

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:

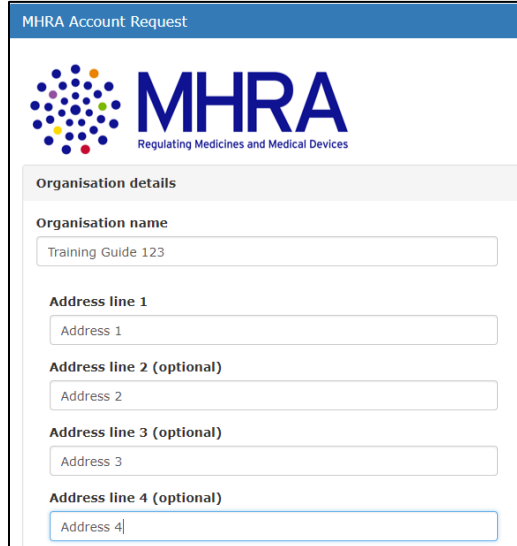
- You have been given sole permission to act as the first responsible administrator on behalf of your company. (Registering as your company's administrator without permission could cause unnecessary confusion and delays to your company's operational activities).
- You have your 5-digit company number 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 will be directed straight to the MHRA account request page via the following link:
<https://mhrabpm.appiancloud.com/suite/plugins/servlet/registration>




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

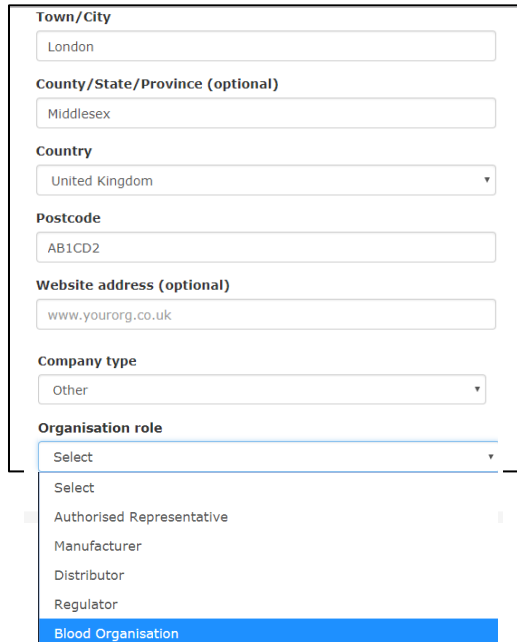
Address line 2 (optional)
Address 2

Address line 3 (optional)
Address 3

Address line 4 (optional)
Address 4

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
Email address <input type="text" value="2801demo@gmail.com"/>
Title (optional) <input type="text" value="Dr."/>
First name <input type="text" value="First"/>
Last name <input type="text" value="Last"/>
Job title (optional) <input type="text"/>
Telephone number <small>(Please enter your phone number without any spaces)</small> <input type="text" value="02071231234"/>

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

What is your primary reason for requesting an MHRA account? <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
Terms and Conditions <input checked="" type="checkbox"/> I have read and agreed to the MHRA Terms and Conditions
Help us make sure you are not a robot <input checked="" type="checkbox"/> I'm not a robot  1 You must then confirm you are not a robot (1) before clicking 'Submit' (2). 2 <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.

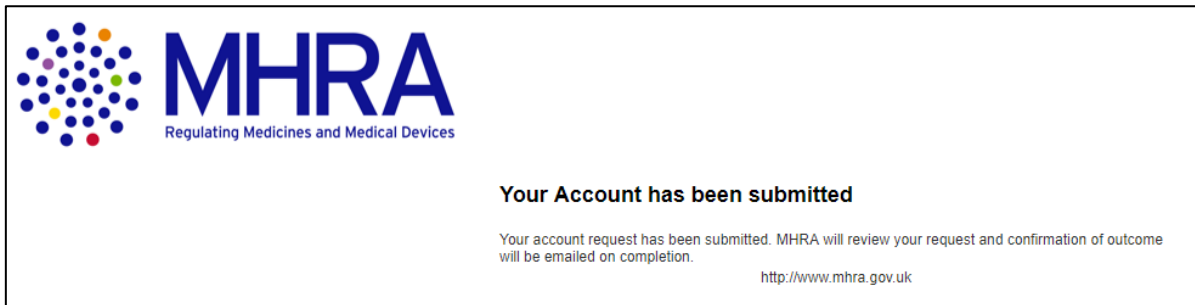




Medicines & Healthcare products
Regulatory Agency

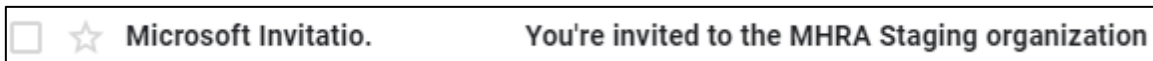


You will then be notified that your account has been submitted.



Step 2:

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



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





Step 3:

Select 'Next'

Microsoft

Create account

Looks like you don't have an account with us. We'll create one for you using **2801demo@gmail.com**.

[Next](#)

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

Microsoft

← 2801demo@gmail.com

Create a password

Enter the password you would like to use with your account.

.....

[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.

Save password?

Username

Password

[Save](#) [Never](#)



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](#).

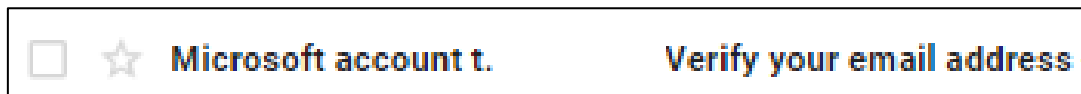
Next



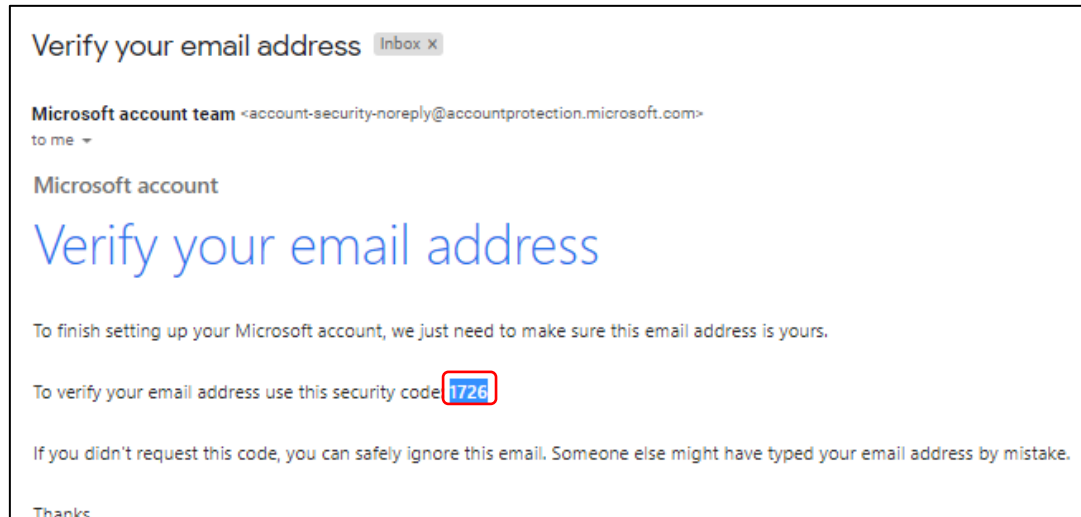
Medicines & Healthcare products
Regulatory Agency



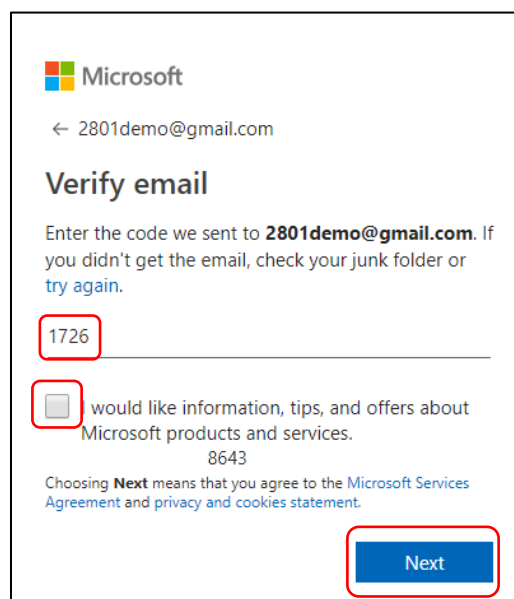
Click the link you have been sent from Microsoft.



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 characters 'HRPS' in blue and 'XdQk' in purple, with a red box highlighting the blue characters. To the right of the image are two buttons: 'New' and 'Audio'. Below the image, it says 'Enter the characters you see' and a text input field contains 'HRPSXdQK'. At the bottom right is a blue 'Next' button.

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

The screenshot shows a Microsoft account creation permissions screen. At the top, it says 'Microsoft' with the logo. Below that, the email address '2801demo@gmail.com' is shown. The main heading is 'Review permissions'. There is a section for 'MHRA Staging' with a dropdown arrow. Below that, 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 and highlighted with a blue border. Below the options, there is a paragraph of text explaining the permissions and a link to the privacy statement. At the bottom are two buttons: 'Cancel' and 'Accept'.

The screenshot shows a Microsoft account creation security info screen. At the top, it says 'Microsoft' with the logo. Below that, the email address '2801demo@gmail.com' is shown. The main 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 with 'United Kingdom (+44)' selected. Below that is a 'Phone number' input field with '07955373439' entered. There is a blue button that says 'I didn't get a code'. Below that is an 'Enter the access code' input field with '7455' entered. At the bottom right 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

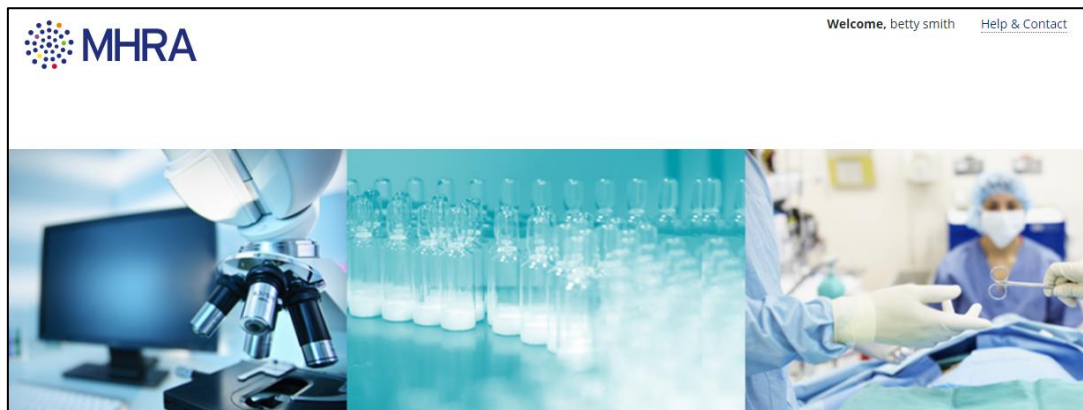
Stay signed in?

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

Don't show this again

No Yes

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



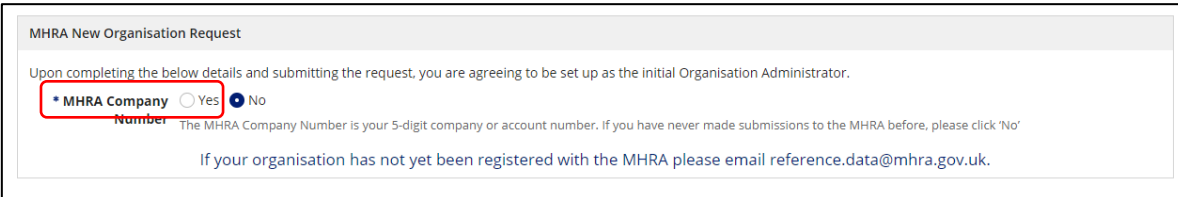
MHRA
Regulating Medicines and Medical Devices

Are you External or Internal Staff

Medical Devices

Medicines & E-cigarettes

Select 'Yes'



MHRA New Organisation Request

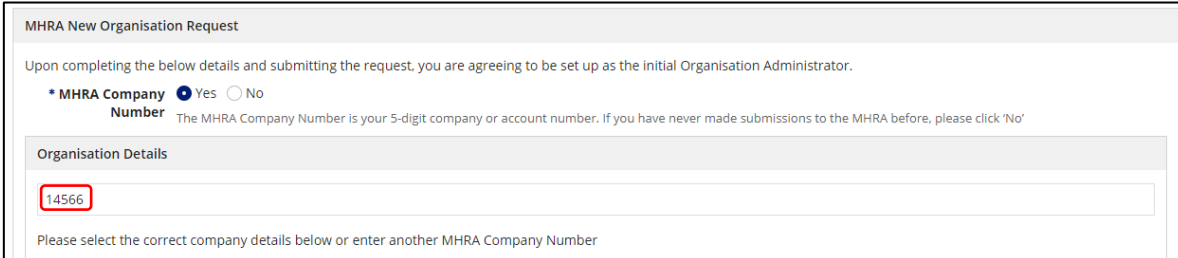
Upon completing the below details and submitting the request, you are agreeing to be set up as the initial Organisation Administrator.

* 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

14566

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
OSI SPECIALITIES (UK) LIMITED	UNITED KINGDOM
Organisation Name	OSI SPECIALITIES (UK) LIMITED
Company Website	
* Organisation Type	<input checked="" type="radio"/> Commercial <input type="radio"/> Non Commercial
MHRA Company Number	14566
OMS Organisation ID	
OMS Location ID	
Company Administrator Details	
First Name	First
Last Name	Last
Email	2801demo@gmail.com
Telephone	02071231234
Company Director Details	
* First Name	First
* Last Name	Last
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

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 x
Dear First Last,
Your MHRA Submissions Access has been completed.
Login to the Submission portal is via the following URL: https://mhrttest.appiancloud.com/suite/
Your username is: 2801demo@gmail.com