

GOOD MANUFACTURING PRACTICE QUALITY CONTROL TESTING LABORATORY
PRE-INSPECTION COMPLIANCE REPORT AND INTERIM COMPLIANCE REPORT
GUIDELINES FOR COMPLETION AND SUBMISSION

Background

The Pre-Inspection GMP QC Compliance Report and Interim Compliance Report forms part of the MHRA risk-based inspection system and is required to be completed by each laboratory named on a UK license.

Pre-Inspection Compliance Report

The Pre-Inspection Compliance Report will be completed in preparation for a Good Manufacturing Practice Quality Control laboratory inspection, prompted by the notification letter. Change is regarded as either an indicator of an increase or decrease in risk or as a risk itself. As such the inspector will consider the changes in planning for the inspection.

Interim Compliance Report

An Interim Compliance Report should be submitted by sites between inspections following significant change or as requested by the inspector. The Interim Compliance Report provides a report to the inspector of actual changes that occur between inspection cycles. Inspectors assess the significance of changes reported and may move the planned inspection period based on the risk presented by the changes. The risk rating will only be changed after a subsequent inspection.

Introduction

The following information is provided for general guidance for completion of the GMP QC Pre-Inspection Compliance Report and Interim Compliance Report.

It is the responsibility of the site to judge what information/data indicates significant change (increase or decrease) in site risk to GMP Compliance, product quality and patient safety. As individual sites are best placed to know what changes an impact on the above attributes could have the decision on what to report is with the site.

This will be reviewed with the inspector during the inspection, it is expected that there may be 'grey areas' where sites believe changes are not significant, but inspectors believe they are or may be significant. Such cases will be discussed during inspection when sites may be requested to justify their position. It is the intention of the MHRA to ensure that the Risk Based Inspection system is applied in an objective manner to allow balanced risk assessments across all applicable sites. Risk rating will be utilised to define future inspection frequency and duration.

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| 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 Microbiology 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? <i>Outstanding or overdue Corrective and Preventive Action (CAPA) – major trend changes in CAPA to be reported rather than individual CAPA i.e. where the ability of the site to close CAPA within own targets is compromised by continual and repeated examples of failure to hit due dates or repeated rescheduling of due dates of significant CAPA items.</i> |
| 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? <i>(i.e. indicating downsizing of operation)</i> <i>Significant addition of staff to meet an upturn in demand should be reported particularly where this equates to around a 10% increase or more and particularly where temporary staff will be used to fill the shortfall.</i> |
| 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 | <p>Have there been any changes in the types or numbers of products tested.</p> <p><i>It may be that a site has re-introduced a product type after a lengthy period. Increase in demand for products may have resulted in increased volumes –this is particularly significant where shift patterns are changed to accommodate or staff are recruited, transferred or made redundant.</i></p> |
| 2 | <p>How many new products/ dosage forms have been introduced since the last inspection and please provide a list.</p> |
| 3 | <p>Have there been any outsourcing activities or bringing back in-house previously outsourced activities directly related to GMP activities?</p> |
| 4 | <p>Other processes/ products changes to report:</p> |

| Equipment and Facilities | | | | | | | | | | | |
|---------------------------------|---|---------------------------|-----------------------------|----------------|---------------------------|--|--|--|--|--|--|
| 1 | <p>Have there been any changes to facilities e.g. addition or change of use of buildings, major refurbishments to buildings or utilities?</p> | | | | | | | | | | |
| 2 | <p>Have there been any new or modified equipment or software used e.g. addition of equipment that introduces new technology to the site?</p> | | | | | | | | | | |
| 3 | <p>Do you sub-contract to other laboratories. <i>If so, please complete the table entering all organisations / sites used.</i></p> <table border="1"> <thead> <tr> <th><i>Name of organisation</i></th> <th><i>Address</i></th> <th><i>Activity performed</i></th> </tr> </thead> <tbody> <tr> <td> </td> <td> </td> <td> </td> </tr> <tr> <td> </td> <td> </td> <td> </td> </tr> </tbody> </table> | | <i>Name of organisation</i> | <i>Address</i> | <i>Activity performed</i> | | | | | | |
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| 4 | <p>Other facilities/equipment changes to report:</p> | | | | | | | | | | |



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| Data Integrity | | | | | | |
|----------------|--|------------|----------------------------|------------------|-------------------------|-------------------------------------|
| 1 | Do you have a policy on data integrity/ governance? Yes / No (no need to supply) <i>This is simply a YES/NO answer</i> | | | | | |
| 2 | Please confirm that computerised system owners and personnel with administrator-level access will be made available for the duration of the inspection. <i>This is simply stating an expectation that the subject matter experts for these systems will be available during the inspection A YES/NO answer is required.</i> | | | | | |
| 3 | Are there any new or modified IT or other computerised systems e.g. Addition of computerised systems such as a new LIMS? <i>This is a YES/ NO answer – where Yes, the system name and date of installation or modification is required.</i> | | | | | |
| 4 | Please complete the listing of <u>principal</u> 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. <i>Please note if the Site Master File contains all the requested details, then please state this here and provide. This table may be sent as an attachment if it is easier for the user. Please note; the request is for principal computerised systems only, this does not include items such as individual departmental spreadsheets.</i> | | | | | |
| | | | | | | |
| | 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.

Any other changes or issues that the site believe may indicate a step change in the sites risk to product quality or of being non GMP compliant, producing defective batches or affecting patient safety

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.

Mitigating Action

It is the intention to take into account mitigating action taken by sites in relation to change. As such relevant mitigating action already taken against changes reported should be recorded in a succinct manner. Evidence of this may be reviewed during the inspection.

Interim Compliance Report - Changes Made Post Inspection

Significant changes confirmed between inspection visits must be reported to MHRA.

The guidance given above for content of the Pre-Inspection Compliance Report should also be applied to the Interim Compliance Report.

The completed form should be sent by e mail to the inspector that last inspected your site with a copy to gxplabs@mhra.gov.uk.

For planned changes these should be advised at implementation of the change or if appropriate e.g. staff redundancies, once the change is confirmed and prior to actual implementation.

These will be assessed by the relevant inspector and impact on the next planned inspection period assessed. It is intended that risk rating will only be amended following subsequent inspection; sites will not be formally advised of any change in their next inspection date although this may be informally communicated by the inspector.

Failure to submit a required Interim Compliance notification of change may be assessed by the inspector as an increased risk factor.