

User Reference Guide - MORE Registrations

A step-by-step guide on using the MORE Platform for Registrations for Submissions of device related incidents.

The following user guide provides details on how to register to the MORE platform, use the functions and manage user registrations.

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Introduction

This document will guide users through the Manufacturer's On-line Reporting Environment (MORE) portal registration process via MORE and managing organisation setup. Every organisation will need to have an initial lead user (known as 'Organisation Lead') whose registration will need to be validated by the MHRA. Registration requests will only be processed by the MHRA if the initial user is already registered on the current legacy MORE system, or when supporting documentation has been supplied for those with no existing account.

Section 1: Background

Adverse incidents involving medical devices which occur in the UK must be reported to the MHRA. When a medical device has been placed on the UK market, vigilance reports must be submitted when incidents occur. Post-market vigilance reports are currently submitted by the legacy MORE system or by emailing a Manufacturer Incident Report (MIR) form to the MHRA.

From 21 November 2022 the MHRA is decommissioning existing MORE services and transitioning to a new MORE portal.

MORE services

You will have read only access to the old MORE system and will be able to download existing reports until 31 August 2023. If you currently hold an account on MORE, we are not migrating any of your data to your new MORE account. We recommend that you download any historical reports from your old MORE account as these will not be available in your account after 31 August 2023. Any draft reports in your old account will need to be re-created in your new MORE account for submission.

In the new MORE portal, registered users will be able to continue to submit MORE forms via XML report upload, manual submission via the web forms within MORE portal or via Application Programming Interfaces (API). The MORE web forms that are available include:

- Manufacturer Incident Report (MIR)
- Field Safety Corrective Actions (FSCAs)
- Trend Reports
- Periodic Summary Reports (PSRs)
- A new web form to enable submission of Serious Adverse Events (SAEs)

When you register on the new MORE portal, you can have multiple user groups under one account in the system. The following user groups will be available for selection during the registration process:

- Manufacturers,
- Authorised Representatives (NI),
- UKRP
- Other importers, distributors, or submitters

If you have an active account in the Device Registration system, your organisation information will automatically populate in the web form if your MORE registration is set up for the same organisation.

User Group Roles

Authorised Representative (NI)

Authorised representatives can be based in Northern Ireland or the EU for placing goods on the market in Northern Ireland and the EU. A manufacturer can delegate some of the duties to an authorised representative, however, they will need to check the specific regulations that apply to confirm what can and cannot be delegated.

UKRP

The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations. The responsibilities of the UK Responsible Person are set out in the UK Medical Device Regulations 2002.

Manufacturer

The person with responsibility for the design, manufacture, packaging and labelling of a device before placing it on the market under its own name. This can be a company or an individual.

Other – Submitter/Importer/Distributor

In some situations, registration will be required from distributors, importers or other types of submitters when they assume the obligations belonging to manufacturers.

Device Registration Data – Device Registration database data

The MHRA will use organisation data from the Device Registration database, the associated addresses, account numbers and the relationship of those that are authorised to carry out vigilance activities on the organisations behalf. The information from the Device Registration database will be used at the point of registration, when logging into associated accounts and for auto population in MORE forms. Changes to information within the Device Registration database will be reflected in the MORE platform.

The names and addresses of organisations available to select within MORE will only include Device Registration data if the status of the registration is 'registered', 'suspended' or 'unregistered'. If the organisation you are looking for is not available from MORE, please review the details in Device Registration database and update, as necessary.

If the Device Registration database data is updated to change or remove relationships, these will automatically update in MORE in line with agency nightly feeds.

Pre-go live: Please note, that relationships of manufacturers to representatives will not be available until the systems go live for reporting.

For more information on Device Registration and guidance, please see [Register medical devices to place on the market - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/guidance/register-medical-devices-to-place-on-the-market)

Access levels and permissions

Organisation Leads

This is the level for the lead user of the organisation. This user is responsible for the initial registration request to MORE and for managing the organisations users, which includes validating and approving/rejecting/deactivating users for that organisation, including other Organisation Leads. An Organisation Lead can send and receive MORE forms.

Assigning an Organisation Lead is a local decision based on who is best placed to perform these activities. Multiple Organisation Leads may exist per organisation. All Organisation Leads linked to an organisation will have the same access levels and permissions when set up. An Organisation Lead is responsible for deactivating user accounts when a user is no longer associated to the organisation and so local processes should be in place to support these activities.

It is the responsibility of the first Organisation Lead to ensure that they are comfortable with any additions to their organisation as well as the level of access each individual user has. For example, Authorised Representative (NI) and UKRP Organisation Leads can create

accounts for new Organisation Leads under the user group 'Manufacturer' that are associated to their company – this means that they can create an account for a user who has access to a greater level of information than they do i.e. a user who will be able to see all the reports submitted by that Manufacturer alongside reports submitted by other Representatives on behalf of that Manufacturer.

If the sole Organisation Lead leaves an organisation, it is their responsibility to set up an alternate Organisation Lead user to manage reports for the organisation. This can be carried out by inviting a new user or upgrading an existing Standard User account to Organisation Lead. If reports need to be downloaded, it is the responsibility of the user to do so before deactivation of accounts takes place.

Standard users

This is the level for the majority of users. It is the level that all new registrations are defaulted to. At the point of approval, the MHRA, or an existing Organisation Lead, can upgrade accounts from standard user to Organisation Lead. A standard user can send and receive MORE reports and will have access to the associated organisations reports and alerts.

Please note: A MORE user account can only have one access role type (Organisation Lead or Standard User). For example, if a user is an Organisation Lead for 'Organisation A' and then they are invited to join 'Organisation B', they will automatically be an Organisation Lead for 'Organisation B'. If mixed access roles are required, then different emails should be used.

We recommend that registrations are made using individual email addresses and not with shared mailboxes to ensure access to MORE is secure and that individual users have an audit trail of their activity.

Dashboard & Menu Bar

Dashboard tiles & functions

When you register to the MORE portal your approval will initially be pending and you will have access only to your personal workspace whilst your registration request is pending. When you sign in you will be presented with a Dashboard containing tiles with various functions, your role type will affect which tiles you have access to. The same functionalities for each of the tiles are available using the menu options which are selectable from the top left hand burger bar of the account screen.

Pre-go live: Please note that some tiles, including 'Reports' are disabled until go live.

Tile Icon	Tile Name	Description
	Resources	Access to help and guidance documents for the system
	User Management	The Organisation Lead (s) (lead administrator) will be able to manage user access within the organisation.
	Notifications	Area for receipt of notifications relating to registrations (if an Organisation Lead), general updates and follow up for submitted reports.
	Reports Submission	Submit reports using the manual MORE forms or xml upload function
	Report Management	Access reports that have been submitted for the organisation. Report management can be used to view the status of the report and to check if submission is successful. If you log into your workspace, you will only see your own reports
	Change Management	Provides an overview of all user requests to join the organisation including, pending, approved, and rejected requests.

The 'Developer' menu option found in the left-hand side menu bar will contain information on Application Programming Interface (API) setup and documentation for integration between organisation IT systems and MORE. This option is only available for Manufacturer Organisation Leads.

Organisation Lead dashboard

An Organisation Lead will see the following tiles on their dashboard when they log into their account as a:

Organisation Lead Authorised Representative account



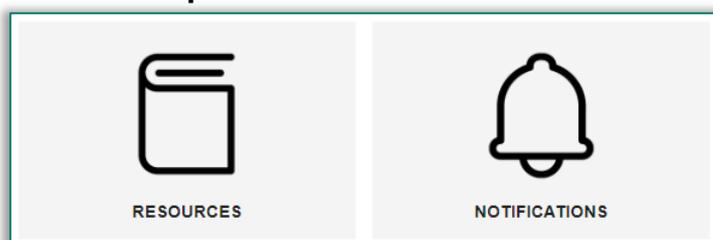
Organisation Manufacturer account



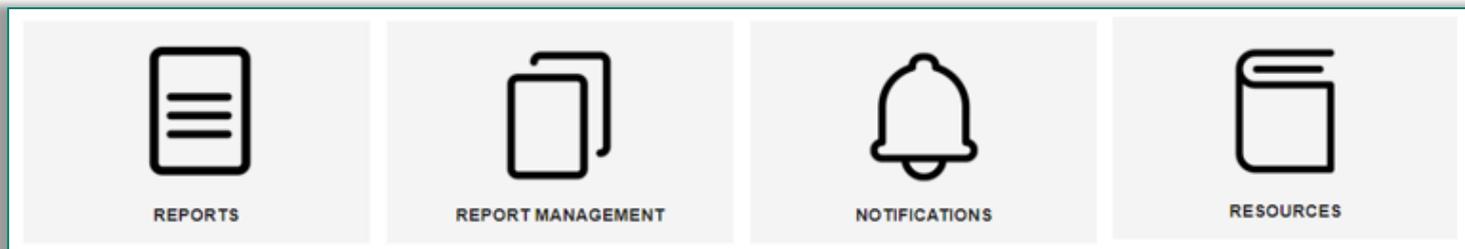
Standard user dashboard

A Standard User will see the following tiles on their dashboard when they log into their account as a:

Standard User Authorised Representative account



Standard User Manufacturer account



My workspace dashboard

For accounts created with 'Other' as the user group, or accounts pending registration, users will have access to the workspace dashboard which will have the below tiles.



'Workspaces' are local areas associated to a single user only and are not associated with any manufacturer or their representatives. All users have access to a personal workspace to allow them to report on a device which is not registered to their organisation(s). If a manufacturer would like to report an incident for a device registered to a different organisation, they can select their 'Workspace' instead of an organisation they are associated to at login. Note: Reports submitted via the 'Workspace' will not be viewable under the 'Report Management' tile for any organisation they are registered to and can be accessed by the user that reported it via their workspace only.

'Workspaces' have two intended uses:

1. To allow manufacturer or representative users to access the portal and submit reports immediately after registering, while awaiting approval, if necessary.
2. For submission of reports regarding medical devices which are not registered in the device registration database.

Section 2: Account creation

We recommend that registrations are made using individual email addresses and not with shared mailboxes to ensure access to MORE is secure and that individual users have an audit trail of their activity.

The first account registration for an organisation will be approved/rejected by the MHRA and the user will be assigned an Organisation Lead level. Please note that you may need to submit validation documents, which are covered in more detail below. All subsequent account requests for registration for an organisation (where an approved Organisation Lead exists) will be managed by the existing Organisation Lead(s) via the MORE portal.

Please ensure that one Organisation Lead is approved to your organisation before submitting an account registration requests (unless you are the Organisation Lead) or this may lead to a delay in your request. All subsequent registrations must be made once the first Organisation Lead has been approved by the MHRA.

Whilst registration is being approved, the user will have access to their workspace and will see a black banner at the top of the page notifying them that their registration is pending. When registration is completed by either the MHRA or Organisation Lead, the user will receive a confirmation email. If you register for more than one organisation under different roles, these will be processed as separate registration requests. The pending registration banner will remain present for each registration that is pending.

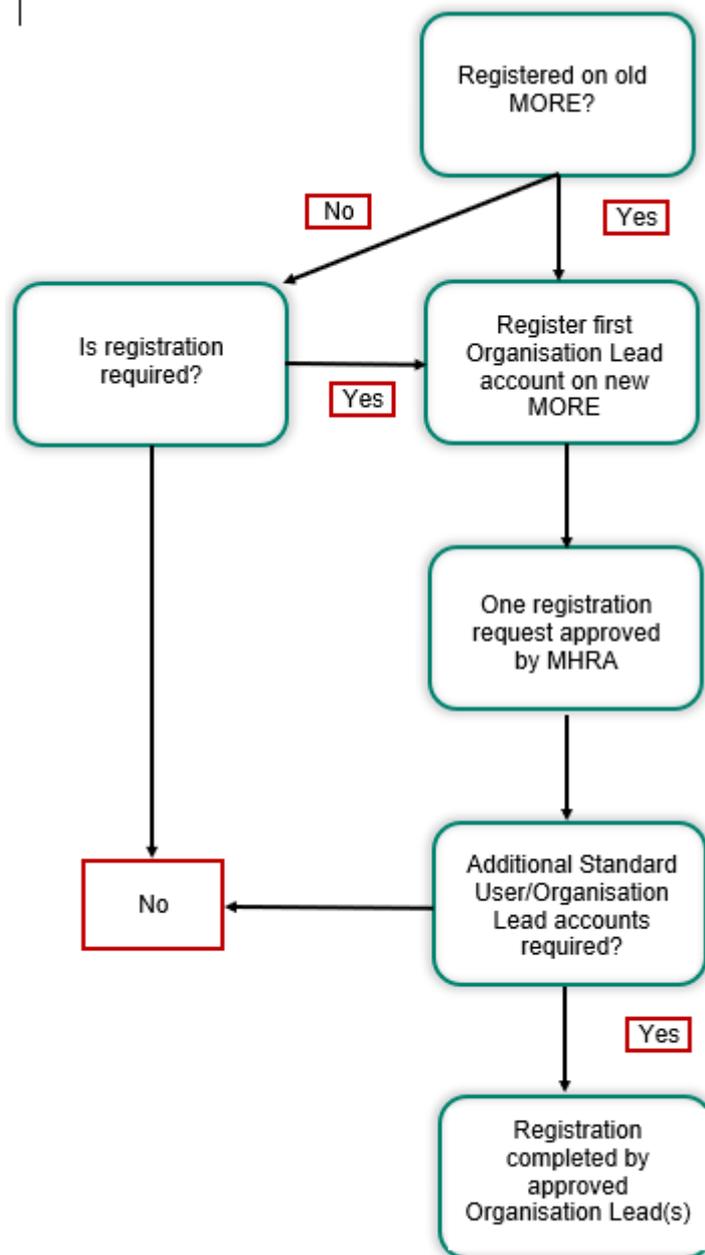


Figure 1. Workflow for registration requests

When you register, you will be able to begin typing in your organisation name which will then display the name of the Manufacturer, Manufacturer address and associated Device Registration Account Number.

Please note that you must select the correct Manufacturer details by checking the device registration account number that is displayed with the name.

Once registration is approved, please note that it will take approximately one hour before the system updates to create the link between the users account and organisation details (as per Device Registration Database details). We would recommend logging into your account at least an hour after registration approval is confirmed.

Validation documentation

Initial registration requests to set up an organisations first user as an Organisation Lead will only be processed when supporting validation documentation has been supplied and validated. This initial registration will need to be validated by the MHRA.

If an applicant is the first person to register for an organisation, and already has an **existing MORE account** with the same email and organisation associations, they **do not need to provide supporting documentation**. The MHRA will verify their registration by matching them to current records and will contact applicants if further information is required.

If an applicant is the first person to register for an organisation, and **does not have an existing MORE account**, they **must submit supporting documentation** when they register for any of the following roles:

- Manufacturer
- Authorised representative
- UKRP

Validation documentation must consist of the below and a [template letter can be found here](#) **‘Annex’**

1. A letter on the manufacturer’s headed paper with the full address, company name and logo
2. Signature from manufacturer CEO, Person Responsible for Regulatory Compliance (PRRC) or a delegated colleague who can accept responsibility over the users approved for the organisation(s), stating that the user is the designated Organisation Lead.
3. Details of the assigned Organisation Lead must include:
 - Role – and date of appointment/activation of role
 - Name
 - Email

4. If the Organisation Lead is a representative of the manufacturer (UKRP or Authorised representative NI) then the letter should include the name of the representative organisation and affiliation
5. Dated within a month of the registration request
6. Details for which class of medical devices they manufacture and will be reporting for via MORE

Validation documentation must be emailed to AIC@mhra.gov.uk at the time of registration. If this is not received, the request will not be processed. If supporting documentation is not received within 1 month after registration, the submission will be rejected. The MHRA will aim to complete all registration requests within 7 working days.

It is required that you use the template letter and email in the **'Annex'** to speed up the registration and validation process and send this from the same email used in the account request.

'Manufacturer/ Authorised Representative /UKRP' account registration

You will need to follow the below steps to register your account.

- From the MORE login page <https://more.mhra.gov.uk/loginselect> create account

- From the create account page please select your role from the 'user group' dropdown list. This will be Manufacturer, Authorised Representative, UKRP or Other Submitter/Importer/Distributor.

- If you select the Manufacturer, Authorised Representative or UKRP as your user role, you will then have to pick the associated organisation using the look up function.
 - You will need to begin typing to display and select your organisation from the drop-down field.
 - If there are multiple options under the organisation name, please select the correct entry based on the account number displayed with the organisation name. The account number aligns with the Device Registration database.
 - The organisation that you select will be pinned below this field as confirmation of your selection.
- Add your details within the personal details fields whilst ensuring all mandatory fields marked with an asterix (*) are completed. Address relates to your own address and does not need to match the organisation address.
- Select your communication preference using the check box
- Create a password using the specified criteria
- Read and check the Terms and Conditions check box to confirm your understanding and acceptance of these terms and conditions
- If all required fields are completed then the 'create user' button at the bottom of the screen will change from grey to blue. Select 'create user' to submit your registration request. When successfully created, a pop-up confirming account creation will appear.
- Once your account is approved you will be able to select your organisation when you log in with your email and password.

NOTE: Please see relevant sections for [validation documentation](#) and '[Annex](#)' for providing supporting documentation to complete the registration process if you are the first user to register for an organisation.

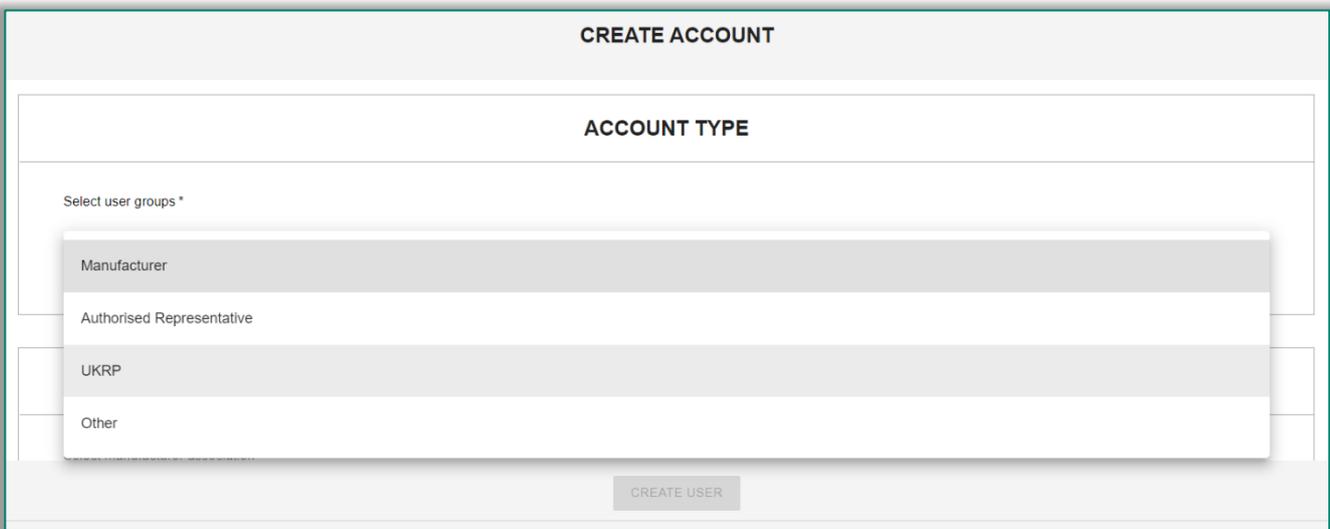
- It is important to ensure you are associated with the correct Manufacturer Organisation as registered in the MHRA Devices Registration Database. The selection of the correct organisation will ensure Manufacturer and device information will be pre-populated in the reporting forms.

- As a manufacturer you will receive notifications for reports submitted against the Organisation by associated representatives and will be able to view these reports in report management. The MHRA will also send Industry Notification of a Public Reports (INPR) to manufacturers for their registered devices, and it is therefore important to consider who is added as a user as well as their associated roles to ensure access to these reports is appropriate, where required.

Multi-role account creation/registration

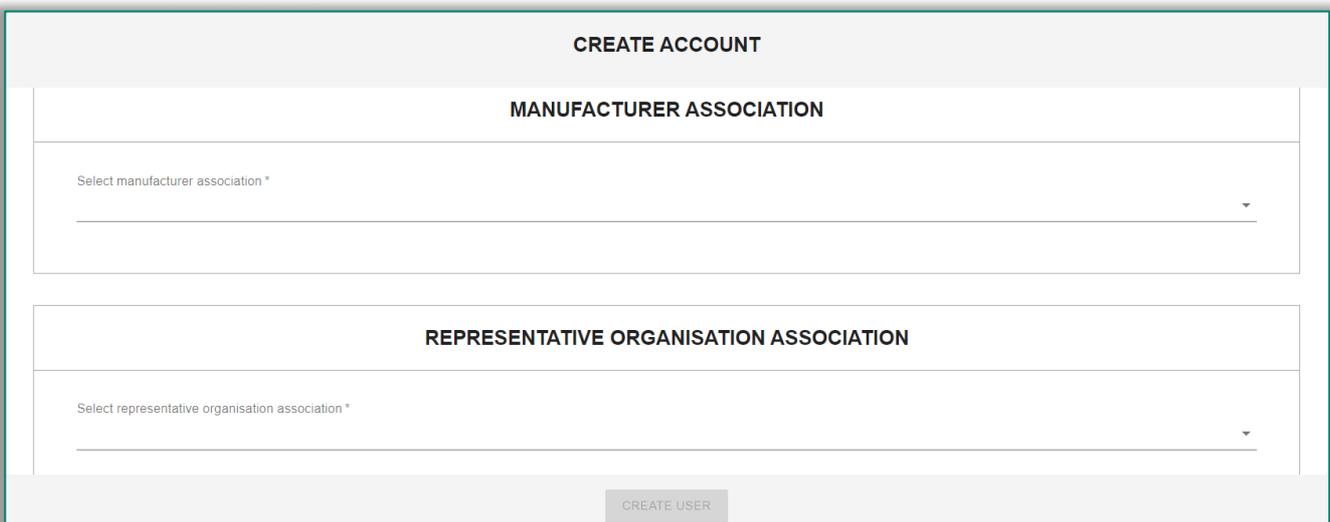
If you are associated with several companies as below, you can select multiple roles during the registration process.

- a UK Responsible Person, or
 - an Authorised Representative, or
 - as a Manufacturer and UK Responsible Person
- From the MORE login page <https://more.mhra.gov.uk/loginselect> create account
 - From the create account page select 'Manufacturer and UKRP' from the 'user group' dropdown list.



The screenshot shows the 'CREATE ACCOUNT' page. At the top, it says 'CREATE ACCOUNT'. Below that is a section titled 'ACCOUNT TYPE'. There is a dropdown menu labeled 'Select user groups *'. The dropdown menu is open, showing four options: 'Manufacturer', 'Authorised Representative', 'UKRP', and 'Other'. At the bottom of the page, there is a 'CREATE USER' button.

- You will then have the option to select the organisation from the 'manufacturer association' panel AND 'representative organisation association' panel using the look up function.
 - You will need to begin typing to display and select your organisation from the drop-down field.
 - The organisation(s) that you select will be pinned below this field as confirmation of selection.



The screenshot shows the 'CREATE ACCOUNT' page. At the top, it says 'CREATE ACCOUNT'. Below that is a section titled 'MANUFACTURER ASSOCIATION'. There is a dropdown menu labeled 'Select manufacturer association *'. Below this is a section titled 'REPRESENTATIVE ORGANISATION ASSOCIATION'. There is a dropdown menu labeled 'Select representative organisation association *'. At the bottom of the page, there is a 'CREATE USER' button.

- Add your details within the personal details fields whilst ensuring all mandatory fields marked with an asterix (*) are completed.
- Select your communication preference using the check box
- Create a password using the specified criteria
- Read and check the Terms and Conditions check box to confirm your understanding and acceptance of these terms and conditions
- If all required fields are completed, then the 'create user' button at the bottom of the screen will change from grey to blue. Select 'create user' to submit your registration request. When successfully created, a pop-up confirming account creation will appear.
- Once your account is approved you will be able to select the organisation you want to report on behalf of or manage the account when you log into MORE.

NOTE: Please see relevant sections for [validation documentation](#) and '[Annex](#)' for providing supporting documentation to complete the registration process if you are the first user to register for an organisation.

- It is important to ensure you are associated with the correct Manufacturer Organisation as registered in the MHRA Devices Registration Database. The selection of the correct organisation will ensure Manufacturer and device information will be pre-populated in the reporting forms.

Other – Submitter/Distributor/importer account creation

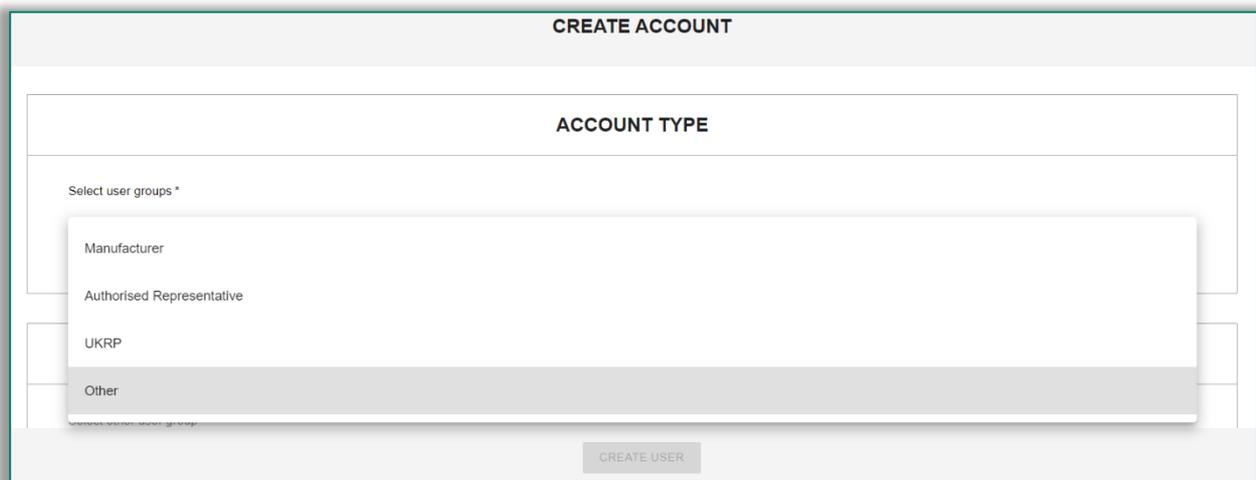
If you are not a Manufacturer, or are not associated with a Manufacturer as a UK Representative Person or an Authorised Representative, for example if you are a Distributor, Importer or Supplier, then you can submit a report for an incident with a medical device by registering with a user role of 'Other'.

If you are a Sponsor of a Clinical study and need to submit a report for an incident with a medical device, you can register with a user role as 'Other'.

If you are submitting reports on behalf of a Manufacturer that is not registered in the MHRA Devices Registration Database, you will need to register as 'Other'.

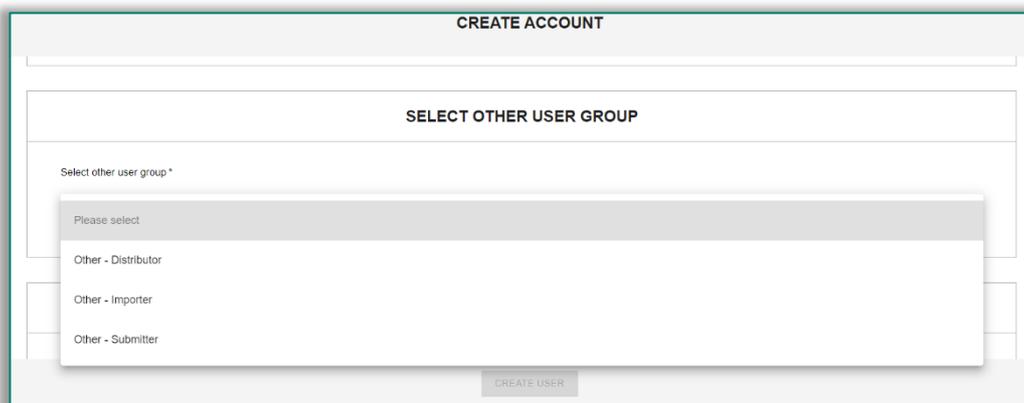
'Other' users do not need to go through an approval process as they will only have access to reports they themselves have submitted.

- From the MORE login page <https://more.mhra.gov.uk/loginselect> create account
- From the create account page select 'Other' from the 'user group' dropdown list.



The screenshot shows the 'CREATE ACCOUNT' page. Under the heading 'ACCOUNT TYPE', there is a dropdown menu labeled 'Select user groups *'. The menu is open, showing the following options: 'Manufacturer', 'Authorised Representative', 'UKRP', and 'Other'. The 'Other' option is highlighted in grey. Below the dropdown menu is a 'CREATE USER' button.

- You will then have the option to select Importer, Submitter or Distributor from the Other user role



The screenshot shows the 'CREATE ACCOUNT' page. Under the heading 'SELECT OTHER USER GROUP', there is a dropdown menu labeled 'Select other user group *'. The menu is open, showing the following options: 'Please select', 'Other - Distributor', 'Other - Importer', and 'Other - Submitter'. The 'Other - Distributor' option is highlighted in grey. Below the dropdown menu is a 'CREATE USER' button.

- Add your details within the personal details fields whilst ensuring all mandatory fields marked with an asterix (*) are completed. Address relates to your own address and does not need to match the organisation address.
- Select your communication preference using the check box
- Create a password using the specified criteria
- Read and check the Terms and Conditions check box to confirm your understanding and acceptance of these terms and conditions
- If all required fields are completed the 'create user' button at the bottom of the screen will change from grey to blue. Select 'create user' to submit your registration request. When successfully created a pop-up confirming account creation will appear.

- If you select the role 'Other' you will be able to submit reports for any Organisation. You will not be associated with a Manufacturer Organisation registered in the MHRA Devices Registration Database and will therefore not be able to select a Manufacturer or their device information for auto-population. Manufacturer and device information will need to be manually entered.

- If you are not associated to a manufacturer organisation you will only receive notifications on the reports you have submitted to the MHRA.

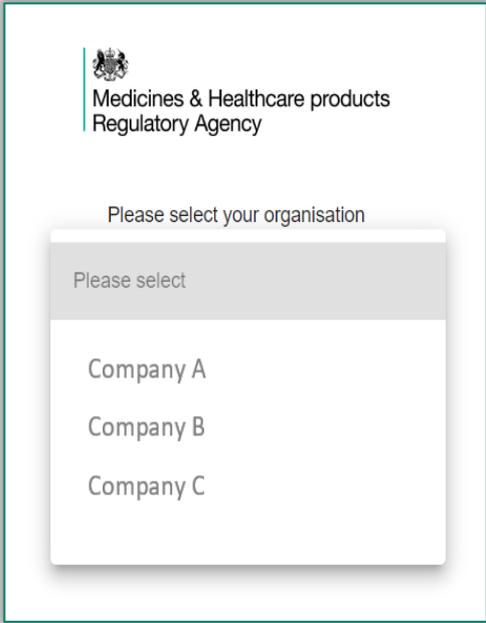
- You will not receive any Industry Notification of Public Reports (INPR) on your MORE account in relation to a device you have reported against if you are not associated with a manufacturer organisation through registration as a Manufacturer, UKRP or Authorised Representative.

Section 3: Logging in to MORE

- From the login page, enter your registered email and password
- Select the organisation from the drop-down list and enter. You will only be able to view organisations for which you have been approved.
- You will then have access to your manufacturer organisation dashboard and menu options.
You will also have access to your personal details which you can edit and update at any stage. This will include name and contact details, such as email.

If you have been set up with a multi-role account for more than one organisation you will need to select the organisation for which you need access. You will not see reports in report management for the other organisations that you represent unless you log out and then log back in and select the organisation.

You will not be able to report against devices for an organisation unless you are correctly logged in for that account. When reporting incidents as a representative, please log in to the manufacturer you are reporting on behalf of to begin submitting reports.



The screenshot shows the login interface for the Medicines & Healthcare products Regulatory Agency. At the top left is the agency's logo and name. Below it, a prompt asks the user to 'Please select your organisation'. A dropdown menu is open, displaying 'Please select' at the top and three options: 'Company A', 'Company B', and 'Company C'.

Auto population of manufacturer and device details in reporting forms will be dependent on which organisation you log into and based on the Device Registration database. Please check that you have selected the correct organisation if the details for manufacturer or device are not as expected.

Password reset

If you have forgotten your password, a reset password email can be sent to your email by selecting the 'Forgot your password?' link on the login page <https://more.mhra.gov.uk/login>. You must enter the email address associated with your account. If you do not receive an email, please check your spam, or junk mail folder.

 <p>Medicines & Healthcare products Regulatory Agency</p> <p>Email</p> <input type="text" value="firstname.lastname@org.uk"/> <p>Password</p> <hr/> <p><small>Field is required</small></p> <p>SIGN IN</p> <p>Forgot your password?</p> <p>Create an account</p>	 <p>Medicines & Healthcare products Regulatory Agency</p> <p>Forgotten your password? Simply enter your email address below and a reset password email will be sent to you.</p> <p>Email</p> <input type="text" value="firstname.lastname@org.uk"/> <p>SUBMIT</p> <p>← BACK</p>	 <p>Medicines & Healthcare products Regulatory Agency</p> <div style="text-align: center;">  <p>SUBMITTED</p> </div> <p>Thank you for submitting a forgotten password request. If the email address you submitted is associated to an existing account, then a password reset email will be sent to the email address assigned to that account.</p> <p>← BACK</p>
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If you are a Standard User and are unable to reset your password using these steps, please contact your Organisation Lead who can contact the MHRA on your behalf. Please include the below email subject title when emailing for a password reset of an Organisation Lead account:

Email subject title: **<MORE platform – Organisation Lead Password reset>**

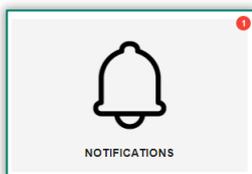
Section 4: Change Management

An Organisation can have one or more Organisation Leads. The first Organisation Lead will have their account request approved by the MHRA. All subsequent requests to be associated to an organisation will be managed by the Organisation Lead(s).

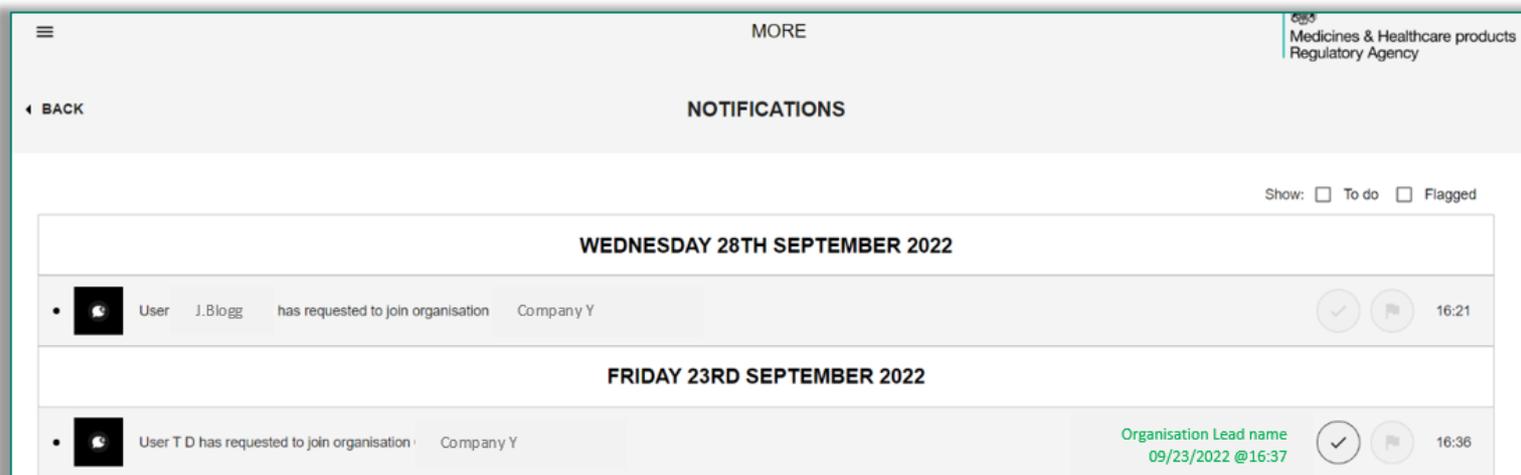
It is the responsibility of the Organisation Lead to regularly check for new registrations and to validate these for approval or rejection appropriately. Local processes must be in place to ensure users remain up to date and that users are deactivated, where necessary.

The MHRA will be unable to progress registrations on behalf of or in the absence of an Organisation Lead. It is therefore important to consider if more the one Organisation Lead is required for your organisation to provide cover and for business continuity.

As an Organisation Lead you will receive a notification request indicated by a red circle in the top right-hand corner of the notifications tile for any new registrations. You will also receive an email notification alerting you to a new registration request(s) which requires action to approve/reject.



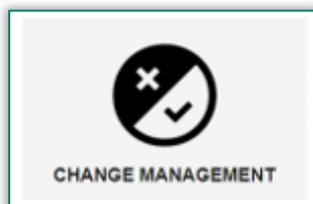
Selecting the notification tile will display all completed and pending registration requests. These will be listed by date. You will also be able to view which Organisation Lead actioned the account request process with a date and time stamp. At the top right-hand side of the page, you can use the filters to select registrations which are yet to be completed ('to do') or those that have been manually flagged.



The screenshot shows the 'NOTIFICATIONS' page in the MHRA system. The page header includes 'MORE' and 'Medicines & Healthcare products Regulatory Agency'. The main content area is titled 'NOTIFICATIONS' and features a 'BACK' button. There are filters for 'Show: To do' and 'Flagged'. The notifications are listed by date, with two entries visible:

- WEDNESDAY 28TH SEPTEMBER 2022**
 - User J. Blogg has requested to join organisation Company Y. Status: To do. Time: 16:21.
- FRIDAY 23RD SEPTEMBER 2022**
 - User T D has requested to join organisation Company Y. Status: To do. Time: 16:36. Organisation Lead name: 09/23/2022 @16:37.

You can also access registration requests for processing directly from the 'Change Management' tile on your dashboard or menu bar.



You can manage all registrations within change management and can filter current or historical information using the date picker options. The 'date from' field will be pre-set and will need to be changed if you want to view entries outside of the defined time period.

You can also filter by organisation if you are the Organisation Lead for more than one company. You will be able to view registration details for each organisation that you are responsible for as an Organisation Lead. If a registration request is in read-only view you will need to log out and log back into the account for the associated organisation to view, edit and/or complete registration.

The approval status drop down can be used to filter for only pending registrations or you can use the multi-select functionality to see all activity for pending, approved and rejected registrations.

The screenshot shows the 'Change Management' interface. At the top right, it says 'Medicines & Healthcare products Regulatory Agency'. Below the header, there are filter options: 'Organisation(s)', 'Approval Status' (highlighted with a red box and showing a dropdown menu with 'Approved, Rejected, Pending'), 'Date From' (01/09/2022), and 'Date To' (30/09/2022). Below the filters is a table with the following data:

SUBJECT	APPROVAL STATUS	AUTHOR	CREATED
User has requested to join organisation: Company X	PENDING	Joe Bloggs	05/09/2022 12:13
User has requested to join organisation: Company X	APPROVED	John Smith	02/09/2022 16:55
User has requested to join organisation: Company X	REJECTED	Jane Doe	02/09/2022 11:00

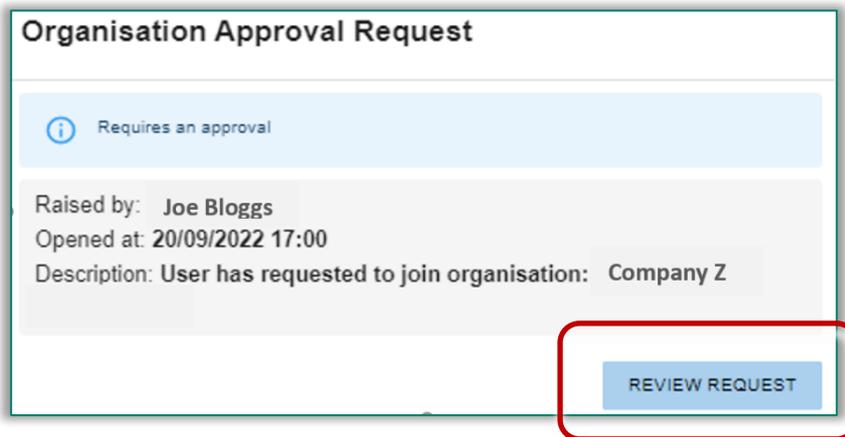
Registration Approvals

Prior to approval, a user will only have access to their 'workspace' but not to the full 'Standard User' or 'Organisation Lead' access levels. You must process any pending registrations in a timely manner to ensure users have access to the required level.

For users who only have access to their workspace (while accounts are pending or 'Other' users), manual organisation data entry will be required. When users have access to only their workspace, they will need to manually enter these details.

To approve a request, you can select the registration from notifications or change management. Both options will display a review request pop up which will include key information on the name of the requester and organisation.

Select review request to view registration details such as Username, email address and organisation.



You will then be able to view the details that the user has registered with and will have the option to select approve/reject the registration.

When an account is approved a confirmation email will be sent to the user via the email used for registration.

All registrations will have a default role of Standard user. If you are approving a request for another Organisation Lead you will need to change the role type on this approval page to Organisation Lead after approval is complete. This user will then have the same access and permissions as you (dashboard tiles) and will also be process registration requests. **The user must be approved before you change their role from Standard User to Organisation lead**

To approve the registration request, click the green tick box and subsequent approve button.

The screenshot shows the user profile page for Joe Bloggs. At the top right, it says "Medicines & Healthcare products Regulatory Agency". The user's name "Joe Bloggs" is centered. Below the name, a notification box says "User has requested to join organisation: Company Z". To the right of this notification are two circular icons: a green one with a white checkmark and a red one with a white 'X'. The green icon is highlighted with a red square. Below the notification, there are buttons for "DE-ACTIVATE" and "EDIT". The main section is titled "PERSONAL DETAILS" and contains a table of user information.

PERSONAL DETAILS	
TITLE Mr	FIRST NAME * Joe
LAST NAME * Bloggs	EMAIL * Joe.Bloggs@companyZ.com
TELEPHONE COUNTRY CODE -	TELEPHONE
TELEPHONE EXTENSION	ADDRESS LINE 1

This screenshot is identical to the one above, but with the "APPROVE" button highlighted by a red rectangle. The "APPROVE" button is a green rectangular button located below the notification box and above the "PERSONAL DETAILS" section.

Click edit and then select Organisation Lead from the role drop down list. You must click 'save' after changing the role type for these settings to take effect.

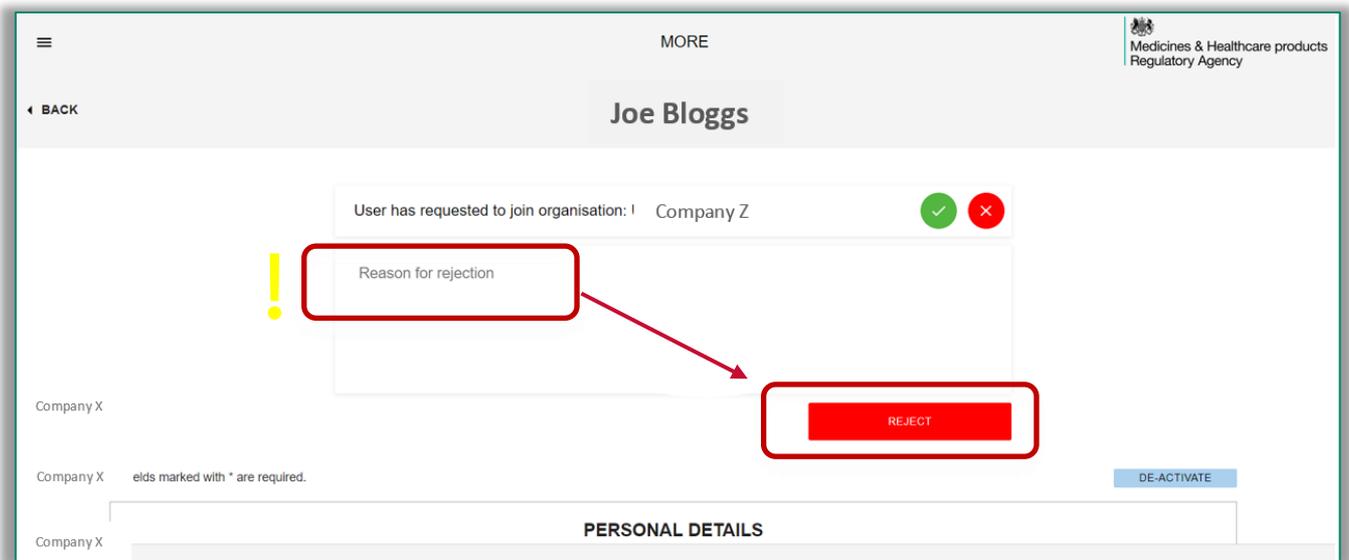
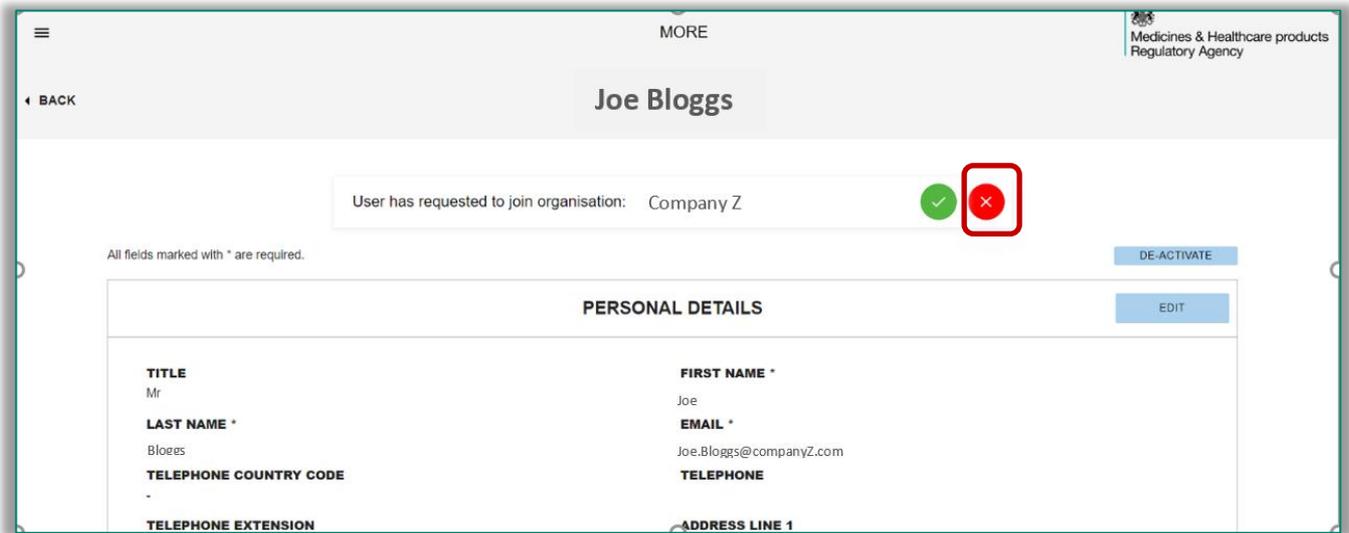
This screenshot shows the configuration page for a role. At the top, there is a header section with the title "ROLE" and an "EDIT" button on the right, which is highlighted with a red rectangular box. Below this, the role is identified as "Standard". The main section is titled "PERMISSIONS FOR" and contains four tiles: "REPORTS TILE" (Default), "REPORT MANAGEMENT TILE" (Default), "REPORT CONFIGURATION TILE", and "REPORT CONFIGURATION (BETA) TILE". An "EDIT" button is located at the top right of the permissions section.

This screenshot shows the same configuration page but with the "EDIT" button from the previous screenshot clicked. The "ROLE" header now has a "CANCEL" button on the left and a "SAVE" button on the right. The "Role" field is active, and a dropdown menu is open, showing the following options: "Please select", "Organisation Lead", and "Standard". The "Standard" option is currently selected and highlighted. Below the role field, the "PERMISSIONS FOR" section is visible, with an "EDIT" button on the right.

Registration Rejections

It is the responsibility of the Organisation Lead to reject any registration requests for users who are unknown to the organisation, have been created in error or are not appropriate for any other reason.

To reject a registration request, you can access the request from the 'Notifications' tile or 'Change management' tile and then select the rejection button marked by a red cross. You will then be able to enter a reason for rejection which will be automatically emailed to the user for further action, if required. It is important that the rejection reason is clear if further action is required.



When a rejection has been completed an email notification will be sent to the user with reasons and additional details. NOTE: Do not reject an account unless you are unable to

identify the user as a member of your organisation. Once the user has been rejected, they will be unable to register again using the same email. If the user profile details are incorrect, it is recommended that these are updated by the Organisation Lead (at the time of approval) or the user (once approved) in place of a registration rejection.

Section 5: User Management

Invite new users

- As an Organisation Lead you can invite new users to join the MORE portal via the 'User Management' tile. You must invite a user by following the steps below which will generate an email for the invitee to complete registration. Go to User management and select the 3 vertical dots in the top right-hand corner

Medicines & Healthcare products Regulatory Agency

Look up user (Name)

Organisation(s) Role(s) Approval Status

Include Deactivated

NAME ROLE USERS ORGANISATION

- Click on invite user to organisation

Medicines & Healthcare products Regulatory Agency

Look up user (Name)

Organisation(s) Role(s) Approval Status

Include Deactivated

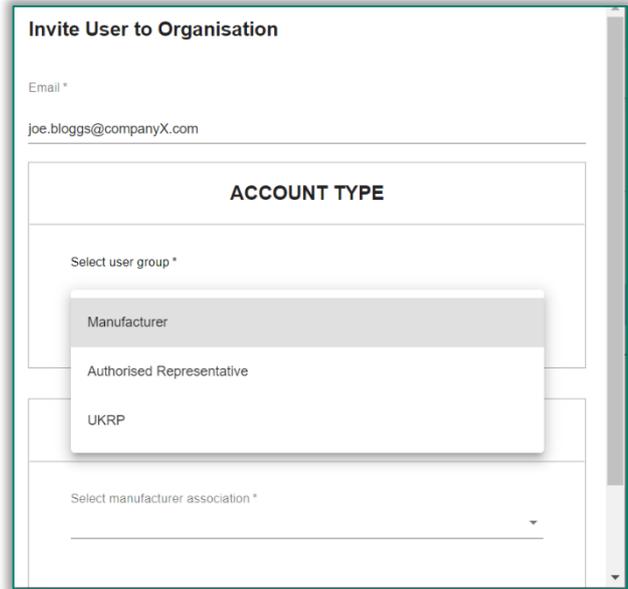
NAME ROLE USERS ORGANISATION

Invite user to organisation

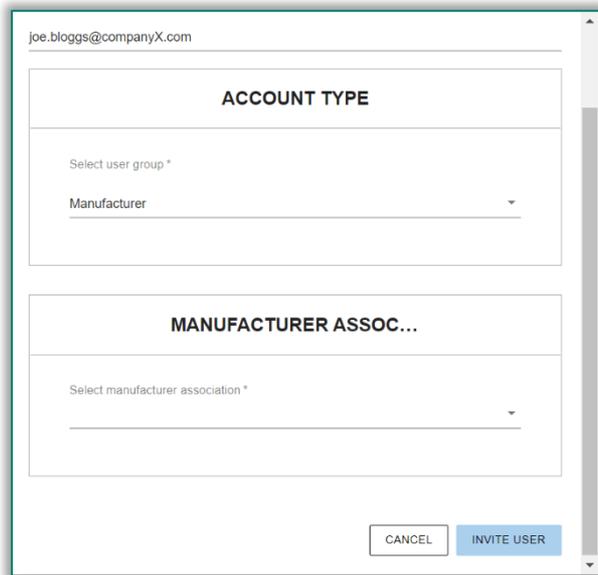
You will be able to add the users email address, their role using the drop-down function and the associated organisations. You will need to begin typing to display and select the organisation that the user needs to be associated to.

Please note: you will only be able to associate the invitee to an organisation that you are associated to, however you can invite them as any user group.

Note: Selecting user role at this stage is only single select.



The screenshot shows the 'Invite User to Organisation' form. At the top, there is a text input field for 'Email *' containing 'joe.bloggs@companyX.com'. Below this is a section titled 'ACCOUNT TYPE'. Inside this section, there is a dropdown menu labeled 'Select user group *' which is currently open, showing three options: 'Manufacturer' (highlighted), 'Authorised Representative', and 'UKRP'. Below the dropdown is another dropdown menu labeled 'Select manufacturer association *' which is currently empty.



The screenshot shows the 'Invite User to Organisation' form. At the top, there is a text input field for 'Email *' containing 'joe.bloggs@companyX.com'. Below this is a section titled 'ACCOUNT TYPE'. Inside this section, there is a dropdown menu labeled 'Select user group *' which is currently set to 'Manufacturer'. Below this is a section titled 'MANUFACTURER ASSOC...'. Inside this section, there is a dropdown menu labeled 'Select manufacturer association *' which is currently empty. At the bottom of the form, there are two buttons: 'CANCEL' and 'INVITE USER'.

Select the invite user button which will automatically send an email to the user (using the email entered).

When the invited recipient receives the email, they will be able to click the invite link which will take them to the registration form. They will need to complete all the mandatory fields (marked with an *) and create an account password using the defined criteria. If the user already has an account, they will be notified by email that they have been added to the organisation.

If you require the user to have Organisation Lead access you will need to first approve their registration request as a Standard User. You will then need to promote their role once they have completed registration (See instructions under section titled [Promoting User roles](#)). Once the approval is complete with the role upgrade (if required), the new registration will be visible as completed and approved in change management.

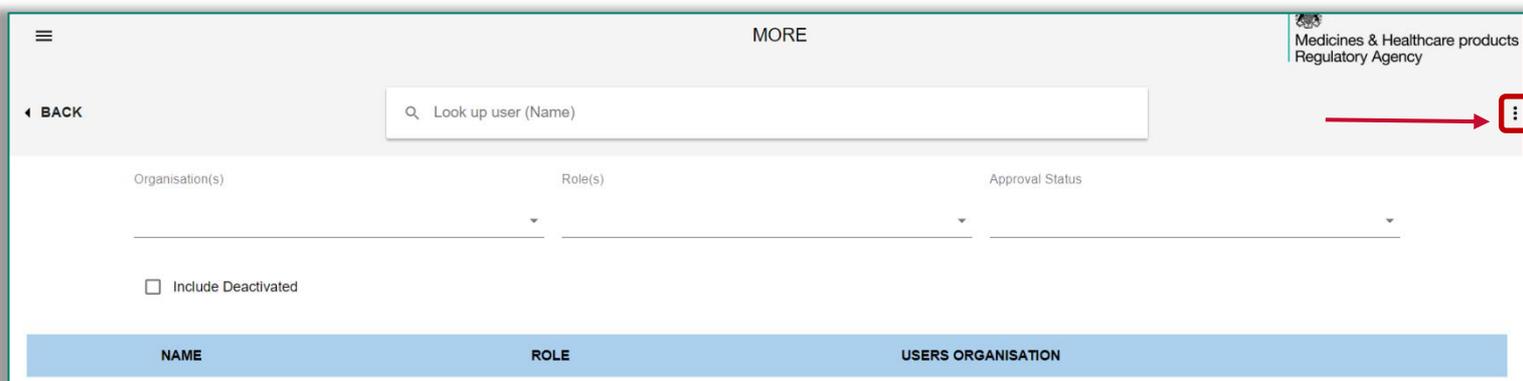
Please note: In the 'User Management' tile, it is preferable that the invite new user option (available from top right-hand corner) is selected in preference of the 'Create new user' button (bottom of the screen) as this method does not generate an email for the new user account. By selecting the 'Create new user' button, an Organisation Lead will need to complete the users details themselves, generate a password and share this with the user via a separate secure route. The Organisation Lead will need to ensure that the new user changes their password as soon as possible.

A record of the newly added user will not be viewable in the Change Management tile and there will be no record of who created the new user account. If the 'Create new user' button or 'invite new user' option is used, local processes must be in place to track these additions, noting that the user profile will be present in the 'User Management' tile for reference and updating if required.

Add existing users

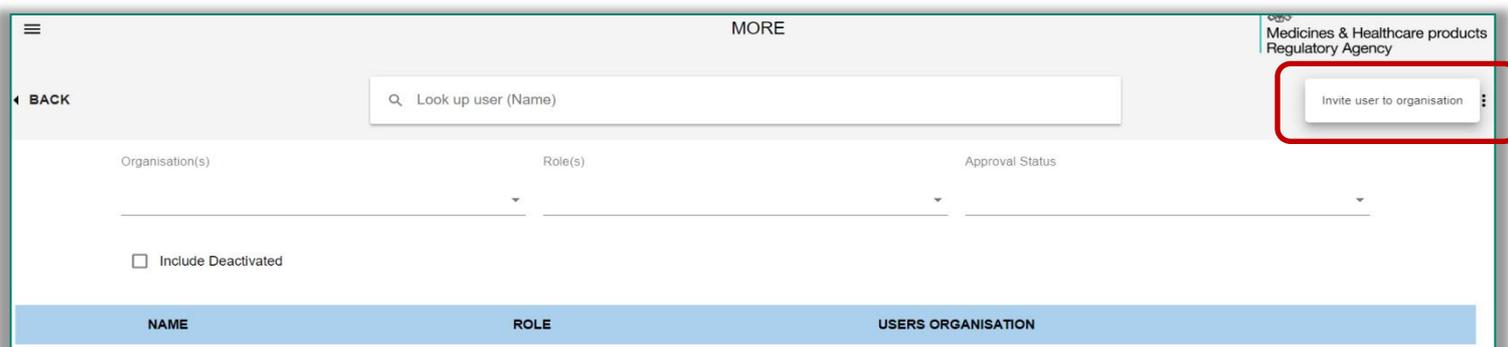
As an Organisation Lead you can invite an existing MORE user to join your organisations account. This is helpful where a user has an account already but needs to be added to additional organisations. You may be notified directly by the user that they have an existing MORE account or the user may notify you that they receive a 'duplicate email' error when trying to register. In this situation you will need to invite them as an existing user.

- Go to User management and select the 3 vertical dots in the top right-hand corner



The screenshot shows the 'User Management' interface. At the top, there is a header with a hamburger menu icon on the left, the word 'MORE' in the center, and the text 'Medicines & Healthcare products Regulatory Agency' on the right. Below the header, there is a search bar with the placeholder text 'Look up user (Name)'. To the right of the search bar, there are three vertical dots in a red box, with a red arrow pointing to it. Below the search bar, there are three dropdown menus labeled 'Organisation(s)', 'Role(s)', and 'Approval Status'. There is also a checkbox labeled 'Include Deactivated'. At the bottom, there is a table header with columns 'NAME', 'ROLE', and 'USERS ORGANISATION'.

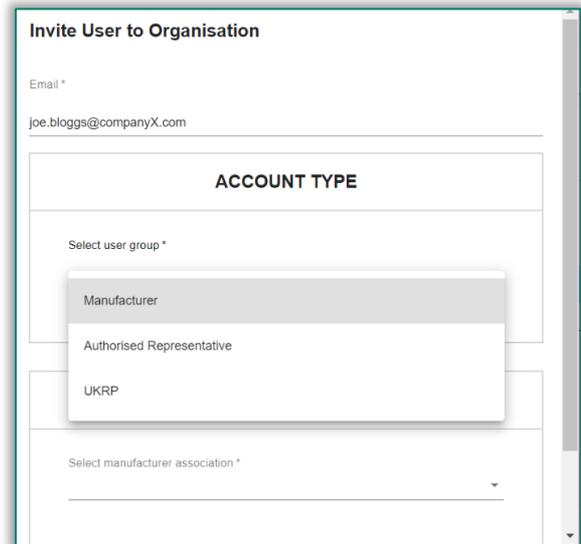
- Click on invite user to organisation



The screenshot shows the 'User Management' interface. At the top, there is a header with a hamburger menu icon on the left, the word 'MORE' in the center, and the text 'Medicines & Healthcare products Regulatory Agency' on the right. Below the header, there is a search bar with the placeholder text 'Look up user (Name)'. To the right of the search bar, there is a button labeled 'Invite user to organisation' in a red box. Below the search bar, there are three dropdown menus labeled 'Organisation(s)', 'Role(s)', and 'Approval Status'. There is also a checkbox labeled 'Include Deactivated'. At the bottom, there is a table header with columns 'NAME', 'ROLE', and 'USERS ORGANISATION'.

You will be able to add the users email address, their role using the drop-down function and the associated organisations. The email address that is used must be the same as the account they already have. You will need to begin typing to display and select the organisation that the user needs to be associated to.

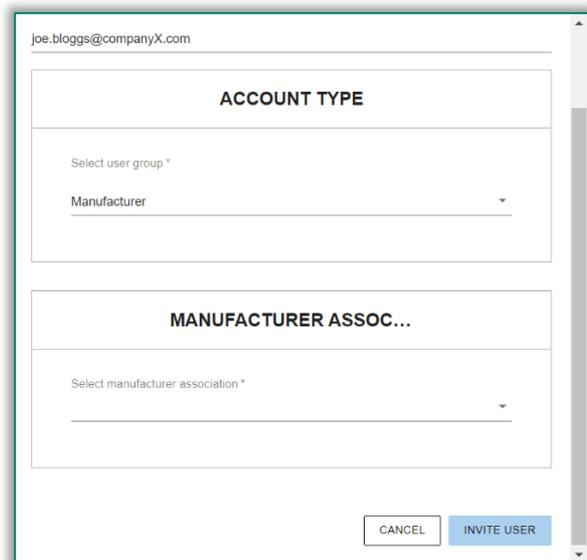
Please note: you will only be able to associate the invitee to an organisation that you are associated to, however you can assign them to any user group.



The screenshot shows a web form titled "Invite User to Organisation". At the top, there is an "Email *" field containing "joe.bloggs@companyX.com". Below this is a section titled "ACCOUNT TYPE" which contains a "Select user group *" dropdown menu. The dropdown menu is open, showing three options: "Manufacturer" (highlighted), "Authorised Representative", and "UKRP". Below the dropdown is another "Select manufacturer association *" dropdown menu which is currently empty.

Note: Selecting user role at this stage is only single select.

Select the invite user button which will automatically send an email to the user (using the email entered).



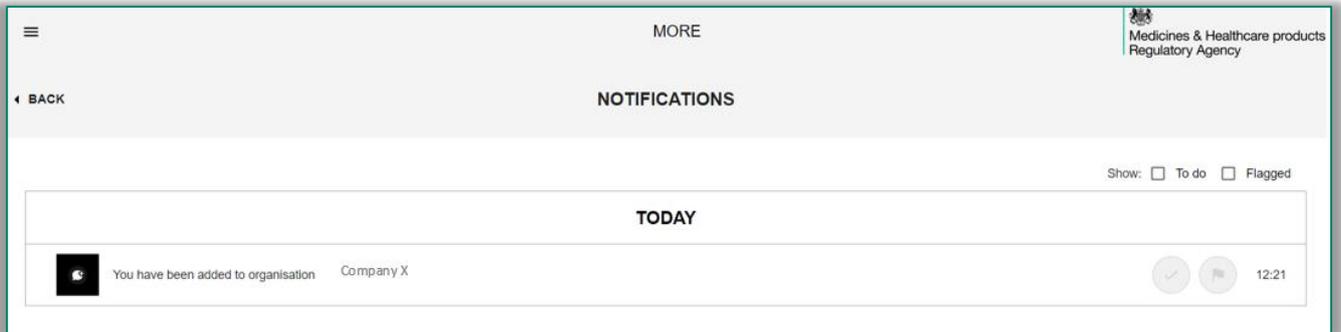
The screenshot shows the same "Invite User to Organisation" form. The "Select user group *" dropdown menu is now closed and displays "Manufacturer". Below this is a section titled "MANUFACTURER ASSOC..." which contains a "Select manufacturer association *" dropdown menu which is currently empty. At the bottom right of the form, there are two buttons: "CANCEL" and "INVITE USER".

When the invited recipient receives the email, they will be able to click the invite link which will take them to the registration form. They will need to complete all the mandatory fields (marked with an *) and create an account password using the defined criteria.

If you require the user to have Organisation Lead access you will need to upgrade their role once they have completed registration (See instructions under section titled

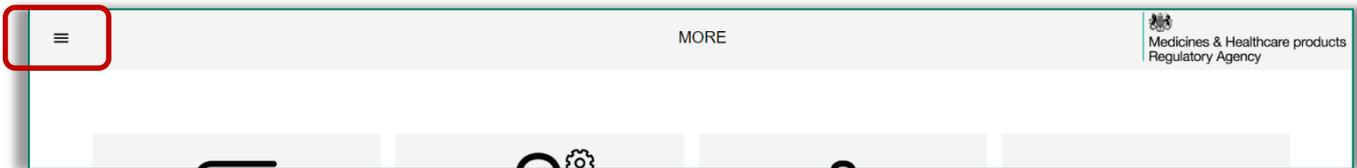
[Promoting/Downgrading User roles](#)). The new registration will be visible as completed and approved in change management.

The invited user will automatically have access to the organisation's details. When they login, the new Company will appear on the organisation selection drop down list. They will also receive a notification to inform them that they have been added to the organisation.

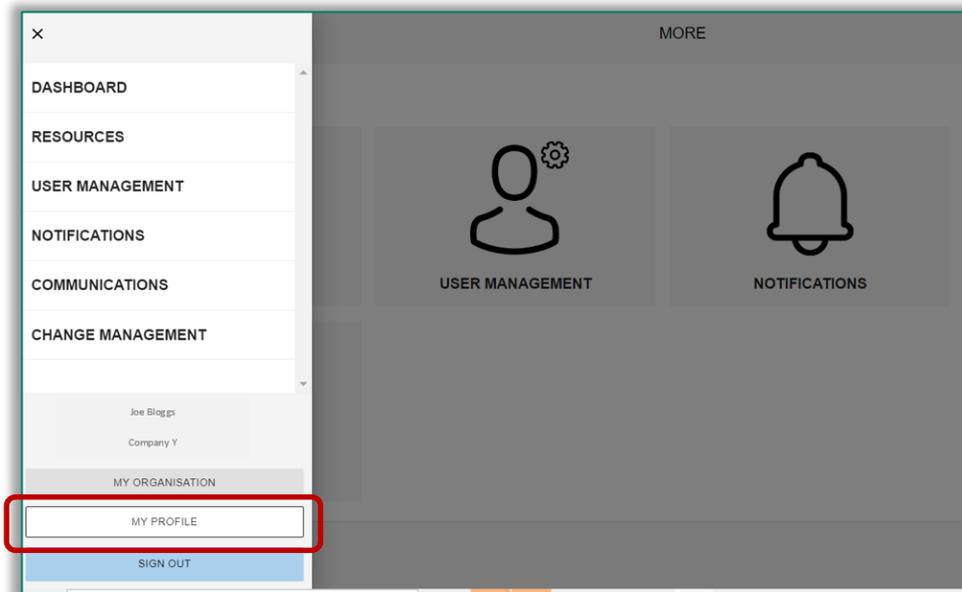


Editing user profiles

During registration or post registration, a user can edit their profile details, for example if there are changes to their name or contact details including email. By logging into their account and selecting the burger menu in the top Left-hand side of the screen.



Select 'My profile' to view and edit all personal details.



Select edit in the top-right of each section which requires review and click save before exiting the profile.

An Organisation Lead can edit profiles for Standard Users from within their organisation by selecting the user's name in the User Management tile, editing and saving as above.

Promoting User roles

To upgrade a user's account from standard user to Organisation Lead, you will need to locate the users account from the 'User Management' tile by selecting the organisation and using the search bar at the top of the page to locate the user if they are not already displayed on the list. You can click on the standard user as below to access and edit their personal details.

The screenshot shows a user management interface. At the top, there is a search bar labeled 'Look up user (Name)'. Below the search bar are three dropdown menus for 'Organisation(s)', 'Role(s)', and 'Approval Status'. There is also a checkbox for 'Include Deactivated'. Below these filters is a table with the following data:

NAME	ROLE	USERS ORGANISATION
Joe Bloggs	Organisation Lead	Company X
Jane Doe	Standard	Company X

At the bottom of the interface, there is a button labeled 'ADD NEW USER'.

- Click edit and then select Organisation Lead from the role drop down list. You must click 'save' after changing the role type for these settings to take effect.

The screenshot shows the user profile edit interface. The 'ROLE' section is highlighted with a red box and contains an 'EDIT' button. Below it is the 'PERMISSIONS FOR' section, which also has an 'EDIT' button. The permissions section is divided into four categories:

- REPORTS TILE: Default
- REPORT MANAGEMENT TILE: Default
- REPORT CONFIGURATION TILE
- REPORT CONFIGURATION (BETA) TILE



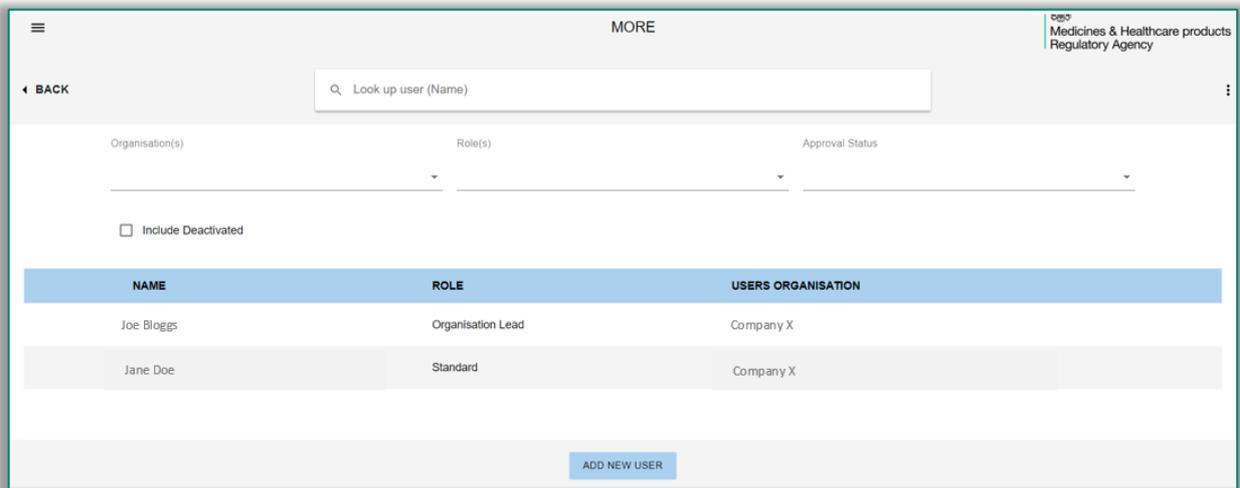
To downgrade a user’s role from Organisation Lead to Standard user you must contact the MHRA at AIC@mhra.gov.uk. An Organisation Lead will not have permissions to amend another Organisation Leads account, therefore a request to downgrade a user’s role to Standard User must be submitted to the MHRA. Please provide the users full name, email address role and organisation when requesting account downgrades. Please include the below email subject title when emailing for an Organisation Lead account downgrade:

Email subject title: **<MORE platform – Downgrading user role>**

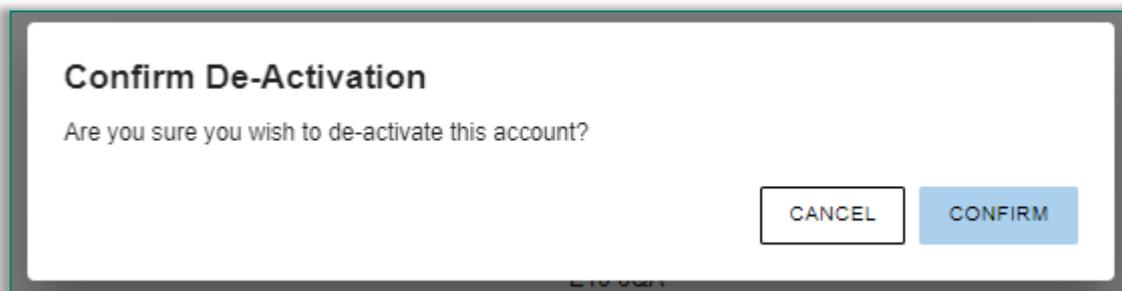
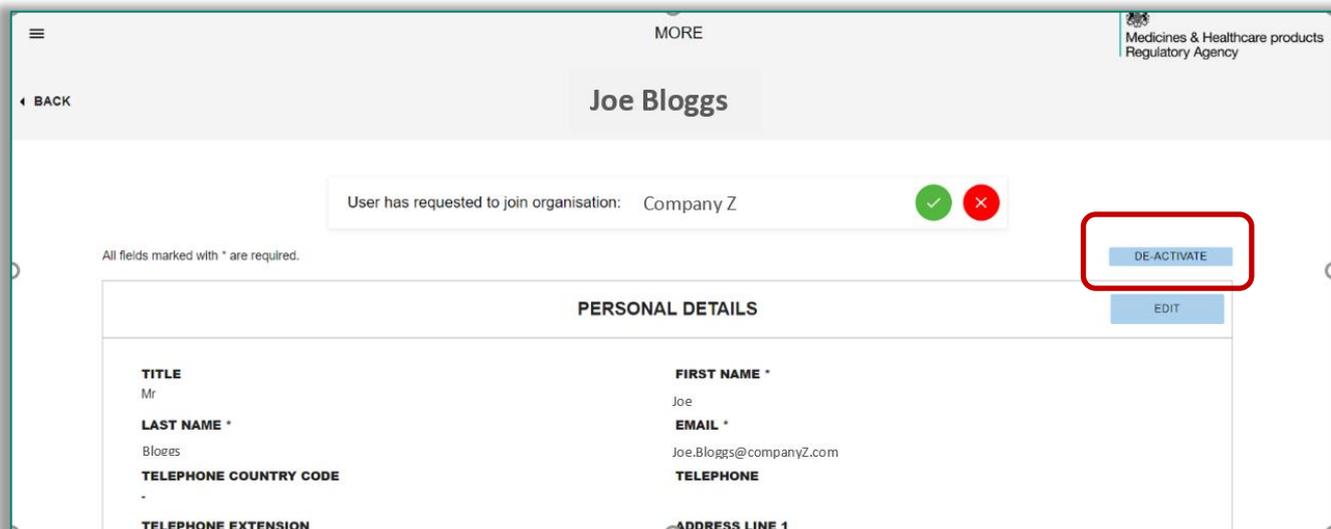
Deactivating users

An Organisation Lead can deactivate a Standard user account following the below steps.

Go to User management and select the user from the available list or search their name from the search bar at the top of the page.



Select the users name to display their profile details. In the top right-hand corner, click the deactivate button. A pop up will appear for account deactivation confirmation. The user will no longer have access to their account.



If an Organisation Lead leaves a company and their account needs to be deactivated, you must contact the MHRA at AIC@mhra.gov.uk. An Organisation Lead will not have permissions to amend another Organisation Leads account, therefore a request to downgrade a user role to standard user must be submitted to the MHRA. Please provide the users full name, email address role and organisation when requesting account downgrades.

Please include the below email subject title when emailing for the deactivation of an Organisation Lead account:

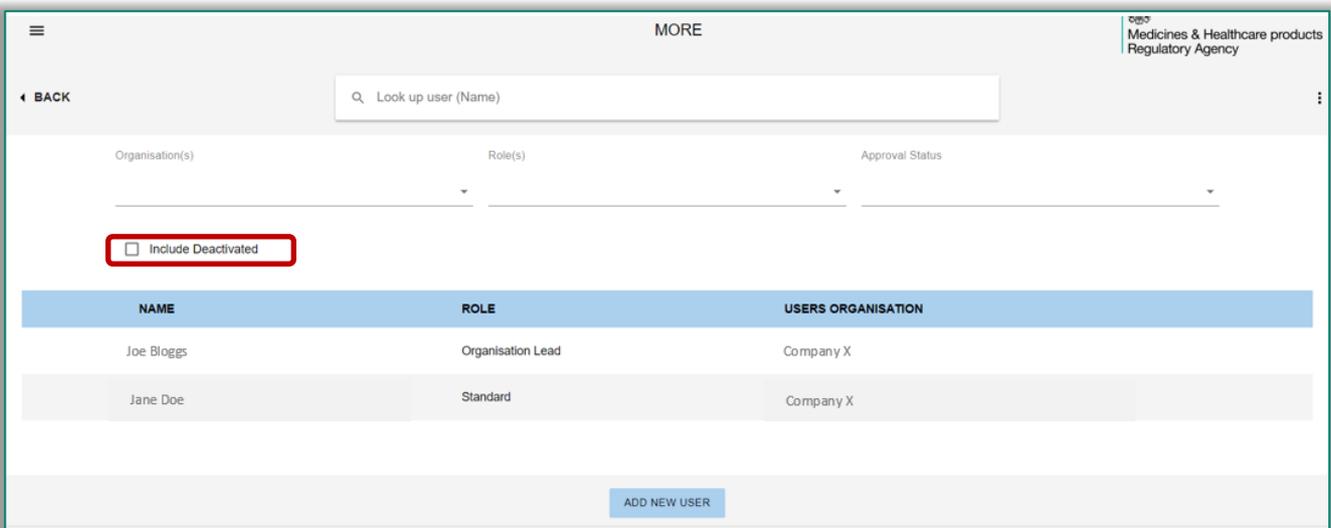
Email subject title: **<MORE platform – Deactivation of user account>**

If there is only one Organisation Lead for a company and they are requesting an account deactivation for themselves, it is their responsibility to ensure that an appropriate Organisation Lead has been set up in their place to process any future registration requests. This can take place by [upgrading a standard users account](#), by [inviting a new user](#) or by [inviting an existing user](#).

Reactivating users

A deactivated user can be reactivated using the same process. An Organisation Lead can reactivate a Standard user account following the below steps.

Go to the 'User Management' tile and select the user from the available list or search their name from the search bar at the top of the page. You will need to select the check box for 'include deactivated' users to display any deactivated accounts.

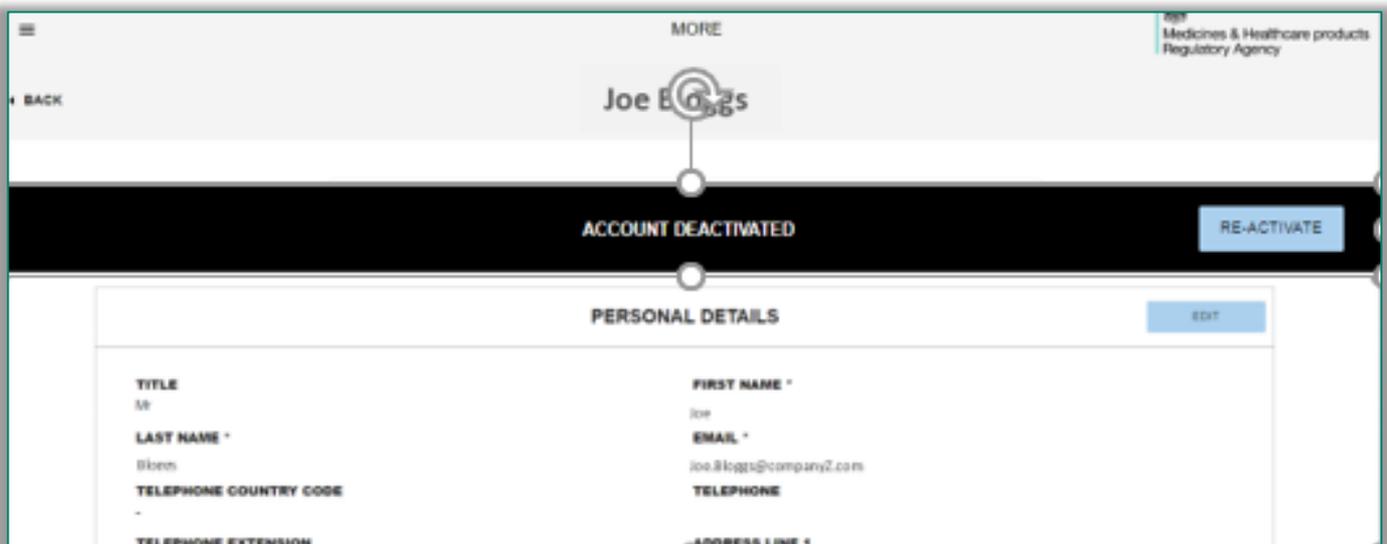


The screenshot shows the 'User Management' interface. At the top right, it says 'Medicines & Healthcare products Regulatory Agency'. Below the header, there is a search bar labeled 'Look up user (Name)'. Underneath the search bar, there are three dropdown menus for 'Organisation(s)', 'Role(s)', and 'Approval Status'. A checkbox labeled 'Include Deactivated' is highlighted with a red box. Below this, there is a table with the following data:

NAME	ROLE	USERS ORGANISATION
Joe Bloggs	Organisation Lead	Company X
Jane Doe	Standard	Company X

At the bottom of the interface, there is a button labeled 'ADD NEW USER'.

Select the users name to display their profile details. In the top right-hand corner, click the reactivate button in the top right-hand corner. The user will then be able to log into their account using their registered credentials.



The screenshot shows the user profile page for 'Joe Bloggs'. At the top, it says 'Medicines & Healthcare products Regulatory Agency'. Below the header, there is a profile card for 'Joe Bloggs'. Below the profile card, there is a black banner with the text 'ACCOUNT DEACTIVATED' and a blue button labeled 'RE-ACTIVATE'. Below the banner, there is a section titled 'PERSONAL DETAILS' with an 'EDIT' button. The personal details section contains the following information:

TITLE	FIRST NAME *
Mr	Joe
LAST NAME *	EMAIL *
Bloggs	Joe.Bloggs@companyZ.com
TELEPHONE COUNTRY CODE	TELEPHONE
-	
TELEPHONE EXTENSION	ADDRESS LINE 1

Inactive users will be automatically deactivated after six months if the account is not logged into.

In this situation a Standard user must contact the Organisation Lead to have the account reactivated and an Organisation Lead will need to contact the MHRA at AIC@mhra.gov.uk for account reactivation. Please provide the users full name, email address role and organisation when requesting account downgrades.

Please include the below email subject title when emailing for the reactivation of an Organisation Lead account:

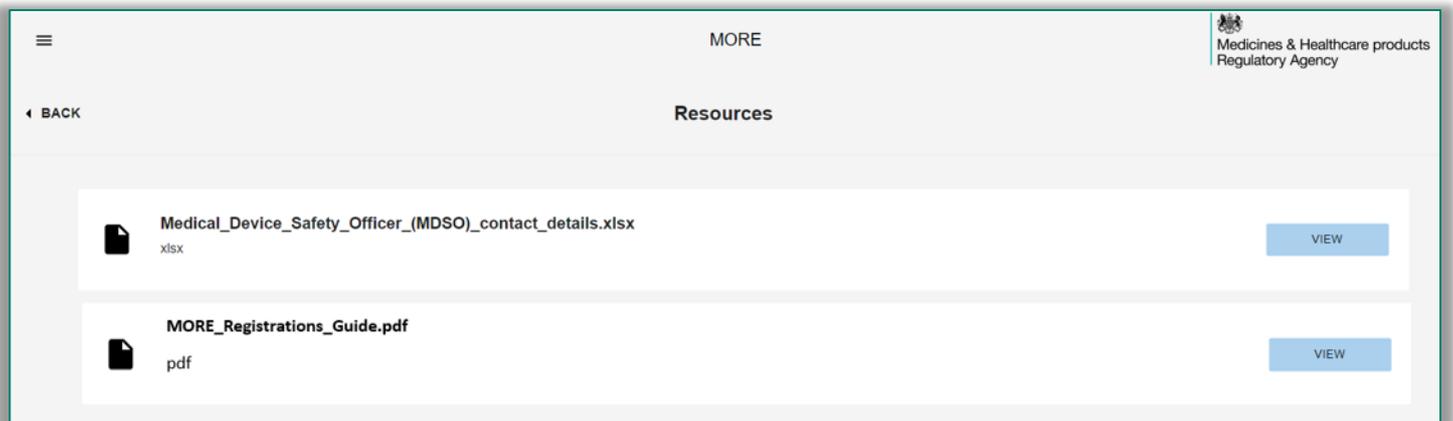
Email subject title: **<MORE platform – Reactivation of user account>**

Section 6: Resources

You can access resources relating to MORE submissions via the 'Resources' tile on the dashboard or left-hand side burger menu.

Resources will host documents, such as MDSO lists, guidance materials to support using MORE registrations and Submissions. Select 'View' to download the document of interest.

It is important to note that content for guidance documents may be updated and an up-to-date copy should be downloaded when required by the organisation.



Glossary

Acronym	
AIC	Adverse Incident Centre
API	Application Programming Interfaces
AR	Authorised Representative
FSCA	Field Safety Corrective Actions
INPR	Industry Notification of a Public Report
MDSO	Medical Devices Safety Officer
MFR	Manufacturer
MHRA	Medicines and Healthcare Products Regulatory Agency
MIR	Manufacturer Incident Report
MORE	Manufacturer's On-line Reporting Environment
PSR	Periodic Summary Reports
SAE	Serious Adverse Events
UKRP	UK Representative Person

Annex

Validation Template Email

Below is a template email which can be used to send registration validation supporting documentation to AIC@mhra.gov.uk

<<Subject line: MORE registration supporting documentation>>

Dear AIC team,

Please see attached validation documentation for MORE registration. Registration was completed using the email address <<email>> on <<DD/MM/YYYY>> for organisation '<<organisation name>>'.
<<organisation name>>'

Kind regards

<<First name, Last name>>

Template Letter – supporting documentation

Below is a template letter which can be used to form the registration supporting documentation which will be sent to AIC@mhra.gov.uk at the time of registration for the lead user of an account. This should be used to complete registration for users who do not currently have a MORE account registration.

Organisation official letterhead

Organisation Name
Organisation Address
Address
Postcode/zip code

Date: Must be within 1 month of registration

Dear MHRA,

Re: MORE registration supporting documentation

As CEO, Person Responsible for Regulatory Compliance (PRRC) or authorised representative of <Organisation> I can confirm that <User first name and last name> is registering to MORE as the Organisation Lead under the role of <Manufacturer/UKRP/Authorised Representative>. The email address that they have registered with is <Email>

I can confirm that <Organisation> manufactures devices <medical device class> and we will be reporting incidents in relation to these via MORE.

Kind regards,

Signed

CEO Name/Authorised representative Name & Signature

Help and Contact Details

If you are experiencing issues with MORE registrations and submissions, or have any questions, please contact your Organisation Lead in the first instance.

If you are an Organisation Lead and are experiencing issues or unable to resolve issues for other users associated to your Organisation lead, please email details of your questions to AIC@mhra.gov.uk.

Revision History

This table sets out the revision history for the last three versions.

Version No.	Effective date	Change
1.0	10/2022	First version
2.0	04/2023	Update to registration documentation and template letter (page 12 and 41)
3.0	08/2023	Inclusion of workspace definition