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## **GLP Conformity Assessment**

### **Note to Applicants**

**INSTITUTO PORTUGUÊS DA  QUALIDADE**

Ministério da Economia

Rua António Gião, n.º 2  
2829-513 CAPARICA  
PORTUGAL

Tel. 21 294 81 00/21 294 82 15  
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(Please note that although we have made efforts to provide a faithful translation, we consider that only the Portuguese version of the Procedure is relevant to the GPL recognition.)

## **NOTE TO APPLICANTS**

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### **SCOPE**

The aim of the present document is to give guidance to test facilities performing studies within the scope of the OECD Principles of Good Laboratory Practice (GLP), regarding either chemicals or pharmaceutical products or cosmetics, to enter the national programs for OECD/EU mutual acceptance of data.

### **RECOGNITION PROCESS**

The recognition of GLP conformity is granted to test facilities complying with the OECD Principles of Good Laboratory Practice, as lay down in Decree Law 99/2000, of 30 May. The evaluation is performed in accordance with the criteria established in the annex to the DL 95/2000, of 23 May.

The GLP recognition system is managed by the Portuguese Institute for Quality (IPQ) and by the National Institute for Pharmacy and Medicines - INFARMED, in compliance with the Decree Law 95/2000, of 23 May, that transcribes the EC Directive 2004/9/CE. These general criteria are complemented by a set of OECD documents available at the OECD website.

### **APPLICATION PROCEDURE**

A test facility must submit the preliminary application to the Monitoring Authority, either INFARMED (pharmaceuticals) or IPQ (industrial chemicals and pesticides).

The preliminary application for the concession of GLP conformity must be addressed to the Chairman of the Board of Administration of the Monitoring Authority. It must be written in Portuguese, in commercial paper from the test facility (or the entity responsible for it), allowing its identification and the identification of the social responsibility.

Once the application is received, a questionnaire is sent to the test facility. Within thirty days the questionnaire should be returned duly filled in to the respective monitoring authority, including the following elements as annex:

#### *Questionnaire*

The aim of the questionnaire is to collect general information, and also to assist the applicant to evaluate its degree of conformity with the GLP requirements, such as

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expressed in the annex to the DL the 99/2000. The answers must be precise and reflect the current situation of the Laboratory. Each page should be signed and dated by the person responsible for the application.

*Documents identifying the functioning and organisation of the test facility:*

- ◆ Organisation chart
- ◆ Personnel: job description, training, experience
- ◆ Study Directors and Quality Assurance Manager's Curricula
- ◆ Type of studies carried under GLP
- ◆ List of Standard Operating Procedures (SOP's)
- ◆ List of relevant equipment
- ◆ Environmental conditions
- ◆ Layout of the facilities

The inspection team, both IPQ's and INFARMED's GLP inspectors, will review the documents received and, when applicable, may request further information.

The applicant will be informed of the composition of the inspection team and of alternative dates for the pre-inspection.

In general the pre-inspection lasts one day; the inspection can last 2 to 3 days depending on the dimension of the facilities and the number and complexity of the studies.

### **CONTACT WITH THE MONITORING AUTHORITIES**

Further clarifications must be addressed to:

*NATIONAL INSTITUTE FOR PHARMACY AND MEDICINES - INFARMED*

Celeste Freire

Parque de Saúde de Lisboa

Av. do Brasil, 53

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## **NOTE TO APPLICANTS**

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### ***PORTUGUESE INSTITUTE FOR QUALITY - IPQ***

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### **REFERENCE DOCUMENTS**

- Decree Law 95/2000, of 23 of May
- Decree Law 99/2000, of 30 of May
- National Monitoring Program
- Directive 2004/9/CE
- Directive 2004/10/CE

For complementary information on particular aspects of the application of the Good Laboratory Practice, the OECD GLP Principles as well as the OECD Consensus Documents on GLP can be visited at the OECD website:

[www.oecd.org](http://www.oecd.org)