To:

**Information for a testing facility application for GLP recognition via ISRAC.**

Organization seeking to be part of Israel GLP monitoring program should present the following documents:

1. Description of the testing facility, including the structure map and a clear indication of the GLP areas.

2. Organizational structure and job descriptions that refer to at least:

2.1 GLP testing facility's Management;

2.2 GLP testing facility's Quality Assurance;

2.3 Study Director (SD)

2.4 Archive Manager

2.5 IT (Information Technology) computer department

3. Officials' CV for the personel described above.

4. A comprehensive and updated list of procedures of the testing facility including their versions' number.

As well as a copy of the procedures that describe the following processes:

Receiving and handling and storage of samples, Equipment-maintenance and calibration, Computerized system: validation, operation and their maintenance, Numbering of the studies, Collection procedure of raw data, including the use of computerized systems, Writing a study protocol, Writing a study report, Quality-assurance planning and performing internal audits, and the Quality Assurance plan for the testing facility.

5. Updated list of completed GLP studies. The list shall include at least 3 studies at the time of ISRAC's audit assessment, in each area of expertise.

6. A copy of one study protocol and report for each area of expertise.

7. Please complete the following table detailing the Areas of expertise of the testing facility.

8. Please sign the application form.

Regards,

GLP Head of Department

 **Definition of the Areas of expertise of testing facilities accordong to the GLP principles**

|  |  |  |
| --- | --- | --- |
|  | 2Areas of expertise - | 1List of Chemicals - |
|  | Physical-chemical testing | 1. Industrial Chemicals
2. Pharmaceuticals
3. Veterinary Medical Products
4. Pesticides
5. Food Additives
6. Feed Additives
7. Cosmetics
8. Biocides
9. Other Products
10. Medical Devices
 |
|  | Toxicity studies |
|  | Mutagenicity stdies |
|  | Environmental toxicity studies on aquatic and terrestrial organisms |
|  | Studies on behavior in water, soil and air; bioaccumulation |
|  | Residue studies |
|  | Studies on effects on mesocosms and natural ecosystems |
|  | Analytical and clinical chemistry testing |
|  | Other studies, specify |

(1) whether they are prepartion or materials: from GLP agreement

(2) from GLP / OECD documents

The definition of a research areas of the testing facility, operating in compliance with GLP principles is by defining an area of expertise and a chemical from the table above.

For example: a research facility specializing in analytical chemical studies of pesticides (6-f)

ISRAC

12 Kineret st.

Airport City

P.O.B 89, Lod, 7015002

**Admission Request**

1. We (the testing facility) here by request to join the GLP monitoring program for compliance to the principles of Good Laboratory Practices (GLP) of the Israel Laboratory Accreditation Authority (ISRAC).

Areas of expertise under GLP of the testing facility (select the appropriate field):

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Test items  | a | b | c | d | e | f | g | h | i | j |
|  | Physical-chemical testing |  |  |  |  |  |  |  |  |  |  |
|  | Toxicity studies |  |  |  |  |  |  |  |  |  |  |
|  | Mutagenicity studies |  |  |  |  |  |  |  |  |  |  |
|  |  Environmental toxicity studies on aquatic and terrestrial organisms |  |  |  |  |  |  |  |  |  |  |
|  | Studies on behavior in water, soil and air; bioaccumulation |  |  |  |  |  |  |  |  |  |  |
|  | Residue studies |  |  |  |  |  |  |  |  |  |  |
|  |  Studies on effects on mesocosms and natural ecosystems |  |  |  |  |  |  |  |  |  |  |
|  | Analytical and clinical chemistry testing |  |  |  |  |  |  |  |  |  |  |
|  | Other studies, specify: |  |  |  |  |  |  |  |  |  |  |

1. Signature of certifying accept and acknowledge all the items are presented herein.
2. Details of the applicant:

|  |  |
| --- | --- |
| Research facility name (Hebrew) |  |
| Research Facility Name (English) |  |
| The name of the unit/ department recognized, if different from the organization (in Hebrew) |  |
| The only name of the unit/ department recognized, if different from the organization (in English |  |
| Description of the organization's legal entity (individual, corporation, public organization, partnership, etc.( |  |
| Company Registration Number  |  |

**Note**: *Please attach a certificate (Registrar of Companies, the Registrar of Associations, etc.). If the applicant testing facility is part of a bigger organization, the certificates have to be given to the bigger organization as well as specifying the range of fields of activity of this organization.*

|  |  |
| --- | --- |
| Address |  |
| Contact Person: |  |
| Position |  |
| Mailing address |  |
| Tel: |  |
| Fax: |  |
| E mail address: |  |
| Main site: |  |
| subsites: [ ] No / [ ] Yes, except: |  |

**4.** **Declarations**

4.1 Organization Statement of ownershipes:

|  |  |  |  |
| --- | --- | --- | --- |
| Owner Name: |  | part owned(%) |  |
|  |  |  |  |
|  |  |  |  |

Please list all the owners so that the sum of the parts will be 100% owned.

Please add an approval (e.g. company directory, association directory).

In the case of a corporation or partnership: Is voting rights and management partially overlapping the ownership?

[ ]  Yes [ ]  No

If not, please specify:

|  |
| --- |
|  |

Please specify changes in the ownership status during the three years prior to the application

|  |
| --- |
|  |

Areas of involvement of the owner besides his engagement in the testing facility (including subsidiaries, parent companies and affiliated companies of the organization):

|  |
| --- |
|  |

4.2 A statement regarding recognized research facility website (ISRAC Form #

T2-000005-01).

A research facility may add its web site link to its name on ISRAC website under recognized research facilities or recognized labs section.

I hereby declare that the web site of the research facility listed above is our responsibility and ISRAC has no berring on its website content. I hereby declare that the information that is registered on our research facility website is updated according to accreditation / recognition scope and doesn't mislead.

5. This request is a concent to the following conditions:

5.1 to facilitate performance of surveillance audits of the testing facility and to garant access to all areas in which is performed or stated an activity according to Good Laboratory Practice (GLP).

5.2 to allow the entry at any time of inspectors and experts from ISRAC to carry out surveillance assessment (inspection) or assessment study (study audit).

5.3 to present and provide all documents required by ISRAC, in their entirety in order to allow the performance of the inspection or study audit eather in the laboratory and at ISRAC.

5.4 ISRAC shall publish from time to time and will update the status of the testing facilities compatibility to the GLP principles and forward this report to OECD countries, the European Community as required by the Mutual Recognition Agreements.

5.5 to act upon the requests in accordance with the principles of Good Laboratory Practices (GLP) Principals of the OECD, the requirements of ISRAC and ISRAC's interpretation of those documents.

5.6 to update within 14 days of any change in the senior staff of the laboratory: Management, Quality Assurance Manager, Principal Investigator, Study Director.

5.7 to cover the costs of participation in the program. These expenses include:

ISRAC's expenses, including the performance of the audit, review of corrective action etc...

In accordance with the evaluation by ISRAC, submitted in advance and before the inspection.

6. **Approval of the application**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Testing facility name | Name and Title | Date | Signature |