

Attachment 22

Postal Audit Document

Calibration Service Provider Audit Questionnaire

Company Name _____

Address _____

Telephone Number _____

Fax Number _____

Contact Email address _____

1. Please provide details of the calibration/maintenance service that your company provides. In doing so, please identify any work which is not conducted at the premises above and identify any work that is subcontracted to a third party (refer to attachments if necessary)

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2. Does the site which supplies the service operate a quality management system in accordance with the requirements of ISO 9001:2000?

☐ YES

☐ NO

3. If so, is it formally certified by an accredited certification body?

☐ YES (*If yes, please attach a copy of the registration certificate*)

☐ NO

4. Are there any other formal certifications or accreditations in place?

List any additional certifications/accreditations, which your company holds (*attach any associated, relevant certificates documentation which clearly demonstrate the scope*):

☐ Not Applicable

5. Is there a training program for all employees?

☐ YES

☐ NO

Does the training you provide include job specific training?

☐ YES

☐ NO

Does the training you provide include cGMP/GLP training?

☐ YES

☐ NO

Is this training formally documented?

☐ YES

☐ NO

How do you evaluate the competency of employees?

☐ Not Applicable

Describe your company's program to ensure personnel are aware of current pharmaceutical industry trends and practices:

☐ Not Applicable

Is the training process governed by a formal procedure?

- ☐ YES, Reference: _____
- ☐ NO

6. Please detail the specific documentation that you provide when carrying out calibration/maintenance and the documentation which you retain:

☐ Not Applicable

Describe your document retention policy (e.g. length of retention, storage conditions, types of documents retained). Please note this question refers to the documentation of the service provided, not financial or proprietary documentation which is specific to your company:

☐ Not Applicable

Is your documentation management process governed by a formal procedure?

☐ YES, Reference: _____

☐ NO

7. Please provide an organogram of the quality department and provide a brief description of their responsibilities. Please note, this organogram must show the personnel at the site which provides calibration/maintenance services.

☐ Not Applicable

Does this site have a quality policy/manual established?

☐ YES, Reference: _____

☐ NO

8. Do you have a deviation/non-conformance/atypical event reporting system in place at this site?

☐ YES

☐ NO

Is the deviation/non-conformance/ atypical event reporting system process governed by a formal procedure?

☐ YES, Reference: _____

☐ NO

Briefly describe your program for recording, correcting, and communicating deviations that occur while providing servicing/calibration/maintenance services:

9. Does your company have a change control system?

☐ YES ☐ NO

Is the change control process governed by a formal procedure?

☐ YES, Reference: _____

☐ NO

Describe how you alert customers to internal changes in the way you provide your service or changes to your policies/procedures:

10. If your company provides a service using your own equipment, standards, etc., please answer the following questions:

Is there a procedure in place for the routine calibration and preventative maintenance of all equipment used?

- ☐ YES
- ☐ NO
- ☐ Not Applicable, *Skip to the next question*

Briefly describe the procedure for equipment that does not meet the acceptance criteria for calibration:

Briefly describe your equipment qualification program (include references to any measures in place to assure the continued performance of test equipment):

Are these processes governed by a formal procedure?

☐ YES, Reference: _____

☐ NO

11. Has your company been formally audited by any governmental regulatory agencies?

☐ YES

☐ NO

List the governmental regulatory agencies which have audited your company:

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12. Does your company subcontract work to other service providers?

☐ YES

☐ NO

Does your company intend to subcontract some or all of the services provided to another Third Party Service Provider?

☐ YES

☐ NO

If yes, please indicate the name of the subcontractor(s) you intend to use:

Does your company have a formal procedure for the management, approval and use of subcontractors?

☐ YES, Reference: _____

☐ NO

☐ Not Applicable

Please briefly describe your process for the management, approval and use of subcontractors:

☐ Not Applicable

13. In providing your service does your company use any materials of animal origin (e.g. lubricants, seals, gaskets, etc.):

☐ YES

☐ NO

If yes, please list those materials:

Approval by Third Party Service Provider Representative

Printed Name

Title

Signature & Date

Prepared By:

Date:

Pharma Co. QA rep 1

Approved By:

Date:

Pharma Co. QA rep 2

Version history	
0	New document
1	Contact information added and updated for clarity.