PRE INSPECTION COMPLIANCE REPORT
For manufacturing, testing and importation sites

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

Please identify your site details:

Site name	
Licence holder where different from above	
Licence number (s) and type (not applicable to non UK sites)	
Site number (on licenses)	
Full address of site **Including Post Code (Zip 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: gmpinspectorate@mhra.gsi.gov.uk. For detailed instructions, please refer to Page 7.

Medicines and Healthcare Products Regulatory Agency

PRE INSPECTION COMPLIANCE REPORT
For manufacturing, testing and importation sites

Section 2 All changes since the last inspection

Please provide information on site 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 using the Interim Compliance Report 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
Please include information on any mitigating action taken where appropriate

Shift in performance

1	Please specify markets/territories supplied from each manufacturing unit on the site, with output figures for each unit per year since last inspection (all global markets).
2	Does the site operate a common Quality system regardless of product destination?
3	Has the company identified any Pharmaceutical Quality System trends or significant changes? Deviations / complaints / recalls *(if yes provide details)*
4	Has there been any slippage or amendment to actions agreed with an Inspector to correct deficiencies from a previous inspection?
5	Other Performance Changes to report:

Key Personnel or Personnel Numbers

1	Have there been any key organisational changes that would not be picked up through the manufacturing licensing process e.g. change of site manager (senior person on site) where this individual is not named on the license? Non UK sites should also report changes in key QA or Production personnel.
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:

PRE INSPECTION COMPLIANCE REPORT
For manufacturing, testing and importation sites

Company Ownership/ Structure or Status

1	Has there been any Change of ownership of the site 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:

PRE INSPECTION COMPLIANCE REPORT
For manufacturing, testing and importation sites

Processes/ Products

1	Have there been any changes in the types or numbers of products manufactured / handled. This should include re-introduction of a product after a period in excess of one year without manufacture and any products subject to shortages in supply.
2	Please populate the table for all molecules handled on site - regardless of market or commercial status (this can be attached as a separate table)

Molecule	Classification*	Facility / Building	Manufacturing area (s)	Filling line (if different)	Primary Packing line	Dedicated	
						Facility	Equipment

* This is to be detail such as hormone, immunosuppressant, potent, beta lactam, non-potent chemical etc.

3	Have there been any outsourcing activities or bringing back in-house previously outsourced activities directly related to production or Quality Control?
4	Have any GMP compliance issues been identified with any API sources that would lead to the conclusion that the source was not or may not be GMP compliant e.g. critical or numerous major findings in an audit of the API site, recurring failures on incoming goods testing of the API?
5	Have there been any Sterility test failures since the last inspection?
6	Has there been any Media fill failures resulting in re-validation in accordance with guidelines in annex 1of the EU GMP Guide?
7	Have there been any significant changes in the number of rejected batches? Please provide the number since last inspection and details.
8	For sites operating under a regional or global corporate structure: please list any centralised functions located at this site (e.g. artwork generation, supplier management, IT support etc)
9	Other Processes/ Products Changes to report:

PRE INSPECTION COMPLIANCE REPORT
For manufacturing, testing and importation sites

Facilities/Equipment

1	Have there been any changes to facilities e.g. addition or change of use of buildings, major refurbishments to buildings or utilities, or problems with any of these, that may affect product quality or the ability to manufacture/supply?
2	Has there been any new or modified equipment used for storage, control, processing e.g. addition of equipment that introduces new technology to the site?
3	Do you use contract laboratories or sterilisation sites? *(for non-UK sites only)* *If so, please complete the table entering all organisations / sites used.*
4	Please provide numbers of all out of specification testing results, per year, since the last inspection (report phase I & II investigation numbers separately). Microbiology and chemistry OOS numbers should be provided in separate lists.
5	Other Facilities/Equipment Changes to report:

Name of organisation	*Address*	*Activity performed*

PRE INSPECTION COMPLIANCE REPORT
For manufacturing, testing and importation sites

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. Note: if a corporate or global function performs this then a communication channel with remote access and visibility to all systems will be sufficient.
3	Has there been any new or modified IT or computerised systems used for storage, control, processing e.g. Addition of computerised systems such as a new LIMS or manufacturing execution systems or major modifications to such systems?
4	Please complete the listing of principal computerised systems (e.g. ERP, LIMS, chromatography systems, eBMR, MES, 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				

Other changes, quality or compliance issues to be notified.

Section 3 Anticipated Changes

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.

PRE INSPECTION COMPLIANCE REPORT
For manufacturing, testing and importation sites

Section 4

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 the QP or QA Manager/Pharmacist 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.

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

When complete please return this form to the inspector by one of the following methods:
- Complete electronically and email to inspector with a scanned copy of the signature page.
- Complete a hard copy then scan as a single file and e mail to the inspector.
- If no scanning facilities are available email all pages except the signature page to the inspector prior to the inspection and provide a signed page to the inspector at the inspection.
- When sending to the inspector, please copy in gmpinspectorate@mhra.gsi.gov.uk