

## 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](mailto: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 will be directed straight to the MHRA account request page via the following link:  
<https://mhrabpm.appiancloud.com/suite/plugins/servlet/registration>

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**Step 1:**

You will be directed to the MHRA Account Request page where you will fill in your organisation's details. Only complete mandatory fields.



MHRA Account Request

 **MHRA**  
Regulating Medicines and Medical Devices

**Organisation details**

**Organisation name**  
Training Guide 123

**Address line 1**  
Address 1

**Address line 2 (optional)**  
Address 2

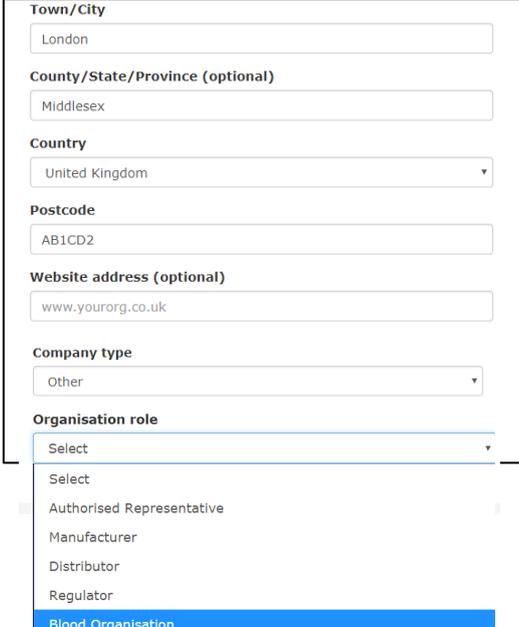
**Address line 3 (optional)**  
Address 3

**Address line 4 (optional)**  
Address 4

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Select 'Other' from 'Company Type' drop-down menu.

Then select 'Authorised Representative' from the 'Organisation Role' drop-down menu.



**Town/City**  
London

**County/State/Province (optional)**  
Middlesex

**Country**  
United Kingdom

**Postcode**  
AB1CD2

**Website address (optional)**  
www.yourorg.co.uk

**Company type**  
Other

**Organisation role**  
Select

- Select
- Authorised Representative
- Manufacturer
- Distributor
- Regulator
- Blood Organisation



Please fill out your 'User details' here.

*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.*

User details
<b>Email address</b> 2801demo@gmail.com
<b>Title (optional)</b> Dr.
<b>First name</b> First
<b>Last name</b> Last
<b>Job title (optional)</b> 
<b>Telephone number</b> (Please enter your phone number without any spaces) 02071231234

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Select the first 'primary reason for requesting an MHRA account' then confirm you agree with the MHRA terms and conditions.

<b>What is your primary reason for requesting an MHRA account?</b> <input checked="" type="radio"/> All submissions not related to Medical Devices or Blood Quality & Safety <input type="radio"/> Medical Devices - Register and/or Order Certificates of Free Sale
<b>Terms and Conditions</b> <input checked="" type="checkbox"/> I have read and agreed to the <a href="#">MHRA Terms and Conditions</a>
<b>Help us make sure you are not a robot</b> <input checked="" type="checkbox"/> I'm not a robot  <b>1</b> <b>You must then confirm you are not a robot (1) before clicking 'Submit' (2).</b> <b>2</b> <input type="button" value="Submit"/>
<input type="button" value="Cancel"/>

*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](mailto:submissions@mhra.gov.uk).*





Medicines & Healthcare products  
Regulatory Agency



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



**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.

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**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 X

**Microsoft Invitations** <invites@microsoft.com> [Unsubscribe](#)  
to me ▾



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 



**Step 3:**

Select 'Next'

The screenshot shows the Microsoft account creation interface. At the top left is the Microsoft logo. Below it, the text reads "Create account". A message states: "Looks like you don't have an account with us. We'll create one for you using 2801demo@gmail.com." At the bottom right, there is a blue button with the text "Next" inside, which is highlighted with a red rectangular border.

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

The screenshot shows the Microsoft password creation interface. At the top left is the Microsoft logo. Below it, the text reads "Create a password". Above this, there is a back arrow and the email address "2801demo@gmail.com". A message states: "Enter the password you would like to use with your account." Below this is a password input field with a blue underline and a series of dots. At the bottom right, there is a blue button with the text "Next" inside, which is highlighted with a red rectangular border.

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.

The screenshot shows a "Save password?" dialog box. It has a close button (X) in the top right corner. There are two input fields: "Username" and "Password". The "Password" field is masked with dots and has an eye icon to its right. At the bottom, there are two buttons: "Save" and "Never". The "Never" button is highlighted with a red rectangular border.



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

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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](#).

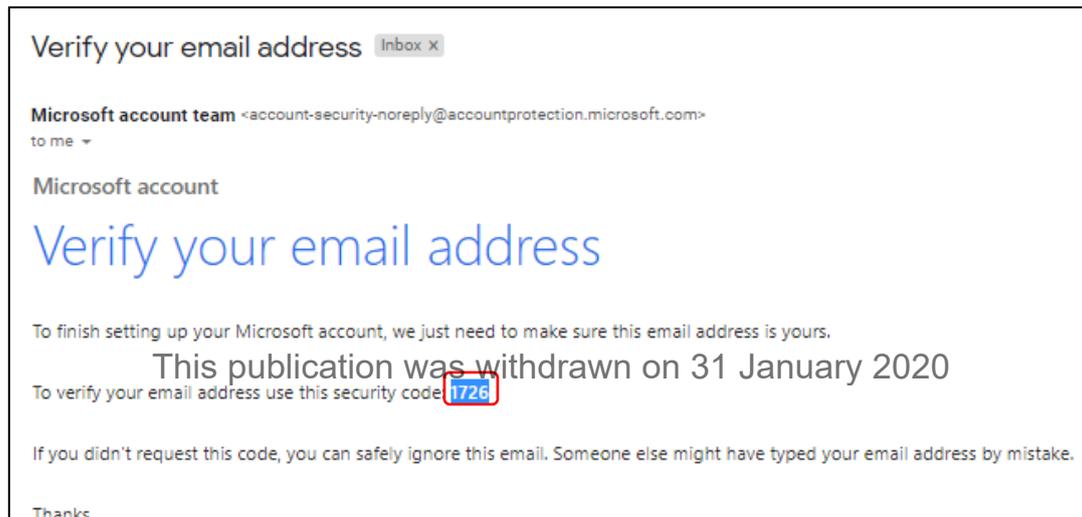
Next



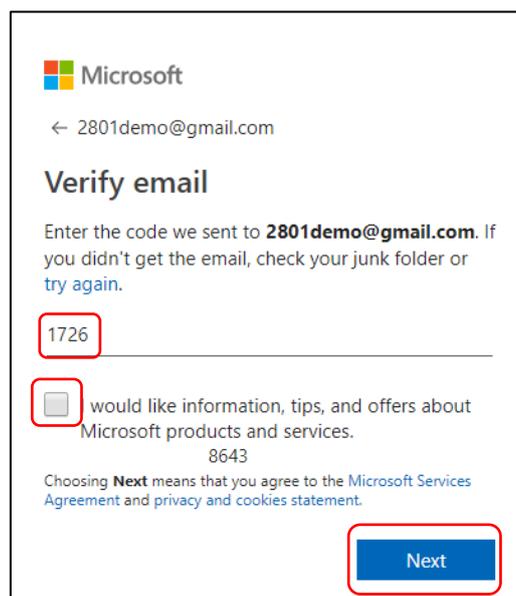
Click the link you have been sent from Microsoft.



The email will contain a four-digit code.



Enter this code into the Microsoft Verification page and deselect 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'.

The screenshot shows a Microsoft account creation screen. At the top, it says 'Microsoft' with the logo. Below that, the email address '2801demo@gmail.com' is shown. The main heading is 'Create account'. A message states: 'Before proceeding, we need to make sure a real person is creating this account.' There is a CAPTCHA image showing the letters 'HPPS' and 'Xdqk' in a stylized font, with 'HPPS' highlighted in red. To the right of the image are two buttons: 'New' and 'Audio'. Below the image, it says 'Enter the characters you see'. At the bottom right, there is a blue 'Next' button.

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

The screenshot shows a Microsoft 'Review permissions' screen. At the top, it says 'Microsoft' with the logo and the email address '2801demo@gmail.com'. The heading is 'Review permissions'. Below that, there is a section for 'MHRA Staging'. It says: 'The organization MHRA Staging would like to:'. There are two options: 'Sign you in' and 'Read your name, email, and perhaps photo'. The 'Read your name, email, and perhaps photo' option is selected. Below this, there is a detailed explanation of the permissions and a link to the privacy statement. At the bottom, there are 'Cancel' and 'Accept' buttons.

The screenshot shows a Microsoft 'Add security info' screen. At the top, it says 'Microsoft' with the logo and the email address '2801demo@gmail.com'. The heading is 'Add security info'. A message states: 'When you need to prove you're you or a change is made to your account, we'll use your security info to contact you.' Below that, it says: 'We'll text you the code you'll use to verify your phone number.' There is a 'Country code' dropdown menu set to 'United Kingdom (+44)'. Below that, there is a 'Phone number' input field with the value '07955373439'. To the right of the input field is a blue button that says 'I didn't get a code'. Below that, there is an 'Enter the access code' input field with the value '7455'. At the bottom right, there is a blue 'Next' button.

*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.



2801demo@gmail.com

**Stay signed in?**

Do this to reduce the number of times you are asked to sign in.

Don't show this again

No Yes

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You will be redirected to the MHRA Submissions homepage.



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#### Stage 4:

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





**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  Yes  No

**Number** 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](mailto:reference.data@mhra.gov.uk).

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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  Yes  No

**Number** 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'.



Company Name	Country
TEST COMPANY PLC	UNITED KINGDOM
Organisation Name	TEST COMPANY PLC
Company Website	
• Organisation Type	<input checked="" type="radio"/> Commercial <input type="radio"/> Non Commercial
MHRA Company Number	32974
OMS Organisation ID	
OMS Location ID	
Company Administrator Details	
First Name	Firstname
Last Name	Lastname
Email	testcompany@tmails.co.uk
Telephone	02030000000
Company Director Details	
* First Name	First
* Last Name	Last
<a href="#">COMPLETE REGISTRATION</a>	

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Upon completing your registration you will see this page.

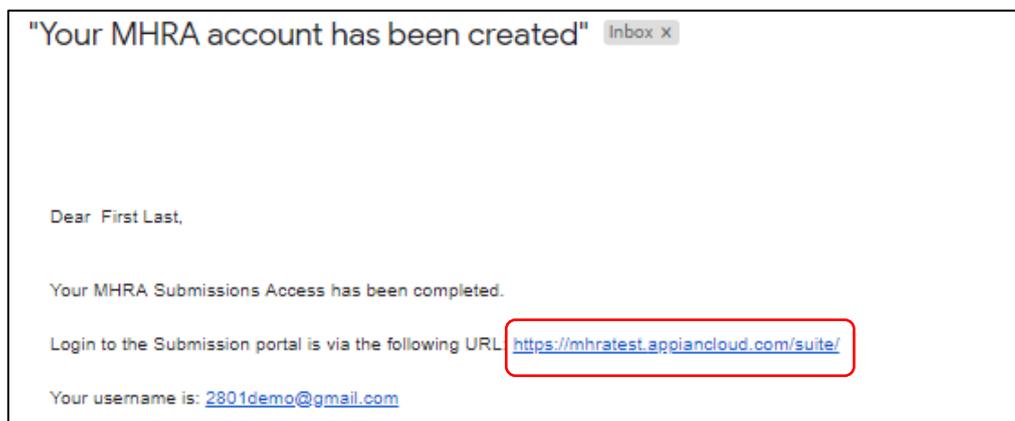
#### MHRA New Organisation Request

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

### 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.





## 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

**ALPHA Release** This is a new service - your feedback will help improve it  
Please do not click the browser's back button. Navigate using the buttons provided by the application.

Welcome, Firstname Lastname Help & Contact

**MHRA**

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**User Management**  
Management of user details by company administrators

**Announcements (3)**  
Portal for general announcements

**FAQs**  
Frequently asked questions

**Help and Support**  
General information and contact

**Manage my subscriptions**  
Enabling / disabling email announcement notifications

Homepage /



#### 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 <input checked="" type="radio"/> Commercial <input type="radio"/> 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
<a href="#">COMPLETE REGISTRATION</a>	

#### 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 companies 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 PL	true

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CLOSE ADD NEW ORGANISATION