This section gives a brief overview on the application of the GLP Directives in the European Union. All Member States have transposed the GLP Directives and here you have a quick overview of the situation by country.

The Member States listed below have established functioning national GLP compliance monitoring programmes. Norway has transposed GLP Directives 87/18/EEC and 88/320/EEC which are an integral part of the EEA Treaty, and they also have an operational monitoring authority.

**Austria**
- The Federal Ministry for Agriculture and Forestry, Environment and Water Management, department I/3 is the GLP monitoring authority for all chemicals except medicinal products and veterinary drugs. The Austrian Federal Office for Safety in Health Care (BASG) is the competent monitoring authority for substances relevant in medicinal products. Inspections are performed on its behalf by the Austrian Agency for Health and Food Safety (AGES).
- Routine inspections take place every 2-3 years.
- GLP monitoring programme started in 1989 (industrial chemicals) and 1991 (pesticides).

**Belgium**
- The Federal Department of Public Health, the Food Chain Safety and Environment is in charge of the GLP monitoring authority, Scientific Institute of Public Health, which is responsible for all chemical products
- The test facilities in the national monitoring programme work on a wide range of chemical products: industrial chemicals, medicinal products, veterinary drugs, phytopharmaceuticals, food additives and cosmetic products.
- Laboratories are inspected every 2-3 years.
- The GLP monitoring programme started in November 1988.

**Cyprus**
The Competent Authority for GLP is the Ministry of Commerce, Industry and Tourism and in particular the Cyprus Organization for Promoting Quality (CYS).

A Memorandum of Cooperation between the Cyprus Organization for Promoting Quality and the General State Laboratory of Greece has been signed on 18 July 2007. It includes the possibility to carry out joint GLP inspections on Cyprus.

There are no GLP compliant test facilities on Cyprus yet.

**CzechRepublic**

The Ministry of Environment is responsible for ASLAB, the national GLP monitoring authority dealing with all sectors except pharmaceuticals. The State Institute for Drug Control (SUKL), under the responsibility of the Ministry of Health, is responsible for both human and veterinary pharmaceutical products.

Routine inspections are carried out every 2-3 years.

The GLP monitoring programmes started in 1997.

**Denmark**

The Ministry of Health and the Ministry of Trade and Industry are in charge of the designation of the GLP monitoring authorities: Danish Medicines Agency (Lægemiddelstyrelsen) covers medicinal products and veterinary medicinal products. The Danish Accreditation and Metrology Fund (DANAK) (Erhvervsfremme Styrelsen) covers plant protection products, biocides, and food additives.

Inspections are carried out by the Danish Medicines Agency and the Danish Accreditation and Metrology Fund (DANAK).

Routine inspections are carried out every 2-3 years.

The GLP monitoring programmes were launched on 1 March 1989, but there has been a GLP inspection programme for chemicals since 1981.

**Estonia**

The Ministry of Social Affairs is in charge of the GLP monitoring authority, the Estonian Accreditation Centre (EAK). The Estonian Accreditation Centre is cooperating with the Swedish Board of Accreditation and Conformity Assessment, SWEDAC. SWEDAC will take part in joint inspections with EAK in Estonia and will also train Estonian personnel.

**Finland**

The GLP monitoring authority is the National Product Control Agency for Welfare and Health (STTV), which is responsible for the GLP programme and also monitors directly test facilities carrying out safety studies on chemicals. The Agency has delegated GLP inspections of test facilities carrying out safety studies on medicinal products to the National Agency for Medicines.

The GLP inspection programme started in 1990.

**France**
The Groupe interministériel des produits chimiques (GIPC) is in charge of the GLP monitoring authority Cofrac for chemicals others than medicinal products, cosmetics and veterinary drugs. The Ministry of Labour and Social Affairs is in charge of the GLP monitoring authority Agence française de sécurité sanitaire des produits de santé (AFSSAPS) for medicinal products and cosmetics. The Ministry of Labour and Social Affairs together with the Ministry of Agriculture and Fisheries are responsible for the Agence française de sécurité sanitaire des aliments, comprising the Agence nationale du médicament vétérinaire, the GLP monitoring authority for veterinary drugs.

The test facilities in the three monitoring programmes work on a wide range of chemical products: new and existing chemicals, medicinal products, veterinary drugs, cosmetics, food additives, animal feed additives, pesticides.

Routine inspections are carried out in intervals of between 15 months (GIPC) and two years (AFSSAPS).

The GLP monitoring programme was started in 1984 for medicinal products, in 1999 for veterinary drugs and in 1985 for other chemicals.

**Germany**

The Federal Ministry for Environment, Nature Conservation and Nuclear Safety is in charge of the designation of the GLP monitoring authorities. There is one GLP monitoring authority in each Land. Their work is co-ordinated by the Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment - BfR).

The test facilities in the national monitoring programme work on a wide range of chemical products: industrial chemicals, medicinal products, veterinary drugs, food additives, animal feed additives, pesticides, explosives and cosmetics.

Routine inspections of test facilities are conducted on a regular basis. Test facilities have to apply for a renewed routine inspection at the latest four years after the last inspection. Additional inspections and study audits may be carried out on request.

The GLP monitoring programme was launched on 1 August 1990.

**Greece**

The Ministry of Finance is in charge of the GLP monitoring authority, General Chemical State Laboratory.

Test facilities in Greece work mostly on plant protection products.

Routine inspections are performed every second year.

The GLP monitoring programme was started in 1995.

**Hungary**

The Ministry of Health is in charge of the GLP Monitoring Authority for medicinal products for human use, the National Institute of Pharmacy.

Routine inspections are carried out every two years.
GLP monitoring programme was launched by a Joint Decree of the Ministers of Health and of Agriculture and Rural Development (31/1999) in 1999.

Ireland

The Irish Department of Enterprise, Trade and Employment is in charge of the designation of the GLP monitoring authority, The Irish National Accreditation Board (INAB).

Products involved are the chemical substances as defined in directive 67/548/EEC.

Routine inspections are performed every second year.

Legislation was approved in January 1991, and the Irish authorities implemented the GLP monitoring programme in 1992.

Italy

The Ministry of Health is in charge of the GLP monitoring authority, Dipartimento prevenzione (Department of prevention), which operates through an ad-hoc committee comprising those departments of the Ministry of Health involved in GLP (Department of prevention, Department for pharmaceuticals and pharmaco-surveillance, Department of veterinary drugs and Department of food and nutrition) and the Istituto superiore di sanità (National institute of health). Test facilities in the national monitoring programme mainly work on medicinal products, veterinary medicinal products, pesticides, food additives, cosmetics, and industrial chemicals.

Routine inspections are carried out every two years.

The GLP monitoring programme was started in 1986.

Latvia

The Ministry of Environmental Protection and Regional Development of Republic of Latvia is responsible for the implementation of the GLP Directives.

The GLP monitoring authority - Latvian National Accreditation Bureau (LATAK) is nominated by the government.

The GLP monitoring programme was launched by the Regulation of Cabinet of Ministers No.398 (03.09.2002) in 2004.

The GLP inspection programme started in 2007 (pharmaceutical compounds), but has not yet been subject to an OECD or EU evaluation visit.

Routine inspections are carried out by LATAK every 2 years.

Lithuania

The Ministry of Environment is responsible for the national GLP monitoring authority, the Lithuanian National Accreditation Bureau (LA). LA is cooperating with the Irish GLP monitoring authority Irish National Accreditation Board (INAB). Routine inspections will be carried out every second year, but so far no laboratory has yet joined the programme.
Luxembourg

- Luxembourg has transposed Directives 2004/9/EC and 2004/10/EC and nominated the Institut luxembourgeois de la normalisation, de l'accréditation, de la sécurité et qualité des produits et services (ILNAS) as the coordinating authority for GLP inspections. ILNAS has obtained the agreement of the Belgian GLP monitoring authority for conducting joint inspections in Luxembourg.

Malta

- The Maltese GLP monitoring authority is the National Accreditation Body (NAB-MSA). This is a technically independent Directorate of the MSA (Malta Standards Authority) which is a public authority established by an Act of Parliament.

- The MSA has concluded an agreement with the Irish National Accreditation Board (INAB) to carry out joint GLP inspections on Malta on 15 December 2005. The agreement has been concluded for an initial duration of three years and may be prolonged by the two parties. There are no GLP compliant test facilities on Malta yet.

- More information about GLP in Malta is available on http://www.msa.org.mt.

Netherlands

- The Ministry of Health, Welfare and Sport is in charge of the GLP monitoring authority, the Health Care Inspectorate.

- The test facilities in the national monitoring programme work on a wide range of chemical products: industrial chemicals, medicinal products, veterinary drugs, and pesticides.

- The GLP monitoring programme was started in March 1987.

Poland

- The Ministry of Health is in charge to indicate Poland’s GLP Monitoring Authority.

- The Bureau for Chemical Substances and Preparations is Poland’s GLP Monitoring authority.

- With regard to GLP, the Bureau inspects laboratories which carry out tests of a wide range of chemical products.

- The GLP monitoring programme was started in 2002.

Portugal

- The Ministry of Health is in charge of the GLP monitoring authority Instituto da farmacia e do medicamento (Infarmed) (Institute for pharmacy and medicaments) for medicinal products, veterinary drugs and cosmetics, and the Ministry of Economy is in charge of the GLP monitoring authority Instituto portugues da qualidade (IPQ) (Portuguese institute for quality) for other chemical products.

- Routine inspections are carried out every two years.
The GLP monitoring programme started in 1993 for industrial chemicals and in 1994 for medicines.

**Slovakia**

- The Ministry of Economy is the governmental body in charge of the GLP monitoring authority, Slovak National Accreditation Service (SNAS).
- Routine inspections are carried out every 16 months.
- At the current stage medicinal products and veterinary drugs, industrial chemicals, plant protection products, cosmetics, biocides, food and feed additives are covered by GLP monitoring.
- The GLP monitoring programme was launched under SNAS in 1996.

**Slovenia**

- The Ministry of Health is in charge of the GLP monitoring authority.
- The National Chemicals Bureau covers all chemicals.
- Test facilities in Slovenia work on medicinal products, veterinary drugs, feed additives, biocides and industrial chemicals.
- Routine inspections are carried out every two years.
- The GLP monitoring programme was launched in 2000.

**Spain**

- The Ministry of Health and Consumption, Directorate General of Pharmacy and Hygiene, is in charge of the GLP monitoring authority Agencia Española del Medicamento (Spanish Agency for Medicinal Products) for medicinal products. The Entidad Nacional de Acreditación (ENAC), National Entity for Accreditation, is dealing with all other products.
- At the current stage, only medicinal products and plant protection products are covered by GLP monitoring.
- No bilateral agreements exist.
- The GLP monitoring programme was launched in 1995 for medicinal products and in 1998 for plant protection products.

**Sweden**

- The Ministry of Social Affairs is in charge of the GLP monitoring authority Läkemedelsverket (Medical Products Agency, MPA) for pharmaceuticals, cosmetics and hygienic products and the Ministry of Foreign Affairs is in charge of the GLP monitoring authority Styrelsen för ackreditering och teknisk kontroll (Swedish board of accreditation and conformity assessment, SWEDAC) for other chemicals. Since 1998 there exists an agreement between the MPA and SWEDAC concerning GLP monitoring.
- Routine inspections are carried out every year (SWEDAC) and every two years (MPA).
• The GLP monitoring programmes were started in 1979 (MPA) and 1991 (SWEDAC).

**United Kingdom**

• The Department of Health is in charge of the GLP monitoring authority, United Kingdom GLP compliance monitoring authority, which is a part of the Medicines Control Agency, and is responsible for all chemicals.

• The test facilities in the national monitoring programme work on a wide range of chemical products: new and existing chemicals, medicinal products, veterinary drugs, cosmetics, food additives, animal feed additives, pesticides.

• Routine inspections are carried out every two years.

• The GLP monitoring programme was started in January 1983.

**EFTA COUNTRIES**

**Norway**

• The Ministry of Trade and Industry is in charge of the GLP monitoring authority Norwegian Accreditation.

• Routine inspections are carried out every two years.

• No bilateral agreements have been concluded.

• The GLP monitoring programme was started in 1994.

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N.B. The information in this document is copied from the archived European Commission/DG Enterprise-website and has not been updated.