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Annex 13

WHO guidelines for preparing a laboratory information file

Background

The WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted in its thirty-eighth report in 2003 the *Guidelines for preparing a laboratory information file* (WHO Technical Report Series, No. 917, 2003, Annex 5).

The content of these guidelines is closely related to *WHO guidelines on good practices for pharmaceutical quality control laboratories*, which have recently been revised (the revised version was adopted by the WHO Expert Committee at its forty-fourth meeting in 2009).

The WHO Expert Committee on Specifications for Pharmaceutical Preparations discussed the need for a revision of both sets of guidelines at its forty-third meeting in 2008 and recommended that if the *Guidelines for good practices for national pharmaceutical control laboratories* were revised, the *Guidelines for preparing a laboratory information file* should be revised accordingly.

On the basis of the above and following the usual consultation process, the following text will replace the previously published guidelines.

1. General information on the laboratory
2. Quality management system
3. Control of documentation and records
4. Personnel
5. Premises
6. Equipment
7. Materials
8. Subcontracting of testing
9. Handling of samples
10. Validation of analytical procedures
11. Investigation of out-of-specification results
12. Stability testing (where applicable)
13. Microbiological testing (where applicable)

A laboratory information file (LIF) is a document prepared by the laboratory. It contains specific and factual information about the operations carried out at the named site and any closely integrated operations of the laboratory. If only some of the operations are carried out on the site, the LIF needs to describe only those operations, e.g. sampling, chemical analysis or stability testing.

An LIF should be written in English, succinct and, if possible, should not exceed 30 A4 pages, excluding appendices.

The laboratory should give a short description of its activities under each of the following headings. Policy or essential steps for each activity should be described and reference to a standard operating procedure (SOP) or other supporting documents should be given, where applicable. Where appropriate, supportive documentation should be appended.

1. General information on the laboratory

1.1 Brief information on the laboratory (including name, physical (location) and mailing address, contact details and brief history). If the laboratory is part of an organization or company, provide details of its position within the organization or company, including reporting lines (e.g. organizational chart).

1.2 Summary of all laboratory activities, including objectives of the laboratory, categories of customers, types of sample tested. In addition, state the relation (if any) to a manufacturing site.

1.3 Areas of expertise proposed for prequalification (list methods and tests, for examples see the List of Prequalified Quality Control Laboratories).[1]

Type of analysis	Finished products	Active pharmaceutical ingredients
Physical/chemical analysis		
Identification		
Assay, impurities and related substances		
Microbiological tests		
Bacterial endotoxin testing (BET)		
Stability testing		

1.4 Brief description of a policy for participation in proficiency testing schemes and collaborative trials and for the evaluation of the performance. Attach the list of tests in which the laboratory has participated in the last three years, including the organizer and results.

[1] http://www.who.int/prequal/lists/PQ_QCLabsList.pdf.

2. Quality management system

2.1 Short description of the quality management system implemented in the laboratory, including reference to the standard used (such as *WHO good practices for pharmaceutical quality control laboratories*, ISO 17025, good manufacturing practices) and existence of a quality manual.

2.2 Information on inspections carried out by national or regional authorities and external audits performed in the laboratory in the last three years, including reference to valid accreditation, certificate, authorization or licence.

2.3 Brief description of the procedures for internal audits, implementation of corrective and preventive actions and complaints.

3. Control of documentation and records

3.1 Brief description of the procedures for the control of and changes to documents that form a part of the quality documentation. Attach a list of valid SOPs.

3.2 Brief description of the procedures for the preparation, revision and distribution of necessary documentation for specifications, standard test procedures, analyst workbooks or worksheets.

3.3 Brief description of any other documentation related to product testing, including reports, records, arrangements for the handling of results (including laboratory information management systems (LIMS), where used).

3.4 Brief description of the procedures for release of certificates and analytical reports.

4. Personnel

4.1 Number of employees engaged in the following activities:

Activity	Number
Supervisors	
Chemical sector	
analysts	
technicians	
Microbiological sector	
microbiologists	
technicians	
Quality assurance staff	
Staff trained for sampling	
Other	
Total number of employees in the laboratory:	

4.2 Organization chart showing the arrangements, responsibilities and reporting lines in the laboratory.

4.3 Qualifications, experience and responsibilities of key personnel.

4.4 Outline of arrangements for initial and ongoing training and its recording.

5. Premises

5.1 Simple plan or description of the layout of the laboratory areas with an indication of scale (architectural or engineering drawings not required, but photographs may be submitted if available).

5.2 Nature of construction and finishing.

5.3 Brief description of ventilation systems including those for microbiological testing areas, storage areas, etc. (Include reference to air circulation and control of temperature and relative humidity.)

5.4 Brief description of special areas for the handling and storage of hazardous materials such as highly toxic (including genotoxic), poisonous and flammable materials.

5.5 Description of planned programmes for preventive maintenance of the premises and the system for recording maintenance activities.

5.6 Brief description of the procedures for cleaning of areas and equipment.

5.7 Short description of the storage areas (size, location) including arrangements for the storage of materials and retention samples.

6. Equipment

6.1 Brief description of the main equipment used in the laboratory. Attach a list of equipment in use, in tabular form, indicating the equipment and its brand model and date of installation.

6.2 Brief description of the planned programme for the preventive maintenance of equipment and the system for recording the maintenance activities.

6.3 Brief description of arrangements and status for qualification of equipment (installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ)) as well as calibration of measuring equipment, including the recording system.

6.4 Brief description of computer system and its validation and data integrity management, including access to data and frequency of back-up.

7. Materials

7.1 Brief description of general policy for purchasing and handling of materials (including chemicals and reagents and availability of safety data sheets) and for handling of waste. Brief description of the procedure for selection and evaluation of suppliers.

7.2 Brief description of the water system in the laboratory, its qualification and arrangements for the sampling and testing of the water.

7.3 Brief description of the system for purchasing, preparation, handling and storage of reference substances and reference materials.

8. Subcontracting of testing

8.1 List of activities contracted out to other laboratories, including names and addresses of subcontractors of subcontractors. Description of the way in which the compliance with standards for activities contracted out is assessed.

9. Handling of samples

9.1 Brief description of general policy for sampling. If the laboratory is responsible for sampling describe briefly the procedures used and standards applied.

9.2 Brief description of the procedures for handling of samples from their receipt to storage after completion of testing. Where possible, flow charts describing important steps and work allocation in the laboratory should be supplied.

10. Validation of analytical procedures

10.1 Brief description of general policy for validation of analytical methods, including verification of pharmacopoeial methods or analytical procedures validated by manufacturers

11. Investigation of out-of-specification results

11.1 Brief description of the procedure for recording and investigation of out-of-specification results.

12. Stability testing (where applicable)

12.1 Brief description of the stability testing procedure.

12.2 Brief description of the conditions under which samples are kept, the arrangements for monitoring and the equipment used.

13. Microbiological testing (where applicable)

13.1 Brief description of the activities for microbiological testing.

13.2 Brief description of preparation and control of media and types of media used.

13.3 Brief description of the procedure in place for positive and negative controls.

13.4 Brief description of validation policy.

13.5 Brief description of arrangements for waste disposal.