

FOI 23/676

Dear

Thank you for your information request dated Friday, September 15, 2023, where you asked the below. We confirm that we hold information to satisfy this request, and we have included our responses beneath each of your questions in italics. You should be aware that an assessment is made on a case by case basis as to whether the use of a Compliance Monitor is suitable to ensure adequate remediation.

1. From April 2022 to current day how many GMP IAG cases how been referred for remediation supervision by an eligible Compliance Monitor using the CM process?
Three
2. What process licence types do the above GMP IAG cases referred to the CM process hold e.g., MIA, MIA(IMP), MS or WDA(H)
All MIA
3. What product types or sector of the pharmaceutical industry do the above GMP IAG cases referred to the CM process come from e.g., API, IMP, Biotech, NHS, Contract manufacture, Generics, sterile products manufacturer, non-sterile products manufacturer, Importer/PLPI?
Non-sterile manufacturing, radiopharmaceuticals, aseptic manufacture
4. From April 2022 to current day how many GDP IAG cases how been referred for remediation supervision by an eligible Compliance Monitor using the CM process?
None

We trust that this information is useful and meets your request. However, If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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

Or

by writing to:

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

Yours Sincerely,
HQA FOI team