

COUNTRY: Finland

1. NATIONAL GLP COMPLIANCE MONITORING PROGRAMME(S)

1.1 Name(s) of the national GLP Compliance Monitoring Programme(s) responsible for each of the chemical groups listed in 2.1. below and, if applicable, name(s) of the monitoring authority(ies). Indicate in bold the Programme(s) covered by this questionnaire.

Finnish Medicines Agency (Fimea)

1.2 Name(s) of the government bodies responsible for the establishment of the national GLP Compliance Monitoring Programme(s).

Finnish Medicines Agency (Fimea)

2. NATIONAL LEGISLATIVE REQUIREMENTS FOR GLP:

2.1 Specify legislative and regulatory documents that require the application of GLP for testing of the following chemical groups and indicate the name and address of the data receiving authority for each:

2.1.1 industrial chemicals

Act on Chemicals (744/1989)

**Finnish Safety and Chemicals Agency (Tukes), P.O.Box 66, Opastinsilta 12 B, FI-00521 Helsinki, Finland
(European Chemicals Agency (ECHA) is evaluating chemicals centrally in EU)**

2.1.2 pharmaceuticals

Act on Medicines (395/1987)

**Finnish Medicines Act (Fimea), P.O.Box 55, Mannerheimintie 103b, FI-00301 Helsinki, Finland
(Centralized authorisation in EU: European Medicines Agency)**

2.1.3 veterinary medical products

Act on Medicines (395/1987)

**Finnish Medicines Agency (Fimea), P.O.Box 55, Mannerheimintie 103b, FI-00301 Helsinki, Finland
(Centralized authorisation in EU: European Medicines Agency)**

2.1.4 pesticides

Act on Chemicals (744/1989)

**Finnish Safety and Chemicals Agency (Tukes), P.O.Box 66, Opastinsilta 12 B, FI-00521 Helsinki, Finland
(European Chemicals Agency (ECHA) is evaluating chemicals centrally in EU)**

2.1.5 food additives

EU legislation: EY 1331/2008

Safety of food additives is centrally evaluated in EU by European Food Safety Authority (EFSA)

2.1.6 feed additives

EU legislation: EY 1831/2003

Safety of feed additives is centrally evaluated in EU by European Food Safety Authority (EFSA)

2.1.7 cosmetics

EU legislation: EY 76/768

Safety of cosmetic products is centrally evaluated in EU.

2.1.8 biocides

Act on Chemicals (744/1989)

Finnish Safety and Chemicals Agency (Tukes), P.O.Box 66, Opastinsilta 12 B, FI-00521 Helsinki, Finland

(Active substances are evaluated centrally in EU)

2.1.9 other products (specify)

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and provide appropriate links to any documents available in English or English translation, if available.

- 2.2 For the submission of data for regulatory purposes, do the domestic regulators require the application of GLP principles other than the OECD Principles of GLP? If so, identify these principles and provide appropriate links to the referenced principles available in English or English translation, if available.

No

- 2.3 If GLP principles other than the OECD Principles of GLP were identified in 2.2, has a comparison of these principles to the OECD Principles of GLP been performed? If so, provide appropriate links to any documents reporting the comparison available in English or English translation, if available

NA

- 2.4. For each group of chemicals listed in 2.1 above, specify the type of testing for which GLP is mandated using the table given in Appendix A.

Requirements described in European Community legislation are followed, there are no national additional requirements.

3. GLP COMPLIANCE MONITORING PROGRAMMES

Provide answers for each of the questions below for each of the chemical groups specified under 2.1 above which are covered by the Monitoring Programme(s) concerned by this questionnaire.

3.1 Starting date for the monitoring programme.

The GLP compliance monitoring programme in Finland was established in 1991. First inspection for pharmaceuticals was carried out in 1991 and for chemicals in 1998. Responsibility of the programme was moved to Fimea on 1 November 2009 by the Act of the Finnish Medicines Agency. Inspectors of Fimea had already before performed the GLP inspections in the GLP programme in Finland.

3.2 Name(s) and full address(es) (including telephone, telefax numbers and e-mail address(es)) of the GLP compliance monitoring authority(ies) and the person(s) in charge of each.

**Finnish Medicines Agency (Fimea)
Mannerheimintie 103b (P.O.Box 55)
FI-00301 Helsinki
Finland
Phone: +358 9 473 341
Fax: +358 9 714 409
E-mail: registry@fimea.fi
Web: www.fimea.fi**

**Contact person: Pirkko Puranen
Phone: +358 50 364 27 44
E-mail: pirkko.puranen@fimea.fi**

3.3 Name(s) and full address(es) (including telephone, telefax numbers and e-mail address(es)) of the authority(ies) and the person(s) responsible for international communication on GLP inspection and audit procedures if different from those given under 3.2. Provide appropriate links to any documents available in English or English translation, if available.

Same as above

3.4 What is the complete (national) legal basis for monitoring GLP compliance? Provide appropriate links to any documents available in English or English translation, if available.

Act on Finnish Medicines Agency (2009/593), Act on Chemicals (744/1989), Act on Medicines (395/1987)

For each of the authorities mentioned in 3.2, above, answer all of the following questions:

- 3.5 Identify any programme documents that describe the procedures for conducting test facility inspections and data audits. Provide appropriate links to any document available in English or English translation, if available.

GLP inspections and data audits are carried out according to the internal Standard Operating Procedures of Fimea.

- 3.6 Describe the powers of the inspectors to access the test facilities and test data. [If GLP requirements monitored by one authority have different legal bases (see question 2), specify the powers granted under each of these cases.]

Inspectors have an access to the test facilities and test data. They also have a right to take photographs. Legal basis is the Act on Medicines 395/1987.

- 3.7 List the number of inspectors in each compliance monitoring authority (specify full-time or part-time), the level of education, training and experience required to fill the position.

There are two qualified inspectors (one full time inspector performing also GMP- and ATMP-inspections, and one part-time inspector performing also GMP-inspections in microbiological laboratories and acting as senior scientist in Fimea OMCL microbiology laboratory. Both inspectors have more than 10 years experience in GLP. One person is under training.

Education:

Minimum education is Ms degree on a relevant field. Both qualified inspectors have PhD degree (microbiology and genetic toxicology), and the one in training has a MSc degree in chemistry.

Work experience:

Preliminary experience in laboratory work in suitable field is required, minimum 5 years.

Present inspectors have extensive work experience in research, industry, hospital and OMCL laboratories, in safety assessment of chemicals and pharmaceuticals for approvals and marketing authorisations, and laboratory accreditation.

Training:

Theoretical and in-job training is given according to the quality system of the inspectorate of Fimea. External training consists of OECD training courses, commercial courses and participating GLP-inspections in other countries as observers. Minimum 10 days external training/year is required.

- 3.8 What percentage of their work load do the inspectors spend on inspections and study audits and GLP related activities? How many full-time equivalents does this represent?

Inspector, who has main responsibility of GLP, spends about 40 %, another inspector about 20 %, and the trainee about 5 %, of their work time in GLP related activities. Besides them, the head of the inspectorate, the director of the process, the lawyer and the secretary of the inspectorate spend some working time on GLP. The overall time is about 0,7 man year.

- 3.9 What is each inspector's relationship with the compliance monitoring authority (employee, external contractor, etc.)?

The inspectors are full time employees of Fimea.

- 3.10 Has the scope of GLP coverage of the compliance monitoring authority(ies) been extended since submission of the previous questionnaire? If so, please describe the process used to ensure adequate access to expertise. The answer could address such issues as analysis of current competencies, additional training of inspectors, access to external expertise, co-operation with domestic regulators and other compliance monitoring authorities.

Finnish Safety and Chemicals Agency (Tukes) was established at the beginning of 2011 to cover safety assessment of all chemicals. Co-operation meetings between Tukes and Fimea are arranged at least once a year to discuss about current GLP questions.

4. EXPLANATION OF ORGANISATION AND MANAGEMENT OF GLP COMPLIANCE MONITORING

- 4.1 Describe in detail how the GLP compliance monitoring in your country is organized, including a description of the relationship between monitoring authority(ies) and the receiver of the test data (i.e. regulatory authority(ies)).

Finnish Medicines Agency is responsible of the GLP programme in Finland. It performs the routine inspections and study audits and grants acceptance decisions and GLP statements to the facilities. It also is a receiving authority for some safety studies (regarding medicines).

A working group has been established for co-operation with receiving authorities and training sessions for assessors have been organised. However, since Finland is a member of EU, national authorities are relatively seldom directly receiving authorities, because mostly evaluations are done centralised by EU authorities like EMA, ECHA and EFSA.

- 4.2 i) How does the monitoring programme determine if a test facility should be inspected?

A test facility enters to the monitoring programme by applying a GLP compliance status. After the facility has been entered the programme, it will be inspected according to the inspection programme of Fimea (every second year, or more often, if significant changes have happened in the facility, or if there are any special reasons based on risk analysis). Inspections may also be performed by a request of a receiving authority (national, other OECD country or EU authority).

- ii) On average how many test facilities are inspected per year?

8 – 10 test facilities/year

- iii) On average how many studies are audited upon request per year?

Study audits upon external requests have not yet been performed. Normally study audits are performed as a part of first and routine inspections.

iv) What is the frequency (a range is acceptable) of inspections of each test facility?

Facilities are inspected every second year.

4.3 i) What are the criteria for doing the first inspection and subsequent re-inspections of a test facility?

A test facility enters to the monitoring programme by applying a GLP compliance status. After the facility has been entered the programme, it will be inspected according to the inspection programme of Fimea (every second year, or more often, if significant changes have happened in the facility, or if there are any special reasons based on risk analysis).

ii) What are the criteria for doing study audits?

Study audits are routinely performed as a part of inspection. A separate study audit could be performed upon a request by a receiving authority (national, OECD country or EU-level authority).

4.4 i) Describe the actions that may be taken if non-compliances with GLP requirements are found during a test facility inspection or during a study audit

If non-compliances are critical, the facility may be ordered already at the closing meeting of the inspection to start immediate corrective actions. If findings are not critical, the facility will receive in 30 days after the inspection a report, where they are requested to provide in 30 days time their response and corrective action plan and schedule.

All findings are presented and explained orally to the facility at the closing meeting of the inspection, and the representatives of the facility have a possibility to ask for clarifications. After the response of the facility has been received by Fimea, the facility is informed, if the response is satisfactorily or if more clarifications are needed. GLP compliance statement can be granted only after the facility has given a satisfactory response.

ii) Summarise the main types of actions taken in the last 2-4 years.

In GLP inspections of Fimea, no critical non-compliances have been found. Therefore no immediate correction orders have been given. Facilities have been asked to provide their responses to non-compliances after receiving the inspection report and the responses have been satisfactory.

iii) What are the criteria for giving a test facility the status of “not in compliance”?

The general criteria are fulfilling OECD GLP Principles requirements. The test facility has a right to give a response, if it is found to be not in compliance. If it is not able to give an acceptable response, the facility would be removed from the programme by withdrawing its GLP compliance status. Refusal from

the inspection would also cause withdrawal of status and removal from programme.

- iv) What is the procedure used to inform other member countries about facilities or studies found to be non-compliant?

OECD and EU GLP WG members would be informed immediately about the non-compliance as well as the national receiving bodies in Finland.

- 4.5 i) How are the records of and reports on inspections and study audits documented (pro forma checklists, reports, etc?)

Inspections and study audits are individually planned without a formal checklist to allow adequate flexibility. A report format is used.

- ii) For how long are records of inspections and study audits retained?

Notes made during the inspection are retained until to the next inspection. Inspection report is retained permanently.

- 4.6 i) How is a test facility informed about the outcome of an inspection or a study audit?

Test facility receives the report in 30 days after the inspection, where they are asked to give their response to the observations in 30 days. If their response is acceptable, they will receive a letter of acceptance and an updated GLP statement. If the response is not acceptable as such, more clarifications are asked.

If there are critical non-compliance findings during an inspection, the facility may be requested to start immediate corrective actions. In that case a written order is given at the closing meeting of the inspection.

- ii) What is the average time between the conclusion of an inspection/audit and the notification of its result to the test facility?

The inspection reports have been sent in 30 days. If 30 days time limits would be exceeded, an internal deviation handling process would be started according to the quality system of Fimea.

- 4.7 How does your programme respond to requests from other national GLP authorities to conduct inspections or study audits, or to release inspection reports?

Currently such requests have not been received, but if asked by authority an inspector or study audit could be performed. An inspection report could be sent after removing confidential trade secrets.