VISITS BY QUALITY ASSURANCE PERSONNEL

TO PHARMACEUTICAL MANUFACTURERS

AND WHOLESALERS

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This is one of the series of NHS national guidance documents issued by the NHS Pharmaceutical Quality Assurance Committee.

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VISITS BY QUALITY ASSURANCE PERSONNEL TO PHARMACEUTICAL MANUFACTURERS AND WHOLESALERS

A. Introduction

This paper lays down the system under which a pharmaceutical company wishing to supply medicinal products to the NHS hospital service is assessed if a visit is considered necessary prior to addition to lists of suppliers. Quality audit protocols and a suitable report format are included. Assessment of commercial aspects of companies is not covered in this document.

B. Quality Audit Protocols

1. Prior to the Visit

   Review any previous visit reports, test data, and any other information relating to the company. Contact members of the NHS QA Committee for any information or problems.

   Decide on the audit team and on who will prepare the report of the audit. The audit team should comprise one Quality Assurance Pharmacist accompanied by one other member of the Contracting Committee. If audits are arranged by two regions it may be appropriate for two Quality Assurance Pharmacists (preferably including the local Regional Quality Assurance Specialist) to perform the audit. It is generally not advisable for one lone auditor to visit. Agree on who will act as the "team leader", on which specific areas each member of the team will concentrate during the audit, and on how the day will be handled.

   Give the company an idea of the timescale of the audit and which areas of the company's operation will be covered.

2. On the day of the Visit

   (a) Start the audit with a meeting with key personnel to cover the subjects in Section C of the report. Key personnel would normally include company directors or senior managers with responsibility for manufacturing, quality control and assurance, sales/marketing and product distribution.

   (b) Following these discussions identify which areas of the company's operation to assess, and work methodically through them. It is generally sensible to start with goods inwards and follow the production process in order, rather than to physically start at one end of the building and finish at the other end. In this way it is easier to build up a mental picture of the sequence of events and whether appropriate measures are taken at specific points in the production process. The audit team must never allow itself to be split up - two pairs of eyes and ears are better than one! Make notes as you go a long - do not rely on memory.

   (c) Following the audit of manufacturing areas, conduct a summary session at which major deficiencies are identified to the key personnel. Do not give verbal approval or rejection of the company's application at this stage but inform them that this will be communicated in writing following the visit.

3. Following the Visit

   It is good manners to write a brief formal letter of thanks for the company's hospitality during the visit within a few days. This should be done by the person delegated to write the report. Prepare a draft report of the audit as soon as possible after the visit, and circulate it to other members of the audit team for comments and corrections, then the list of deficiencies, actions

required, and decisions regarding approval/rejection should be sent to the company for confirmation of factual accuracy and for comment on the deficiencies and actions identified. It should be made clear to the company that the report is confidential and must not be reproduced by the company in whole or in part to any third party. Once a response has been received from the company, the final report can be prepared for distribution within the visiting officers' region and nationally to members of the NHS Pharmaceutical QA Committee. The report is highly confidential by virtue of the commercially valuable information it contains and will only be made available to other NHS personnel with the permission of the author

C. Documentation

A standard report form is not used, owing to the difficulties in designing a form which would be applicable to the wide variety of company facilities to be assessed. Instead, auditors should prepare a report summarising their observations relating to appropriate section of the report format given below.

An audit template is included in this document. It is intended to be used by the auditor as an *aide-memoir* and will help ensure a uniform structure to reports. Some of the proposed headings may not be relevant to a particular company's operations and should be omitted. Similarly other additional headings may be added if desired.

The suggested layout to the audit report is as follows:

Page 1:

CONFIDENTIAL

REPORT OF QUALITY AUDIT

Company Name:
Address:
Telephone / Fax:
Website:
Email:
Audit Date:
Company Personnel present:
NHS Personnel present:
Purpose of Visit:
Costs met by:
Author(s) of Report:

Subsequent pages:

(2) General Company Information
(3) Storage Areas
(4) Manufacturing
(5) Quality Control
(6) Quality System
(7) Summary of Observations
(8) Conclusion and Recommendations

Sections 3, 4 and 5 should be written in a manner which makes clear whether each criterion complies or does not comply with good manufacturing practice requirements. Any items found not to comply may be further sub-divided into critical non-compliance (a single one of which would render the company unsuitable for approval), major non-compliance (which must be corrected before approval could be granted), or minor non-compliance (which must be corrected within an agreed timescale but singly may not prevent company approval). Each section conclusion would state whether, overall, that section complies or does not comply with GMP requirements.

1. Audit Details

Name of region	
Company name	
Address	
Telephone number	
Fax number	
Website	
E-mail address	
Date of Audit	
Names and job titles of company personnel present at the audit	
Names and job titles of NHS personnel present at the audit	
Purpose of visit	
How costs of visit were met	
Dates of any previous audits (and auditors)	

2. General Company Information

Company structure, ownership, subsidiaries, parent company	
Directors and background	
Principal staff responsibilities and qualifications, future contact points	
Staff policy and total number of staff, organisational chart	
Company premises - siting, approximate area, general state of buildings, age, fabric of Construction	
UK operation and facilities	
Export marketing structure and arrangements	
Developments over recent years	

2. General Company Information (continued)

Future plans	
Medicines Act licence status	
Order address	
Product range	
Delivery arrangements (including management of cold-chain)	

3. Storage Areas

Space	
Design	
Tidiness	
Segregation	
Quarantine	
Stock control	
Temperature control and monitoring	
Cleaning, pest control	

3. Storage Areas (continued)

Stock holding ready for delivery	
Transport arrangements	
Section conclusion and comments	

4. Manufacturing

Premises	
Tidiness	
Categories of manufacture and facilities	
Processes used	
Equipment	
Documentation	
Personnel	
Segregation of activities	

4. Manufacturing (continued)

Cross-contamination potential	
Sterilisation	
Workflow patterns	
Cleaning	
Clothing arrangements	
Others	
Section conclusion and comments	

5. Quality Control

Premises	
Tidiness	
Equipment	
Personnel	
Good Laboratory Practice	
Peer-checking of results	
Validation	
Documentation	

5. Quality Control (continued)

Information Management (e.g. LIMS)	
Report generation	
Report Approval	
Sampling	
Raw material control	
Packaging component control	
In-process control	
Finished Product control	
Environmental Monitoring/ Review of monitoring results	

Quarantine system	
Reference samples	
Others	
Section conclusion and comments	

6. Quality System

Outcome of latest MHRA Inspector's visit	
ISO 9000 Registration, or other external quality system accreditation	
Management of Quality System	
Document Control	
Exception and error reporting	
Corrective, Preventative & Improvement actions (CAPA)	
Change Control	
Training Records	
Self-Inspection (Internal Audit)	

6. Quality System (continued)

Contract/SLA Review Including review of any problems with procurement contracts	
Review of product complaints	
Drug recall arrangements	

7. Summary of Observations

Overall quality assurance system	
Personnel	
Maintenance of premises and equipment	
Summary of non-compliances and action required (with timescales)	
Items for special attention on following visits	

8. Conclusions and Recommendations