

## FOI 24/091 - Freedom of Information request - Number of Hospitals holding a ISO 13485 certification

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

Thu 22/02/2024 16:29

Our ref: FOI 24/091

Dear [REDACTED]

Thank you for your FOI request dated Thursday, January 25, 2024 where you asked:

"1. The number of NHS Trusts and NHS Hospitals that hold ISO 13485 Certifications in England, Wales, Scotland and Northern Ireland.

Please provide numbers for NHS Trusts and NHS Hospitals separately."

We would like to clarify which types of records your question relates to in terms of ISO certification. Please note, MHRA do not manage ISO 13485 accreditation, therefore, we would recommend contacting the NHS <https://www.nhs.uk/contact-us/find-out-how-get-help-something-else/>, or possibly UKAS <https://www.ukas.com/about-us/>:

"The United Kingdom Accreditation Service (UKAS) is the national accreditation body for the United Kingdom, appointed by government, to assess organisations that provide certification, testing, inspection and calibration services."

If you think there is information, we may hold in relation to your request then please reply and provide further details, we will then log that as a new request and issue a new reference number.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

Or online via: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Yours sincerely

**MHRA Customer Experience Centre**  
Communications and engagement team

Medicines and Healthcare products Regulatory Agency  
10 South Colonnade, Canary Wharf, London E14 4PU

-----Original Message-----

From: [REDACTED]  
Sent: Thursday, January 25, 2024 4:59 PM  
To: MHRA Customer Services <[MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk)>  
Subject: FOI 24/091 - Freedom of Information request - Number of Hospitals holding a ISO 13485 certification

[You don't often get email from [REDACTED]  
[REDACTED] this is important at <https://aka.ms/LearnAboutSenderIdentification> ]

Dear Medicines and Healthcare Products Regulatory Agency,

Please provide details of the the following:

1. The number of NHS Trusts and NHS Hospitals that hold ISO 13485 Certifications in England, Wales, Scotland and Northern Ireland.

Please provide numbers for NHS Trusts and NHS Hospitals separately.

Yours faithfully,

[REDACTED]

[REDACTED]

Please use this email address for all replies to this request:

[REDACTED]