User reference guide – Gaining access to MHRA Submissions

This document is for those who want to set up user access to medicines and e-cigarettes.

This is the process for the initial company administrator. The administrator can add additional administrators, internal users and external consultants. Please see the user reference guide 'Managing users on MHRA Submissions' for further information on this process.

You will require access to MHRA Submissions if you want to submit the following:

- All medicines regulatory activities
- Medicines clinical trial applications
- E-cigarette notifications
- Broker registrations

Prior to registration please ensure:

- You have been given sole permission to act as the first responsible administrator on behalf of any companies you are registering. (Registering as your company's administrator without permission could cause unnecessary confusion and delays to your company's operational activities).
- You have your 5-digit company number(s) if you have previously submitted to the MHRA. (If you have not submitted to the MHRA, please email reference.data@mhra.gov.uk as you will need to register as a new company prior to beginning this process).
- All third-party consultants/consultancies have their own 5-digit company number and have registered for MHRA Submissions using that number.

New users should visit the MHRA account request page via the following link:
UAM Registration Form | MHRA

Step 1:

You will be directed to the MHRA Account Request page where you will fill in your details. Please note the advice including in the form when selecting which email address to enter. Once you have completed the fields please click 'Submit'.

Note: the email address you use here will be your username for MHRA Submissions. All future communications related to user access management will be sent to this address.

Note: if the below error message appears, it is likely due to your own security permissions or network security settings. You may need to try connecting to your corporate network and re-entering your account details. This should resolve the error. If you are still having issues with submitting your account details please contact submissions@mhra.gov.uk.

You will then be notified that your account has been submitted.

Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
Regulating Medicines and Medical Devices

Your Account has been submitted

Your account request has been submitted. MHRA will review your request and confirmation of outcome will be emailed on completion.

http://www.mhra.gov.uk

Step 2:

An email will be sent to the email address you entered previously.

☐ ☆ Microsoft Invitatio.   You're invited to the MHRA Staging organization

Click the 'Get Started' link to begin Microsoft Security Authentication.

You're invited to the MHRA Staging organization   Inbox ×

Microsoft Invitations <invites@microsoft.com> Unsubscribe
to me ▾

MHRA

You've been invited to access applications in the

MHRA Staging organization

Get Started

Return to the above link at any time for access.

This email has been sent on behalf of the MHRA Staging organization. Please act on this email only if you trust the MHRA Staging organization. This email may have advertising content. You can unsubscribe from future invitations from the MHRA Staging organization at any time. See Microsoft organization privacy statement to learn more about how Microsoft handles your data.

Facilitated by : Microsoft Corporation, One Microsoft Way, Redmond, WA 98052   ■■ Microsoft

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Step 3:

Select 'Next'

You will be asked to create a password for your MHRA Submissions account, then click 'Next'.

Select 'Never' if you do not want your browser to save your password. You will be requested to log in with your details in the future.

Confirm your 'Country/Region' and your 'Birthdate' (users must be over the age of 13 years old – this is a standard Microsoft age verification) and select 'Next'.

■■ Microsoft

← 2801demo@gmail.com

Create account

We need just a little more info to set up your account.

Country/region

United Kingdom ▼

Birthdate

Month ▼   Day ▼   Year ▼

Next

You will then be requested to verify your email address. A code will be sent to the email address you are registering with.

■■ Microsoft

← 2801demo@gmail.com

Verify email

Enter the code we sent to **2801demo@gmail.com**. If you didn't get the email, check your junk folder or try again.

Enter code

☑ I would like information, tips, and offers about Microsoft products and services.

Choosing **Next** means that you agree to the Microsoft Services Agreement and privacy and cookies statement.

Next

Click the link you have been sent from Microsoft.

The email will contain a four-digit code.

Enter this code into the Microsoft Verification page and <u>deselect</u> the tick box if you DO NOT wish to receive information, tips, and offers about Microsoft products and services. Then click 'Next'.

You will be prompted to confirm the characters you see on the screen for security purposes. Simply read the letters (highlighted) and enter them in the character box underneath. Then click 'Next'.

Click 'Accept' once you have reviewed permissions. You can read more via the drop-down options.

Note: The email verification is the regular route. For security purposes, they will occasionally request a mobile phone verification. You will be asked to submit your mobile phone number and the verification code will be sent via a text message. This will not be used for communications by MHRA.

To complete the user access management process, click 'Yes' to automatically proceed to the next stage. You will be sent to the MHRA Submissions homepage. Your registration is complete.

You will be redirected to the MHRA Submissions homepage.

Stage 4:

You will then be returned to the initial landing page. Select 'Medicines & E-Cigarettes' to continue

Medicines & Healthcare products Regulatory Agency

MHRA

MHRA
Regulating Medicines and Medical Devices

Are you External or Internal Staff

Medical Devices

Medicines & E-cigarettes

Select 'Yes'

MHRA New Organisation Request

Upon completing the below details and submitting the request, you are agreeing to be set up as the initial Organisation Administrator.

* MHRA Company Number   ○ Yes ● No

The MHRA Company Number is your 5-digit company or account number. If you have never made submissions to the MHRA before, please click 'No'

If your organisation has not yet been registered with the MHRA please email reference.data@mhra.gov.uk.

In 'Organisation details', enter your MHRA 5-digit company number.

MHRA New Organisation Request

Upon completing the below details and submitting the request, you are agreeing to be set up as the initial Organisation Administrator.

* MHRA Company Number   ● Yes ○ No

The MHRA Company Number is your 5-digit company or account number. If you have never made submissions to the MHRA before, please click 'No'

Organisation Details

32974

Please select the correct company details below or enter another MHRA Company Number

Your company name will be displayed, please select this to display details shown.

Select 'Commercial' under 'Organisation Type' (*note: clinical trial non-commercial sponsors should select 'Non-commercial'*).

Although 'Company Director Details' is a mandatory field, you can enter either details of your local or global company director here. This information will not be validated by the MHRA.

Finally, select 'Complete Registration'.

Upon completing your registration you will see this page.

MHRA New Organisation Request

Your Registration has been submitted, MHRA will process your request. Please logout and await confirmation email

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Step 5: Account completion

You will receive a confirmation email stating that you have access to MHRA Submissions.

The link highlighted below will take you to MHRA Submissions homepage.

"Your MHRA account has been created" Inbox ×

Dear First Last,

Your MHRA Submissions Access has been completed.

Login to the Submission portal is via the following URL: https://mhratest.appiancloud.com/suite/

Your username is: 2801demo@gmail.com
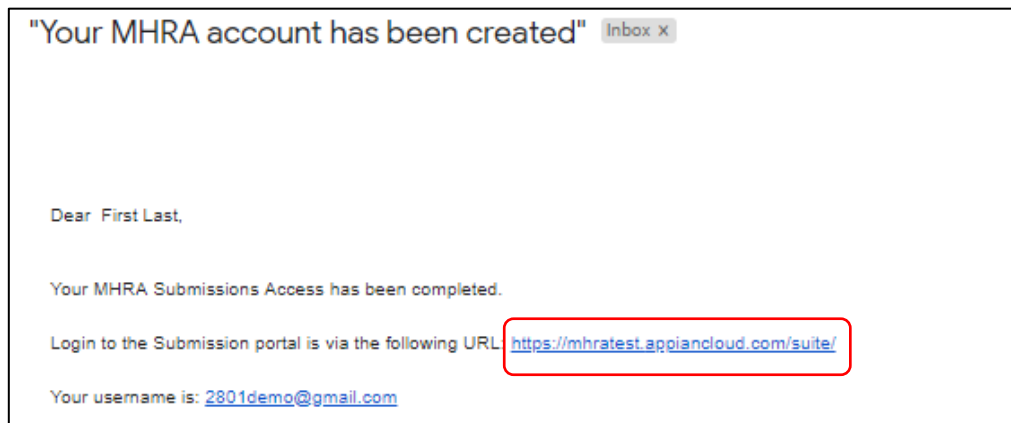
User reference guide – adding additional companies as admin

Once you have successfully registered as an administrator for one company, you can continue to register additional companies within your company group. You must ensure you have been given permission to become admin for all companies within your organisation.

Step 1:

Once you have logged into the MHRA Submission landing page, click on the "User Management" tile
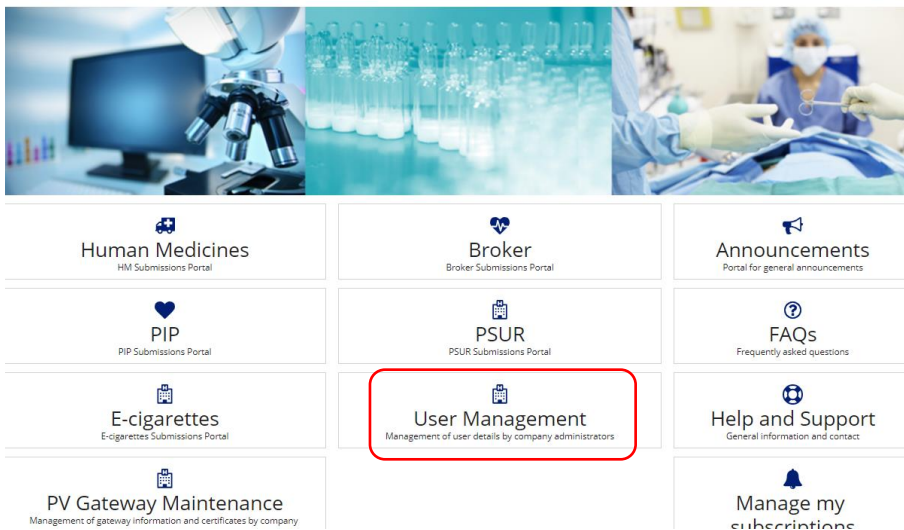
Step 2:

Click "Add New Organisation"
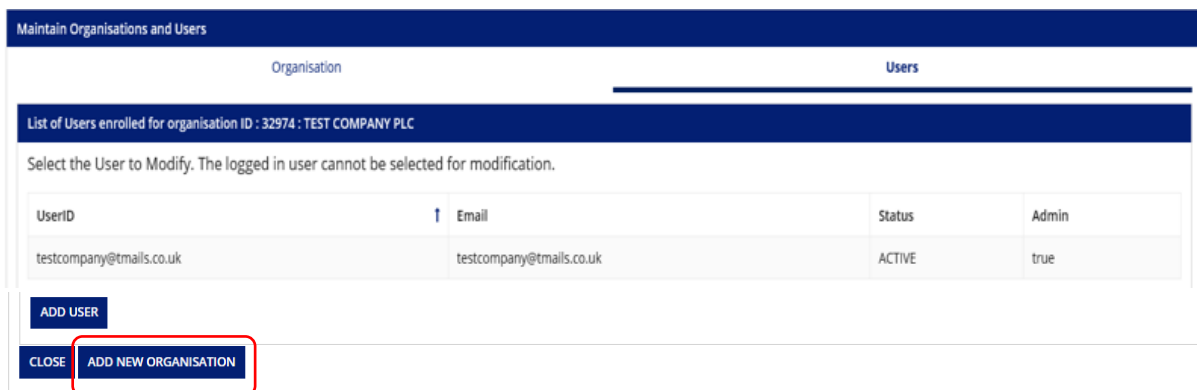
Step 3:

Select the "Yes" radio button under "MHRA Company Number"

Enter the required company 5 digit number you wish to register and hit return

Click on the company when it appears

MHRA New Organisation Request

Upon completing the below details and submitting the request, you are agreeing to be set up as the initial Organisation Administrator.

* MHRA Company Number ● Yes ○ No

The MHRA Company Number is your 5-digit company or account number. If you have never made submissions to the MHRA before, please click 'No'

Organisation Details

33125

Please select the correct company details below or enter another MHRA Company Number

Company Name	Country
TEST COMPANY LIMITED	UNITED KINGDOM

Company Administrator Details

First Name Firstname   **Last Name** Lastname

Email testcompany@tmails.co.uk

Company Director Details

* First Name First   *** Last Name** Last

Step 4:

Select 'Commercial' under 'Organisation Type' (*note: clinical trial non-commercial sponsors should select 'Non-commercial'*).

Although 'Company Director Details' is a mandatory field, you can enter either details of your local or global company director here. This information will not be validated by the MHRA.

Finally, select 'Complete Registration'.

Organisation Details

33125

Please select the correct company details below or enter another MHRA Company Number

Company Name	Country
TEST COMPANY LIMITED	UNITED KINGDOM

Organisation Name TEST COMPANY LIMITED

Company Website

* Organisation Type ● Commercial ○ Non Commercial

MHRA Company Number 33125

OMS Organisation ID   **OMS Location ID**

Company Administrator Details

First Name Firstname   **Last Name** Lastname

Email testcompany@tmails.co.uk

Company Director Details

* First Name First   *** Last Name** Last

COMPLETE REGISTRATION

Step 5:

Upon completing the registration you will receive the below message

MHRA New Organisation Request

The new organisation has been registered successfully.

OK

Step 6:

Returning to the user management page you will see your list of register organisations and where you have admin rights.

From here you can continue to add more companies within your organisation.

Maintain Organisations and Users

Status

The organisation is added successfully.

Organisation	Users

List of Companies enrolled: Firstname Lastname

Select the company to view the list of users

Organisation ID	Organisation Name ↑	Admin
33125	TEST COMPANY LIMITED	true
32974	TEST COMPANY PLC	true

CLOSE   ADD NEW ORGANISATION

User access management – frequently asked questions

Getting Started

1. **Is the choice of initial company administrator important?**

    Yes. Depending on how your team is set up within your organisation there are different factors you should consider when choosing who this initial company administrator is.

    For smaller organisations, a company administrator may also be responsible for making submissions or managing a team who will make submissions.

    For larger organisations, you may have different teams or departments dealing with different areas of your business, e.g. regulatory submissions, pharmacovigilance activities, clinical trial submissions etc. Or you may have different teams submitting the same type of submission. In these situations, please consider carefully who is best placed in your organisation to be the first administrator. This should be a responsible person in either your IT department, central regulatory affairs or clinical trials unit or R&D department. Once your initial administrator is registered, they can add further administrators and cascade responsibilities down throughout their teams/departments.

    It is recommended that a permanent organisation employee is the initial administrator. It is possible to add third party consultants as additional administrators and/or as standard users.

2. **Should each company have more than one company administrator?**

    Unless you are the only person in your organisation, it is recommended that you have at least one other company administrator.

3. Can I register as the first administrator for multiple companies within my organisation?

Yes. Please refer to the Section above "adding additional companies as admin" Please ensure you have received permission to register as the first administrator for all companies under your organisation.

Successfully completing the user access management process

4. Where can I find my 5-digit company number?

The 5-digit company number is a unique number that the MHRA assigns to a company when they register with us.

If your organisation has made a submission to the MHRA before, you will find this number on correspondence you have received from us.

Please see table below which explains where you can find your 5-digit company number from different submission areas:

Pharmaceutical industry	This is the first 5 digits of your PL (Product Licensing) number.
Clinical trial applicants	This is the first 5 digits of the CTA number from a trial that your organisation has previously submitted. This can be found on letter correspondences from the MHRA.
e-cigarette producers	Your 5-digit company number is your MHRA account number. This information is available on your invoices – please note, this is not your EU submitter ID.

Brokers	The broker company number is on the Registration document issued by the MHRA.
Paediatric investigation plan	If your organisation already holds marketing authorisations, this will be the first 5 digits of any of your product licences. If you have never submitted to the MHRA before you will need to be set up as a new company – see below.

If you have never submitted an application to the MHRA before, email reference.data@mhra.gov.uk as you will need to register as a new company prior to beginning this process. Before starting the user access management process, all third-party consultants/consultancies must ensure that they already have a 5 digit MHRA company number. If not, please use the email address above to begin the process as this is a prerequisite.

5. I received an email stating my email is already registered?

This means that a company administrator has already set you up as either an additional administrator or user. You should look for a confirmation email stating that you have access to the MHRA submissions portal. Contact your company administrator for further clarification.

6. I received an error message stating an administrator already exists for my company?

If you are unaware of who your company administrator is, please ask within your company. This company administrator will then set you up as an additional administrator or user.

7. After completing registration, I did not receive a confirmation email?

Please double check all email inboxes. If no confirmation email has been received, please repeat the registration process again. If spelling mistakes were made in the registration details this will affect the receipt of your confirmation email. If the problem persists, please contact the following email address: submissions@mhra.gov.uk.

8. I entered the wrong company number?

After entering the company number, it is important to check the company name displayed before completing the registration process. You can re-enter the correct number. If you have already completed the process and have realised your error, please contact submissions@mhra.gov.uk for correction immediately.

In a scenario where the company number entered does not exist on the system you will be notified with the prompt below in red.

MHRA New Organisation Request

Upon completing the below details and submitting the request, you are agreeing to be set up as the initial Organisation Administrator.

* MHRA Company Number ● Yes ○ No

The MHRA Company Number is your 5-digit company or account number. If you have never made submissions to the MHRA before, please click 'No'

Organisation Details

18042

Your organisation has not yet been registered with the MHRA. Please email reference.data@mhra.gov.uk.

After completion of the user access management process

9. What is the limit of admins/users I can add to my organisation?

There are no limits to the number of company administrators and users you can add. However, careful consideration should be given to how you set up your structure. As the administrator is responsible for adding and removing users

once an organisation is registered, you may need to consider who and how many administrators there are in your organisation.

Note: there is a limitation in the system where a notification is only given when less than five users are added. If adding more than five at a time, after sending the request you will be redirected to the homepage, however your changes will still be saved. To confirm, you can check your newly added users in the 'user maintenance' section.

10. **How do I reset my password?**

   To recover your account, when you are prompted to enter your username on the sign-in screen, click 'Can't access your account?' and you will be guided through the appropriate steps. Please note this will be performed via Microsoft and not the MHRA.

11. **What is the difference between a company administrator and a user?**

   A 'company administrator' has the ability to add, edit or disable other users. They can also see records of submissions made by users.

   A 'user' cannot add other users and can only make submissions for the company number they are registered to. They can be added to multiple company numbers if required.

12. **Will I need to register to the MHRA Submissions portal in order to set up my company's 'PV Gateway' access?**

   Yes. Access to the MHRA submissions portal is required in order to initiate access to the 'PV Gateway' process. This is a one-off exercise and can only be performed by a company administrator. The initial company administrator, if not performing this 'PV Gateway' process can set up a specific company administrator to do this activity instead.

Please refer to the User Guide and FAQs related to 'PV Gateway' process for more information.

Questions about the process

13. **Why do I have to create an account with Microsoft?**

A key part of the process to gain access to the MHRA submissions portal is to authenticate your account via a Microsoft Single Sign On solution, this will allow you to maintain control of your own credentials when accessing the portal.

14. **Why am I forced to enter a mobile number when creating a Microsoft account?**

Microsoft will send a four-digit verification code via the email address you have supplied. In a small number of cases, for added security, Microsoft will also ask for mobile verification. In this instance, you will receive the code via text message in order to complete the authentication process.

15. **Which browsers are compatible and recommended?**

Full compatibility testing has been performed on both Google Chrome and Internet Explorer.

16. **Can we register using a mobile device?**

Although you may be able to access the MHRA submissions portal using a mobile device, it is highly recommended that a desktop or laptop is used to avoid any compatibility issues.