**Please complete one Compliance Report per site or clearly cross refer where information for more than one site is recorded on a single form, e.g. where a small satellite site is used but reported information is not distinguished from the main site.**

The Chapters and Annexes of the EU GMP Guide can be obtained from <http://ec.europa.eu/enterprise/sectors/pharmaceuticals/documents/eudralex/vol-4/index_en.htm>

**Section 1 - Site Details**

|  |  |
| --- | --- |
| **Site name**  |  |
| **Full address of site including Post Code** |  |
| **Contact name for this report** |  |
| **Telephone no.** |  |
| **Fax.** |  |
| **Mobile** |  |
| **Email** |  |

Please return this completed report electronically to your inspector’s email address no less than five **working** days prior to your inspection and please copy: gxplab@mhra.gov.uk.

For detailed instructions, please refer to Page 7.

**Section 2 - All changes since the last inspection**

*Please provide information on changes that the MHRA should be aware of in conducting a GMP compliance risk assessment of the site. This is to include the details submitted previously in order for all changes since the last inspection to be presented. Please add additional numbered pages where required but do not attach reports or procedures.*

***See guidance document on GOV.UK web site for further information and definitions of terms.***

[*https://www.gov.uk/good-manufacturing-practice-and-good-distribution-practice*](https://www.gov.uk/good-manufacturing-practice-and-good-distribution-practice)

*Please include information on any mitigating action taken where appropriate*

|  |
| --- |
| **Site Overview and Performance** |
| 1 | Types of GMP activities undertaken: |
| 2 | Other (non GMP) services. |
| 3 | Volume of GMP work undertaken as a % of total work performed on site.  |
| 4 | Total number of batches or number of tests performed (Please identify, Chemical, Biological Micro non-sterile and sterility testing separately): |
| 5 | Where the site also performs non-GMP work, does the site operate a common Quality Management System regardless of work performed? |
| 6 | Have there been any delays or amendments to actions agreed with an Inspector to correct deficiencies from a previous inspection? |
| 7 | Other performance changes to report: |

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| **Key Personnel or Personnel Numbers** |
| 1 | Have there been any key organisational changes. |
| 2. | Has there been any significant change in total personnel numbers (permanent and/or temporary) and have there been any announced personnel redundancies or termination of long term or embedded contract personnel? |
| 3. | Other key personnel or personnel numbers changes to report: |
| **Company Ownership/ Structure or Status** |
| 1 | Has there been any change of ownership of the site, name change or change of position or role of the site in the wider organisation e.g. site sale or company merger or takeover, organisation restructured and site or QA lead reporting through different group or person? |
| 2. | Has the site/company entered into administration or is it experiencing financial difficulty that has/will result in budget cuts affecting good manufacturing practice compliance? |
| 3. | Other company ownership/ structure or status changes to report: |

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| **Processes and Products** |
| 1 | Have there been any changes in the types or numbers of products tested.  |
| 2 | How many new products/dosage forms have been introduced since the last inspection and please provide a list? |
| 3 | Have there been any outsourcing activities or bringing back in-house previously outsourced activities directly related to GMP activities? |
| 4 | Other processes/ products changes to report: |

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| **Equipment and Facilities** |
| 1 | Have there been any changes to facilities e.g. addition or change of use of buildings, major refurbishments to buildings or utilities? |
| 2 | Have there been any new or modified equipment or software used e.g. addition of equipment that introduces new technology to the site? |
| 3 | Do you sub-contract to other laboratories. *If so, please complete the table entering all organisations / sites used.* |
| *Name of organisation* | *Address* | *Activity performed* |
|  |  |  |
|  |  |  |
| 5 | Other facilities/equipment changes to report: |

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| --- |
| **Data Integrity** |
| 1 | Do you have a policy on data integrity/ governance? **Yes / No** (no need to supply) |
| 2 | Please confirm that computerised system owners and personnel with administrator-level access will be made available for the duration of the inspection.  |
| 3 | Are there any new or modified IT or other computerised systems e.g. Addition of computerised systems such as a new LIMS? |
| 4 | Please complete the listing of principal computerised systems (e.g. sample management/, LIMS, chromatography systems, document management systems, quality management software, access control) in the table below as follows. Please highlight any stand-alone systems. *Please note if the Site Master File contains* ***all*** *the requested details, then please state this here and provide.*  |
| **Type** | **Area** | **Name of Product & Supplier** | **Version or Model** | **Last Qualification Date** | **Any Modifications/ Updates/ Patches** |
| Software | All |  |  |  |  |
| Hardware | laboratory |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| 5 | Other data integrity changes to report |

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| Other changes, quality or compliance issues to be notified. |

**Section 3 - Anticipated Changes**

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| Please advise any changes that are anticipated to happen within a period up to two years. It is expected that these may not be confirmed changes and that information reported will be the best available at the time. A confirmation of actual changes should be submitted on an interim compliance report to the inspector once these are definite. |

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| **DECLARATION** |

To the best of my knowledge and belief the particulars I have given in this form are truthful and complete.

The signatories shall take all reasonable precautions and exercise all due diligence, to ensure that any information he/she provides to the licensing authority, is not false or misleading in any material particular, in accordance with relevant UK Regulations which make it an offence to provide false and misleading information.

**Site based person completing this report:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signed: |  |  | Date: |  |
| Name: |  |  | Position: |  |
| **(BLOCK CAPITALS)** |  |  |  |

**Person accountable for the site approving this report:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Signed: |  |  | Date: |  |
| Name: |  |  | Position: |  |
| (BLOCK CAPITALS) |  |  | (see note below #) |

***# This signatory is expected to be the person responsible for the business e.g. Chief Executive Officer, Site Director, Managing Director or equivalent (this is not likely to be a QA Manager although may be in small companies/facilities). This signatory is responsible for confirming the accuracy of the changes reported and confirming that no other relevant information has been withheld.***

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| --- |
| **Justification for suitability of person responsible to sign on behalf of the company where the role is not listed or equivalent to the above.** |