponds to an authority or a sponsor organisation, including Pharmaceutical companies, CROs, Academia), via the **EMA Account Management portal**.



Only after the access is approved, the user will be considered affiliated with their organisation and will be able to request changes. Change requests for updating an organisation can entail: updating the organisation's name, adding a new location, updating a location, deactivating an organisation, or deactivating a location. Users can select the **scope** of their update in the '**Request reason**' field.



For more information on how affiliated users can submit a Change Request to update details of an existing organisation, users may refer to the document 'E - OMS Change Request' and 'F - OMS Web User Manual', stored in the '[Documents](#)' section of OMS portal.

Label	Description
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
G - Using OMS data in eAF -	Manual - OMS data used in eAF



For more information on how SPOR roles are requested and managed in the EMA Account Management portal, users may refer to the '[Request user access](#)' guide.

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Send a question

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Clinical Trials Information System (CTIS).

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