Dear Enquirer,

This email will be sent to the GMP Inspectorate mailbox. Before forwarding your email, please ensure you are not able to source the required information or Certificates and related documents from the links provided below.

* GMP/GDP webpage: [https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fguidance%2Fgood-manufacturing-practice-and-good-distribution-practice&data=05%7C01%7Cgmpinspectorate%40mhra.gov.uk%7C707c81abade44f3e5a3208db10e01902%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638122326909533426%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=LtA2cxXx09NhFvAizjJRBngHbl0TkYNde4E7qHhHtkU%3D&reserved=0)
* Blood webpage: [https://www.gov.uk/guidance/blood-authorisations-and-safety-reporting](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fguidance%2Fblood-authorisations-and-safety-reporting&data=05%7C01%7Cgmpinspectorate%40mhra.gov.uk%7C707c81abade44f3e5a3208db10e01902%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638122326909533426%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Fb4doprv47MkLLpipKd0eLO1bbVwGA4AfHFfflo9a%2BA%3D&reserved=0)
* Manufacturer's and wholesale dealer's licence applications and variations webpage: [https://www.gov.uk/apply-for-manufacturer-or-wholesaler-of-medicines-licences](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fapply-for-manufacturer-or-wholesaler-of-medicines-licences&data=05%7C01%7Cgmpinspectorate%40mhra.gov.uk%7C707c81abade44f3e5a3208db10e01902%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638122326909533426%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=FsW8o0DF0uCGGR1NlKs4O7cCdYuwaJyvOWnCk6EmDYQ%3D&reserved=0)
* MHRA Inspectorate Blog (use the categories dropdown to select the category you require): [https://mhrainspectorate.blog.gov.uk/](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fmhrainspectorate.blog.gov.uk%2F&data=05%7C01%7Cgmpinspectorate%40mhra.gov.uk%7C707c81abade44f3e5a3208db10e01902%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638122326909533426%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YuC7Is%2BCaHwZW6oJLTQ97%2F23rPycBOO7Bx55PtTXDAY%3D&reserved=0)
* Information issued by the MHRA relating to manufacturing and wholesale authorisations and certificates for GMP, GDP, MIA, WDA: [MHRA | MHRA](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fcms.mhra.gov.uk%2Fmhra&data=05%7C01%7Cgmpinspectorate%40mhra.gov.uk%7C707c81abade44f3e5a3208db10e01902%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638122326909533426%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=S%2F5VHFCVss377uP5F6bPSQu0TtnnrnZciW1a3Zl2zI4%3D&reserved=0)
* Eudralex Volume 4 – GMP guidelines: [EudraLex - Volume 4 (europa.eu)](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fhealth.ec.europa.eu%2Fmedicinal-products%2Feudralex%2Feudralex-volume-4_en&data=05%7C01%7Cgmpinspectorate%40mhra.gov.uk%7C707c81abade44f3e5a3208db10e01902%7Ce527ea5c62584cd2a27f8bd237ec4c26%7C0%7C0%7C638122326909533426%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=YQm4tZ5EjILfehZWAPzL3ZIZMy02zjSMuD7sVXd36rs%3D&reserved=0)

**If your email concerns a question or advice not available in the above links**, please complete the below table. This will allow us to more easily identify your issue, direct your query to the most appropriate person, and identify current areas where formal guidance lacks clarity. Please note, this table must be completed in-order to process your enquiry.

**About you**

|  |  |
| --- | --- |
| Name |  |
| Company |  |
| Job title |  |

**About the facility**

|  |  |
| --- | --- |
| Name |  |
| Address |  |
| Licences held |  |
| GMP process to which your query relates. Please include the product type or licensed activity |  |
| Most recent site inspector |  |

**Question**

|  |  |
| --- | --- |
| Please describe the issue |  |
| Please state the relevant sections of the GMP guide and the published guidance you have consulted and why further guidance is needed. |  |
| Please describe your proposed solution |  |