

MALAYSIA AS NON-OECD MEMBER ADHERING TO MUTUAL ACCEPTANCE OF DATA SYSTEM FOR GOOD LABORATORY PRACTICE

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MINISTRY OF HEALTH**

**NATIONAL REGULATORY CONFERENCE
7-9 MAY 2013**

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- NPCB GLP Compliance Programme

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1. Good Laboratory Practice

3

Quality system concerned with organizational process and conditions under which **non-clinical safety** studies are **planned, performed, maintained, recorded, archived and reported.**



1. Good Laboratory Practice

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The Principles of GLP apply to :

- All **non-clinical** health and environmental **safety studies** required by regulations for the purpose of **registering** or **licensing** those test items.

1. Good Laboratory Practice - Scope

5

- Should be applied to the **non-clinical safety testing** of test items contained in:
 - a) Pharmaceutical products
 - b) Cosmetics products
 - c) Veterinary drugs
 - d) Food additives
 - e) Pesticides products
 - f) Feed additives
 - g) Industrial chemicals

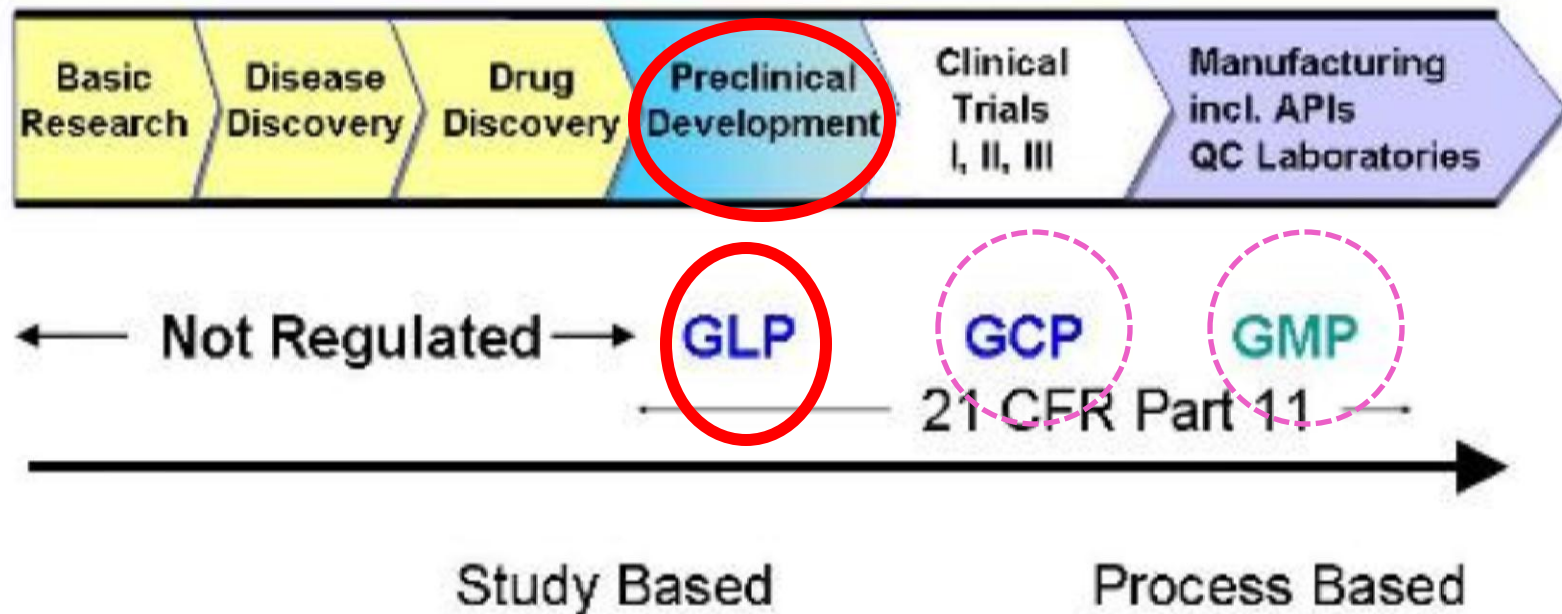
1. Good Laboratory Practice – Area of expertise

6

- physical-chemical testing
- toxicity studies
- mutagenicity studies
- environmental toxicity studies on aquatic and terrestrial organisms
- studies on behaviour 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. Good Laboratory Practice – Pharmaceutical development

7



Part 11 applies for computers that are used in FDA regulated areas.

1. Good Laboratory Practice – Registration flow

8



TEST FACILITY



FINAL REPORT OF
NON CLINICAL
STUDIES



REGULATORY
AUTHORITY

1. Good Laboratory Practice – WHY ?

9

- 1975: Pre-clinical safety data submitted to US FDA for registration of New Drug Application (NDA)
- Inspection on studies and test facilities findings:

1. Good Laboratory Practice – WHY ?

10

- 1975: USFDA findings:
 - >10,000 studies produced in short time
 - Personnel poorly trained & supervised
 - Records not available/inadequate
 - Test system in poor health
 - Animal id not maintained
 - Reported lab test not conducted
 - Falsification of pathology results

1. Good Laboratory Practice – WHY ?

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Examples:

- ⊕ Replacing animals which died during study with new ones, without documenting this facts
- ⊕ Taking hematology data for control animals from control groups not connected with the study
- ⊕ Recorrecting discrepancies in raw data and final report tables by juggling raw data to fit the results table to the final report

1. Good Laboratory Practice – WHY ?

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- >>>> Human health is jeopardised
- >>>> Not conducted according to principles: those products can potentially cause adverse effects on human health and environment

1. Good Laboratory Practice – WHY ?

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- ✓ 1979: US FDA Regulations on GLP
- ✓ 1981: OECD Principles of GLP
- ✓ 1983: US EPA Regulation on GLP
- ✓ 1997: OECD Principles of GLP (Revised)

2. About OECD

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- **OECD = Organization for Economic Co-operation and Development.**
- **34 industrialized countries (NAFTA, EU, European Non-EU, Asia Pacific)**
- **Co-ordinate and harmonize policies, discuss issues of mutual concern and work together to respond to international problems.**

2. OECD countries

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EU

- Austria
- Belgium
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Luxembourg
- The Netherlands

- Poland
- Portugal
- Slovak Republic
- Spain
- Sweden
- United Kingdom

EUROPEAN NON-EU

- Iceland
- Norway
- Switzerland
- Turkey

NAFTA

- Canada
- Mexico
- United states

ASIA - PACIFIC

- Australia
- Japan
- New Zealand
- South Korea

3. 1981 “MAD” Council Decision

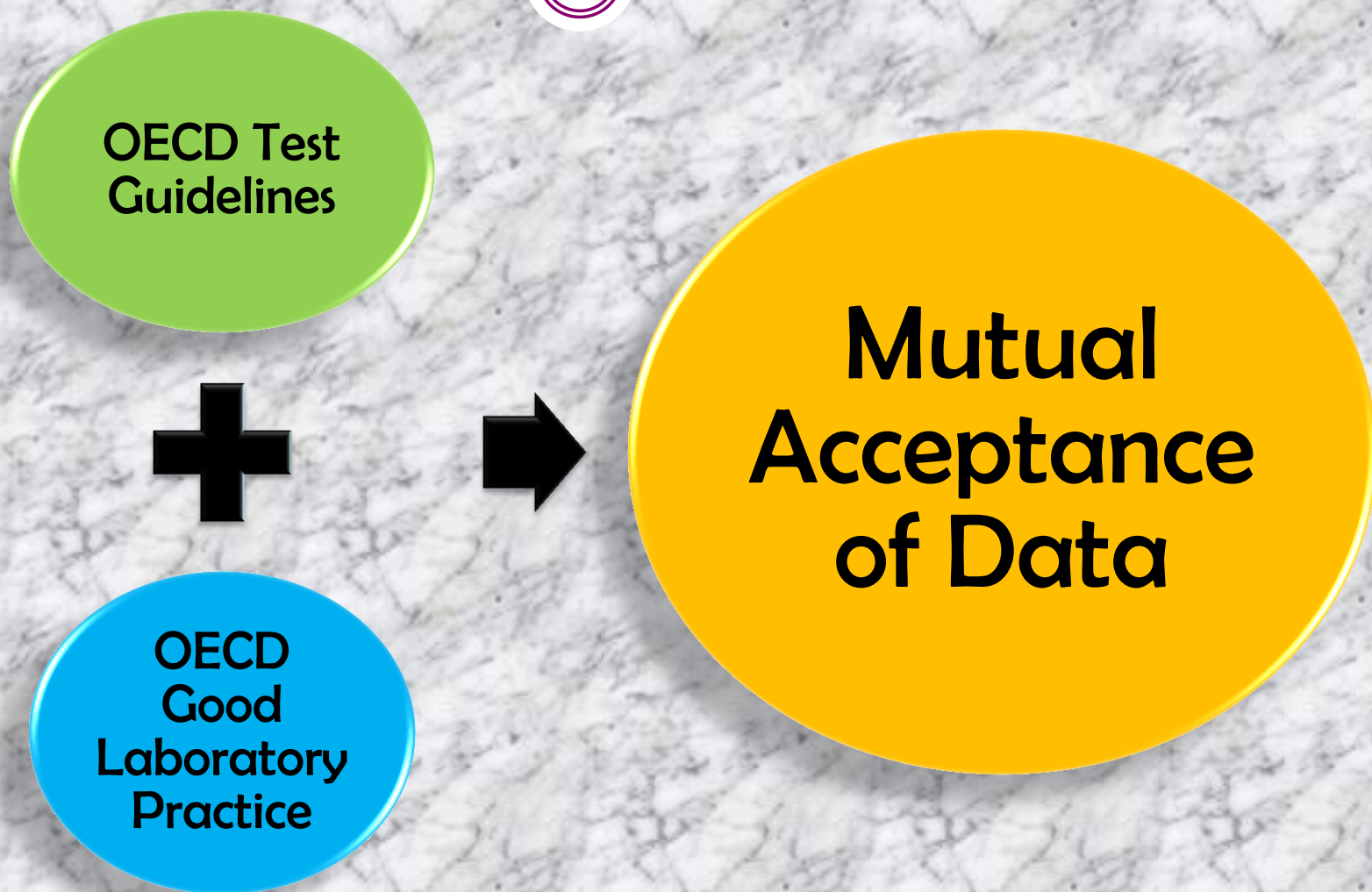
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*OECD Council Decision on Mutual Acceptance
of Data in an Assessment of Chemicals including Pesticides
C(81)30(Final)*

“Decides that the data generated in the testing of chemicals in an OECD Member country in accordance with **OECD Test Guidelines** and **OECD Principles of Good Laboratory Practice** shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment.”

3. 1981 “MAD” Council Decision

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3. 1981 “MAD” Council Decision

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OECD Series on Principles of GLP and Compliance Monitoring

- 15 documents available online
 - ❑ Doc 1 : Principles of GLP
 - ❑ Guidance document for CMA (2, 3, 9)
 - ❑ Consensus document (4,5,6,7,8,10,13)
 - ❑ Advisory document (11,12,14,15)

3. OECD Series on Principles of GLP and Compliance Monitoring

(19)

OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring - Microsoft Internet Explorer

Address: http://www.oecd.org/document/63/0,3343,en_2649_34381_2346175_1_1_1_1,00.html

Organisation for Economic Co-operation and Development

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Environment Directorate

Environment Directorate

- Chemical Safety
 - Biocides
 - Chemical Accidents
 - Chemicals Classification and Labelling
 - Chemicals Hazard/Risk Assessment
 - Chemicals Risk Management
 - Chemicals Testing - Guidelines
 - Co-operation on the Investigation of Existing Chemicals
 - Good Laboratory Practice
 - New Chemicals
 - Pesticides
 - Pollutant Release and Transfer Registers
 - Safety of Manufactured Nanomaterials
 - Biosafety - BioTrack
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 - Environmental Policies and Instruments
 - Environmental-Social Interface
 - Natural Resource Management
 - Trade, Investment and Environment

Home: [Good Laboratory Practice](#) > OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring

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OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring

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OECD Principles of GLP

[No 1: OECD Principles on Good Laboratory Practice](#)

- Les Principes de l'OCDE de Bonnes pratiques de laboratoire (Français);
- Principios de Buenas prácticas de laboratorio (Español)
- OECD-Grundsätze der Guten Laborpraxis (Deutsch)

Guidance Documents for Compliance Monitoring Authorities

[No 2: Revised Guides for Compliance Monitoring Procedures for Good Laboratory Practice](#)

- Guides Révisés pour les systèmes de Vérification de respect des Bonnes Pratiques de Laboratoire (Français)
- Lineamientos revisados para los procedimientos de verificación de la conformidad von las buenas prácticas de laboratorio (Español)

[No 3: Revised Guidance for the Conduct of Laboratory Inspections and Study Audit](#)

- Directives Révisées pour la Conduite D'inspections de Laboratoire et de Vérification d'études (Français)
- Lineamientos Revisados Para Llevar a Cabo la Inspección del Laboratorio y la Auditoría de los Estudios (Español)

[No 9: Guidance for the Preparation of GLP Inspection Reports](#)

- Directives pour la Préparation de Rapports D'Inspection en Matière de BPL

Don't miss

- Documents - Good Laboratory Practice
- Council Acts Related to MAD
- Non-Member Adherents to the OECD System for Mutual Acceptance of Chemical Safety Data
- Links to National Web Sites on Good Laboratory Practice
- National Contact Points
- Links to National Web Sites on GLP
- Contact Us
- Site Map

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3. OECD Series on Principles of GLP

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OECD GLP PRINCIPLES:

1. Organization and Personnel
2. Quality Assurance Programme
3. Facilities
4. Apparatus, Material and Reagents
5. Test system
6. Test and Reference Items
7. Standard Operating Procedures
8. Performance of the Study
9. Reporting of Study Results
10. Storage & Retention of Records and Materials

3. OECD GLP Test Guidelines

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More than 100 Test Guidelines

- **Section 1: Physical-chemical properties**
- **Section 2: Effects on Biotic Systems**
- **Section 3: Degradation and Accumulation**
- **Section 4: Health Effects**
- **Section 5: Other Test Guidelines**

3. OECD GLP Test Guidelines

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OECD Guidelines for the Testing of Chemicals - Microsoft Internet Explorer

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Address http://www.oecd.org/document/40/0,3343,en_2649_34377_37051368_1_1_1_1,00.html#Obtaining_Test_Guidelines Go Links

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 - Chemicals Risk Management
 - Chemicals Testing - Guidelines
 - Co-operation on the Investigation of Existing Chemicals
 - Good Laboratory Practice
 - New Chemicals
 - Pesticides
 - Pollutant Release and Transfer Registers
 - Safety of Manufactured Nanomaterials
- Biosafety - BioTrack
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- Environment in Emerging and Transition Economies
- Environmental Country Reviews
- Environmental Indicators and Outlook
- Environmental Policies and Instruments
- Environmental-Social Interface
- Natural Resource Management
- Trade, Investment and Environment

Home: Chemicals Testing - Guidelines > OECD Guidelines for the Testing of Chemicals

About Publications & Documents Information by Country

OECD Guidelines for the Testing of Chemicals

See Press Release! [English](#); [French](#)
Available free of charge on [SourceOECD](#)

The OECD Guidelines for the Testing of Chemicals are a collection of the most relevant internationally agreed test methods used by government, industry and independent laboratories to determine the safety of chemicals and chemical preparations, including pesticides and industrial chemicals. They cover tests for the physical-chemical properties of chemicals, human health effects, environmental effects, and degradation and accumulation in the environment.

- The complete list of OECD Guidelines for the Testing of Chemicals, including dates of revisions, [English](#), [French](#)
- [How to obtain adopted Test Guidelines](#)
- [How to obtain draft Test Guidelines](#)
- [How to obtain existing Test Guidelines Related Documents](#)
- [How to obtain draft Test Guidelines Related Documents](#)

How to obtain Test Guidelines

All readers can freely access the online edition via [SourceOECD](#), our online library. Readers benefit from all updated and new tests, as they are made available online.

Section 1: Physical Chemical Properties
[English](#); [French](#)
Section 2: Effects on Biotic Systems
[English](#); [French](#)
Section 3: Degradation and Accumulation
[English](#); [French](#)
Section 4: Health Effects
[English](#); [French](#)

Don't miss

- OECD Guidelines for the Testing of Chemicals
- Draft Test Guidelines
- Questions & Answers regarding the OECD Test Guidelines Programme (TGP)
- Animal Welfare
- Other Publications / Draft Publications
- Contact Us
- Site Map

...and also Guidance Document 1

Done

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3. 1997 Council Decision

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OECD Council Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual acceptance of Data C(97)114(Final)

“Decides that **non-Member countries** are given voluntarily adhering to the standards sets by the OECD Council Acts and data generated in accordance with **OECD Test Guidelines and OECD Principles of Good Laboratory Practice** **shall be accepted in other Member countries** for purposes of assessment and other uses relating to the protection of man and the environment.”

3. OECD Council Decisions

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3 Council Decisions accepted by:

- 1981 MAD
- 1989 Compliance Monitoring
- 1997 Non-Members

34 Member countries

AUS, AU, BE, CAN, CZ, DK,
FIN, FR, GER, GR, HU, ICL,
IRE, IT, IS, JP, KO, LU, MEX, NL,
NO, NZ, PO, PT, SK, SP, SWE,
SWI, SLO, TU, UK, USA

Non-Member countries

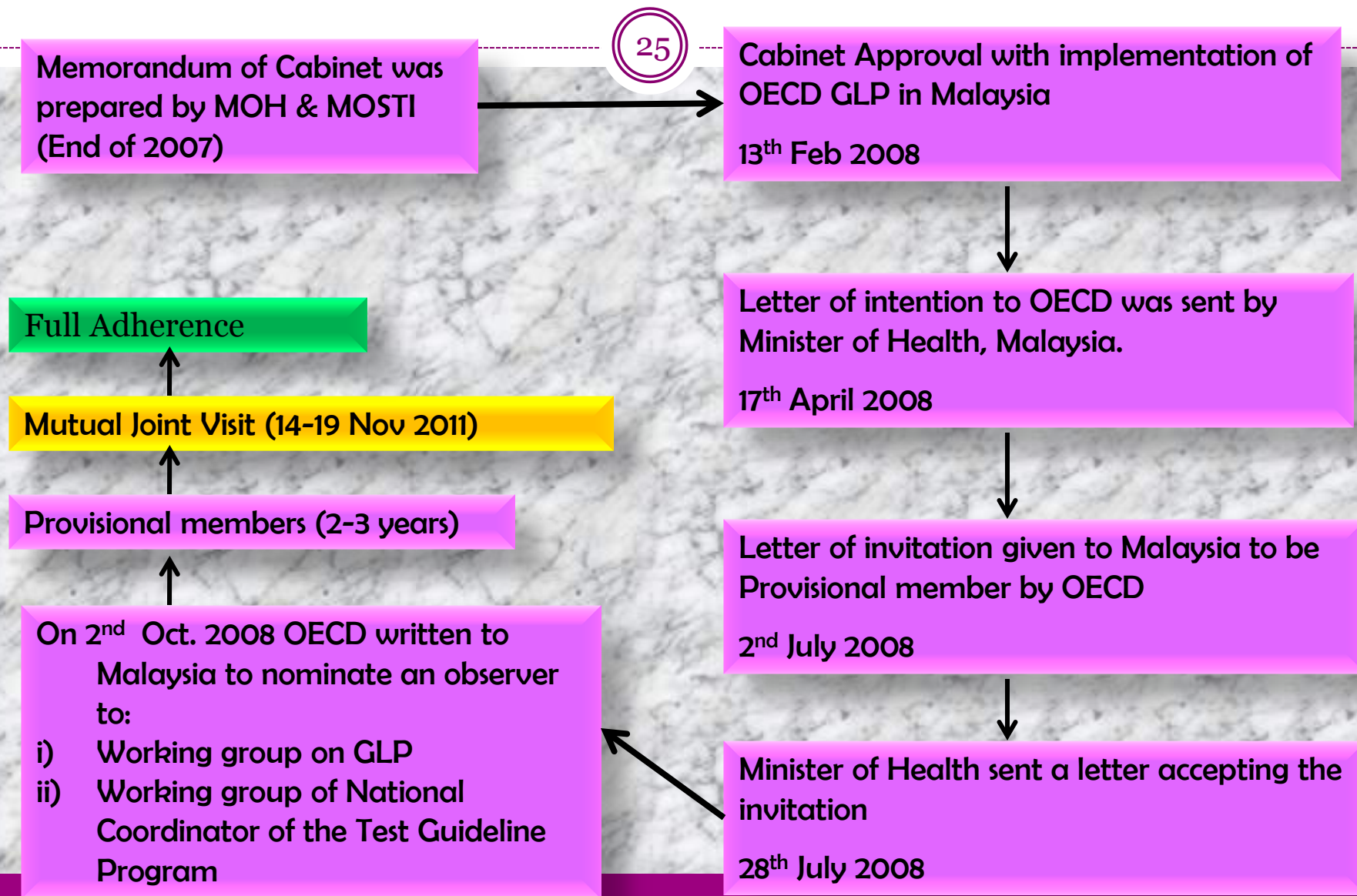
- South Africa (2003)
- Singapore (2010)
- India (2011)
- Brazil (2011)
- Argentina (2011)

Provisional Member

- Malaysia (2008)
- Thailand (2010)

China
Russia
Chinese Taipei

4. Malaysia's actions



4. Malaysia's status in OECD

26

1

- Provisional membership
- Oct 2008 – Nov 2011

2

- Mutual Joint Visit (UK, Switzerland, Japan)
- 14-19 November 2011

3

- 26th Meeting of Working Group on GLP
- 29-31 May 2012

4

- OECD Council Meeting
- 13 February 2013

5

- Announcement of Malaysia Membership to OECD
- [10 April 2013, press release](#)

4. During MJV, 14-19 November 2011

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4. Malaysia's status in OECD

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3 Council Decisions accepted by:

- 1981 MAD
- 1989 Compliance Monitoring
- 1997 Non-Members

34 Member countries

AUS, AU, BE, CAN, CZ, DK, FIN, FR, GER, GR, HU, ICL, IRE, IT, IS, JP, KO, LU, MEX, NL, NO, NZ, PO, PT, SK, SP, SWE, SWI, SLO, TU, UK, USA

Non-Member countries

- South Africa (2003)
- Singapore (2010)
- India (2011)
- Brazil (2011)
- Argentina (2011)

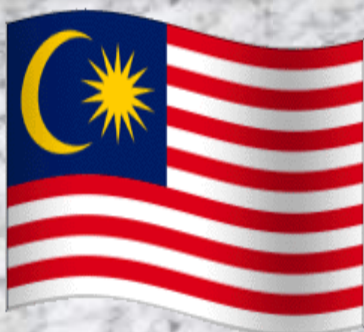
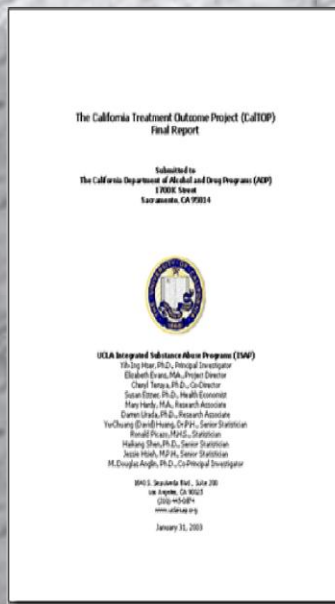
Malaysia (2013)
(6th member)

Provisional Member
• Thailand (2010)

China
Russia
Chinese Taipei

4. Malaysia's status in OECD

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TEST FACILITY IN
MALAYSIA

FINAL REPORT OF
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REGULATORY
AUTHORITIES IN OECD
& NON-OECD
ADHERING TO MAD

5. Compliance Monitoring Authorities

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MINISTRY OF HEALTH
COORDINATOR FOR GLP COMPLIANCE
MONITORING PROGRAM IN MALAYSIA

NATIONAL PHARMACEUTICAL
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MINISTRY OF HEALTH



- I. PHARMACEUTICAL PRODUCTS**
- II. COSMETIC PRODUCTS**
- III. VETERINARY DRUGS**
- IV. FOOD ADDITIVES**

STANDARDS MALAYSIA
MINISTRY OF SCIENCE
TECHNOLOGY & INNOVATION



- I. INDUSTRIAL CHEMICAL**
- II. PESTICIDES**
- III. FEED ADDITIVES/ANIMAL FOOD**
- IV. BIOTECHNOLOGY PRODUCTS**
(NON PHARMACEUTICAL)

5. Compliance Monitoring Authorities

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TEST FACILITY



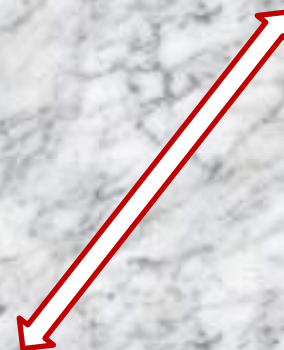
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5. Compliance Monitoring Authorities

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THE STEPS OF A STUDY
(in a test facility)

DOCUMENTS PRODUCED

PLANNING

STUDY PLAN

COMPLIANCE
MONITORING
AUTHORITY

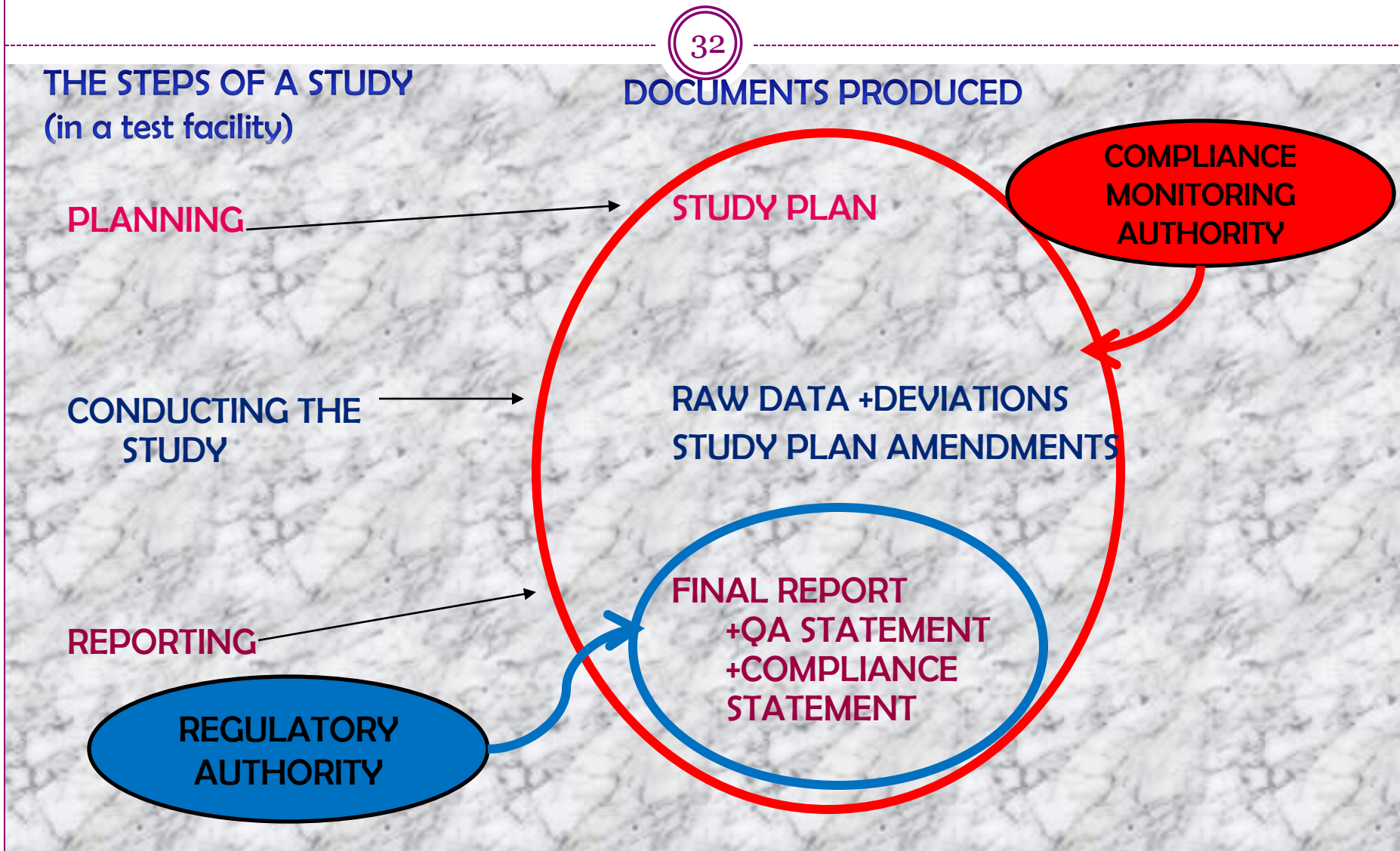
CONDUCTING THE
STUDY

RAW DATA +DEVIATIONS
STUDY PLAN AMENDMENTS

REPORTING

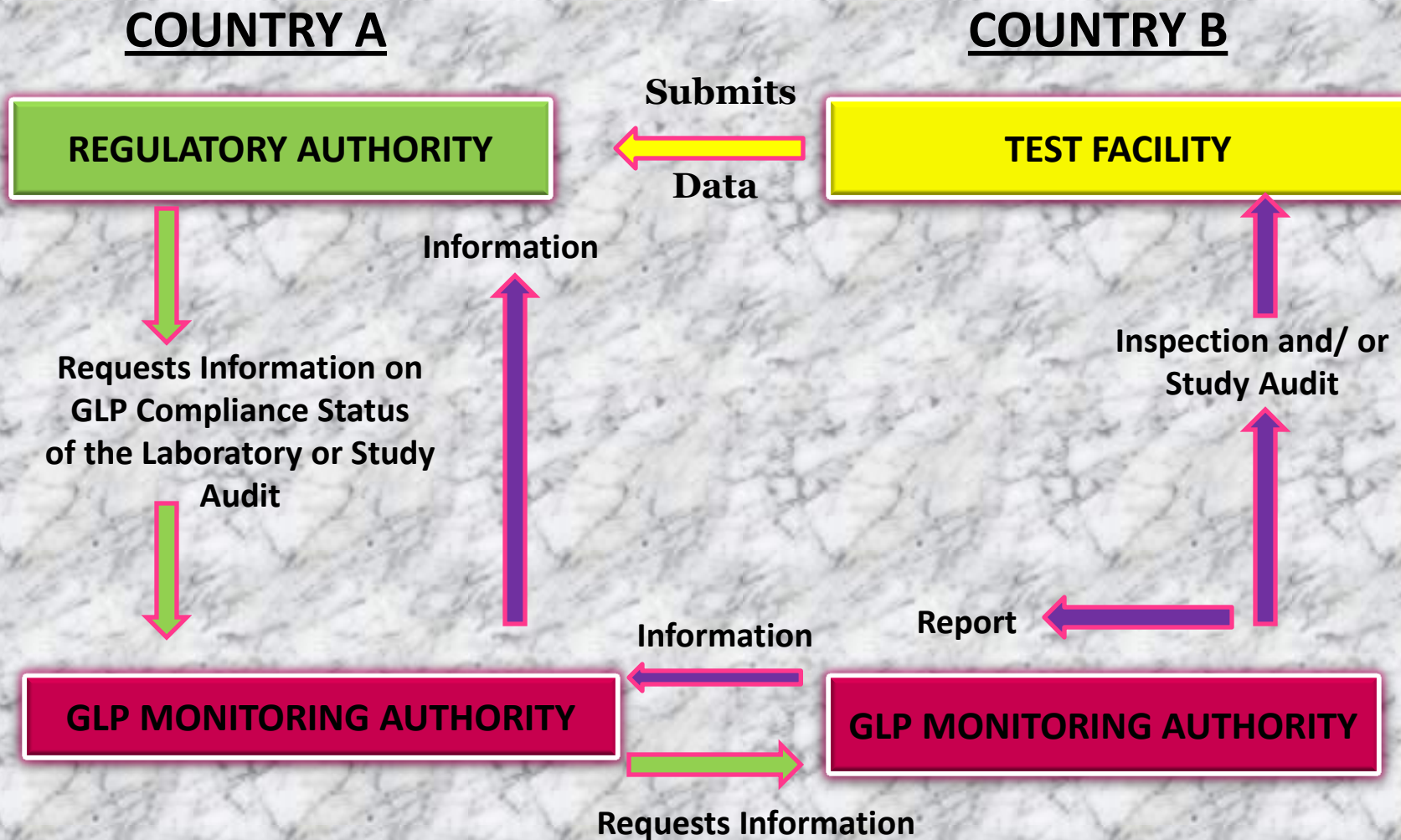
FINAL REPORT
+QA STATEMENT
+COMPLIANCE
STATEMENT

REGULATORY
AUTHORITY



5. Compliance Monitoring Authorities

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6. NPCB GLP Compliance Monitoring Programme

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Consumer
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Public Comment

Ensuring the Quality and Safety of Pharmaceutical, Traditional and Cosmetic Products

ANNOUNCEMENTS PRESS RELEASE CIRCULARS DIRECTIVES DRGD

Ulasan Kepada Laporan Dalam China Press 1 Februari 2013 Bertajuk ... (06 Mar, 2013) **NEW**
Press Release : Consumers Cautioned Against Using Cosmetic ... (17 Dec, 2012)
Press Release : List of Cosmetic Products Containing ... (16 Nov, 2012)
Press Release : Jin Fei Cao San Extract Powder "Sheng ... (11 Oct, 2012)
Press Release : Mymen Plus Capsule 400mg Cancelled (11 Oct, 2012)
Press Reviews - QUBAN SHUANG PRODUCTS MERCURY (17 Mar, 2012)
Press statement : Produk Kosmetik Yang Dikesan Mengandungi Merkuri (03 Feb, 2012)
PRESS STATEMENT PAO NI KANG (20 Jan, 2012)
TRADITIONAL PRODUCT "TWEE HONG SUAH" RECALLED (29 Dec, 2011)
Review for a Press statement regarding Johnson's Baby ... (04 Nov, 2011)
more...

Quest System Information for New Users

Product Registration & Cosmetic Notification
License Application
For Enforcement Pharmacy

Notice: Dear Quest 3 users, please be advised that Quest 3 system is under maintenance and users might experience slower performance. We apologize for any inconvenience caused. (Posted: 21 Jan 2013)

Client Charter & Achievements
Statistic Online Transactions
Feedback Form

QUEST **PRODUCT** **Reporting** **Helodesk**

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INDUSTRY

- General Information
- Drug Registration Guidance Document (DRGD)
- Regulatory Information
- Registration and Notification
- Inspection
- Licensing
- New Products/Indication
- Laboratory & Quality Control
- Forms
- Clinical Trial
- Good Laboratory Practice (GLP) Compliance Monitoring Programme**
- Quest2 List of Manufacturers / Wholesales / Importers
- Quest3 List of Manufacturers / Wholesales / Importers

General Information

Drug Registration Guidance Document

The DRGD is the reference guide for both pharmaceutical products for human use and traditional products.

Regulatory Information

- Regulatory Guideline
- Bioequivalence (BE) guidelines
- Generic product list
- BE studies centres
- Data Exclusivity information.

Registration and Notification

- QUEST system
- Medicinal Products
- Cosmetics
- Veterinary
- Template/Guide for Product Information for generic product.

Inspection

- Good Manufacturing Practice (GMP)
- Good Distribution Practice (GDP)
- Good Laboratory Practice (GLP).

Licensing

Information related to Licensing - Wholesale, Manufacturer or Import.

New Products/Indication

- New Products Approved
- New Chemical Entities
- Additional Indications Approved.

Laboratory & Quality Control

- Guidelines for Protocol of Analysis Submission & Analytical Method Validation

Forms

- General Forms
- Cosmetic
- Veterinary

6. NPCB GLP Compliance Monitoring Programme

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The Malaysian GLP Monitoring Authority

[OECD GLP Documents](#) | [Directive](#) | [Application Procedures](#) | [Application Form](#) | [FAQ](#)
[NPCB GLP Compliance Programme Manual](#) | [GLP Compliant Test Facilities](#)

Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environment safety studies are planned, performed, monitored, recorded, archived and reported. The purpose of the Principles of GLP is to promote the development of quality data.

The Principles of GLP should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetics products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. Non-clinical health and environmental safety studies covered by the Principles of GLP include work conducted in laboratory, greenhouses, and in the field.

The National Pharmaceutical Control Bureau (NPCB) and STANDARDS MALAYSIA (www.standardsmalaysia.gov.my) had been designated as the Malaysian Compliance Monitoring Authorities (CMAs) by the Malaysian Government. NPCB is the CMA for the non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives. Whereas STANDARDS MALAYSIA is the CMA for the non-clinical safety testing of test items contained in industrial chemicals, pesticides, feed additives, and biotechnology (non-pharmaceuticals). For NPCB the decision by the Government of Malaysia is enforced by the issuance of A Directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 in June 2009.

The GLP Compliance Programme (CP) is intended to ascertain whether Test Facilities have implemented requirements as described in documents of Organisation for Economic Cooperation and Development (OECD) Series on Principles of Good Laboratory Practice and Compliance Monitoring. Test Facilities requesting for verification and certification of compliance to Principles of GLP, and subsequent inclusion into the CMAs GLP Compliance Programme need to make the relevant

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6. NPCB GLP Compliance Monitoring Programme

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NATIONAL PHARMACEUTICAL
CONTROL BUREAU (NPCB)
GOOD LABORATORY PRACTICE (GLP)
COMPLIANCE PROGRAMME MANUAL

Document Number:
NPCB/GLP/100

Edition 3

Page number 1 of 22



NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB)
Ministry of Health Malaysia
Lot 36, Jalan Universiti
46200 Petaling Jaya, Selangor

Tel: 603-7883 5400
Facsimile: 603-7955 1030
Website: www.bpfk.gov.my

Edition	Reviewed by	Approved by	Effective Date
First	Head of Clinical Research and Compliance Section, NPCB	Director of NPCB	1 July 2009
Second	Deputy Director Centre for Investigational New Product, NPCB Date :	Director of NPCB Date :	1 January 2011
Third	Deputy Director Centre for Investigational New Product, NPCB Date :	Director of NPCB Date :	1 July 2012

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6. NPCB GLP Compliance Monitoring Programme

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bpfk	GOOD LABORATORY PRACTICE COMPLIANCE PROGRAM	Document No PKPB/006/DH	
	APPLICATION FORM	Date Issued	1 July 2012
		Version	1
		Replaces	Version 2
		Page	1 of 4

Please mark with (+/-) where applicable

Reason for application

☐ New application

☐ Application prompted by the request of national/international authorities

A- ORGANISATION INFORMATION

Name of Company: _____

Address: _____

Tel: _____ Fax: _____

Contact person: _____

Designation: _____

Email: _____

B- TEST FACILITY INFORMATION

Name: _____

Address: _____

Tel: _____ Fax: _____

Contact person: _____

Designation: _____

Email: _____

Registration No: _____ (A copy of ROC to be attached- if applicable)

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- **Complete application submit (post/by hand) to:**
Deputy Director
Centre for Investigational New Product
National Pharmaceutical Control Bureau
Ministry of Health Malaysia
- **Fee : FREE**

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4 types of Inspections:

- 1) Pre Inspection**
- 2) Inspection**
- 3) Surveillance Inspection**
- 4) Extra-ordinary Inspection**

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Pre Inspection

- 1st time
- To familiarize and verify TF has resources to undertake GLP studies
- Within 30 working days after complete application received
- Minimum 1 complete or on-going study

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Inspection

- Full inspection covers Test Facility and Study Audit
- Within 6 months after corrective actions satisfactory
- Minimum 1 completed & on-going study

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Surveillance Inspection

- Same as in Inspection
- Annually for the first 2 years
- Every 2 years from the date of the certificate issued

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Extra-Ordinary Inspection

- Request from other Regulatory Authority or Compliance Monitoring Authority
- Verify corrective actions
- Extension of scope
- Significant changes in Test Facility

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BPFK - The Malaysian GLP Monitoring Authority - Windows Internet Explorer

http://portal.bpfk.gov.my/index.cfm?8menuid=109

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BPFK - The Malaysian GLP Monitoring Authority

[English] [A] [A+] [A++]

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The Malaysian GLP Monitoring Authority

[OECD GLP Documents](#) | [Directive](#) | [Application Procedures](#) | [Application Form](#) | [NPCB GLP Compliance Programme Manual](#) | [GLP Compliant Test Facilities](#)

Good Laboratory Practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environment safety studies are planned, performed, monitored, recorded, archived and reported. The purpose of the Principles of GLP is to promote the development of quality data.

The Principles of GLP should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetics products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these items is to obtain data on their properties and/or their safety with respect to human health and/or the environment. Non-clinical health and environmental safety studies covered by the Principles of GLP include work conducted in laboratory, greenhouses, and in the field.

The National Pharmaceutical Control Bureau (NPCB) and STANDARDS MALAYSIA (www.standardsmalaysia.gov.my) had been designated as the Malaysian Compliance Monitoring Authorities (CMAs) by the Malaysian Government. NPCB is the CMA for the non-clinical safety testing of test items contained in pharmaceutical products, cosmetics products, veterinary drugs and food additives. Whereas STANDARDS MALAYSIA is the CMA for the non-clinical safety testing of test items contained in industrial chemicals, pesticides, feed additives, and biotechnology (non-pharmaceuticals). For NPCB the decision by the Government of Malaysia is enforced by the issuance of A Directive under Regulation 29 of the Control of Drugs and Cosmetics Regulations 1984 in June 2009.

The GLP Compliance Programme (CP) is intended to ascertain whether Test Facilities have implemented requirements as described in documents of Organisation for Economic Cooperation and Development (OECD) Series on Principles of Good Laboratory Practice and Compliance Monitoring. Test Facilities requesting for verification and certification of compliance to Principles of GLP, and subsequent inclusion into the CMAs GLP Compliance Programme need to make the relevant

INDUSTRY

- General Information
- Drug Registration Guidance Document (DRGD)
- Regulatory Information
- Registration and Notification
- Inspection
- Licensing
- New Products/Indication
- Laboratory & Quality Control
- Forms
- Clinical Trial
- Good Laboratory Practice (GLP) Compliance Monitoring Programme**
- Quest2 List of Manufacturers / Wholesales / Importers
- Quest3 List of Manufacturers / Wholesales / Importers

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300-105 LIST OF GLP TF WEBPAGE July 2012[1].pdf - Adobe Reader

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bpfk

GOOD LABORATORY PRACTICE COMPLIANCE PROGRAM

LIST OF GLP COMPLIANT TEST FACILITIES

Document No:

PKPE/300/105

Issue Date	1 July 2012
Version	3
Replace	Version 2
Page	1 of 1

These Test Facilities are entered in the NPCB GLP Compliance Monitoring Program and shall be periodically inspected.

YEAR : 2012

TEST FACILITY & ADDRESS	REGISTRATION NUMBER	SCOPE	AREA OF EXPERTISE	DATE OF CERTIFICATE	CONTACT PERSON
Environmental Technology Research Centre (ETRC), SIRIM Berhad 1, Persiaran Dato' Menteri, Seksyen 2, P.O.Box 7035, 40911 Shah Alam.	GLP 001	Pharmaceuticals Cosmetics Veterinary Drugs Food Additives	Mutagenicity	27 February 2012	Dr. Chan Sau Soon Tel: 03-55446564
Melaka Biotechnology Corporation Lot 7, MITC City, Hang Tuah Jaya, 75450 Ayer Keroh, MELAKA.	GLP 002	Pharmaceuticals Cosmetics Veterinary Drugs Food Additives	Mutagenicity	30 November 2011	Datin Nor Sabrina Mohd Noor Tel: 06-2313622
Info Kinetics Sdn Bhd Suite 126, Kompleks Eureka, Universiti Sains Malaysia, 11800 Minden, Pulau Pinang.	GLP 003	Pharmaceuticals Cosmetics Veterinary Drugs Food Additives	Analytical and Clinical Chemistry	7 May 2012	Dr. Lee Toong Chow Tel: 04-6589220

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- Potential Test Facilities
 - Institute Medical Research - toxicology
 - Institute Pharmaceutical & Nutraceuticals - toxicology

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Awareness & trainings with stake holders

No	Date	Title	Facilitated by
1	July 2007	Awareness Seminar on OECD GLP	NPCB
2	4-5 December 2007	Introduction Workshop on OECD Mutual Acceptance of Data, GLP Compliance Monitoring, KL.	OECD GLP Working Group
3	11-13 November 2008	OECD Principles Of GLP Workshop, KL.	NATA Australia
4	24-26 November 2008	GLP Workshop organised by Institute for Medical Research, Ministry of Health Malaysia	Environmental Protection Agency (EPA), USA
5	3-5 August 2009	Workshop on OECD GLP Documents to Test Facilities, KL	NPCB
6	17 August 2009	GLP Seminar organised by Universiti Darul Iman Malaysia, Terengganu	NPCB
7	17 December 2009	GLP Seminar organised by Institute Medical Research, KL	NPCB

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Awareness & trainings with stake holders

No	Date	Title	Facilitated by
8	3 March 2010	GLP Seminars organised by SIRIM Berhad, Selangor	NPCB & STANDARDS MALAYSIA
9	1 July 2010	Introduction to GLP Seminar organised by Melaka Biotechnology Corporation	NPCB & STANDARDS MALAYSIA
10	19-21 July 2010	OECD GLP Workshop organised by Institute of Pharmaceutical & Neutraceuticals	NPCB & STANDARDS MALAYSIA
11	2-3 August 2010	Workshop for Study Directors and Quality Assurance Personnel of OECD GLP Studies, KL	Norwegian Accreditation (NA), Norway
12	12 January 2012	GLP Program in Malaysia -presentation to NKEA EPP 1 MoA Non-clinical Committee	NPCB
13	9-10 April 2012	Workshop on OECD Principles of GLP	NPCB

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Awareness & trainings with stake holders

No	Date	Title	Facilitated by
14	12 June 2012	Seminar on non-clinical studies organised by Melaka Biotechnology Corporation	NPCB
15	9 September 2012	Introduction to Principles of GLP organised by University Malaya	NPCB
16	6-7 December 2012	Seminar on Principles of GLP organised by Institute of Pharmaceutical & Neutraceuticals	NPCB
17	16-18 December 2012	Seminar on Principles of GLP organised by Drug & Medicine Research Centre, USM	NPCB

7. Benefits

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- **By Malaysia being a non-OECD member adhering to MAD:**

Data developed in Malaysian non-clinical laboratories will be accepted by other Regulatory Authorities in OECD member countries and non-OECD member adhering to MAD

7. Benefits

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This will then:

- ✓ **Avoid duplicative testing**
- ✓ **Cost saved to government & industry**
- ✓ **Facilitate exchange information**
- ✓ **Prevent emergence of non-tariff barriers to trade**

7. Benefits

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It will also:

- ✓ Create new business opportunity for GLP laboratories in Malaysia – increase country economy
- ✓ Create new carrier move to
 - Study Director
 - Principle Investigator
 - QA
 - Archivist.

8. Impact

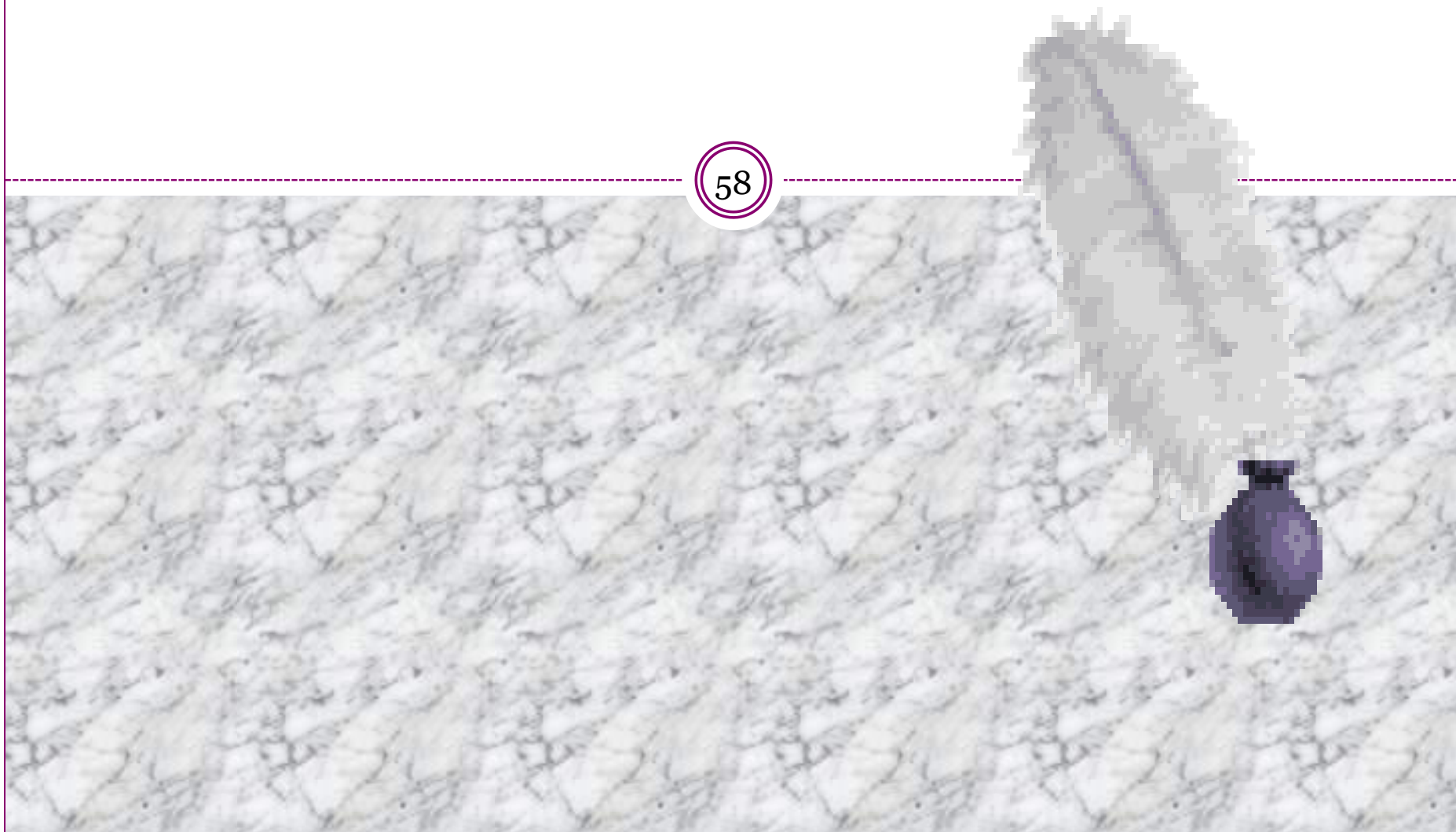
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- **Asia region**
 - Hub for non-clinical studies
 - 3rd in Asia after Singapore and India
 - REACH registration requirements in Europe
 - Pharmaceuticals registration requirements in Europe
- **NKEA EPP1 MoA**
 - Herbal products with high claim
- **New Drug**
 - Non-clinical studies locally

9. Acknowledgement

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- **Malaysian Biotechnology Corporation**
 - Mr. Adrian Abd Ghani, Ms Haniza Hashim, Ms Kurniawati Muhammad
- **SIRIM Berhad**
 - Dr. Chen Sau Sen
- **Senior Director of Pharmaceutical Services**
 - Dato' Eisah Abd Rahman,
- **GLP Compliance Section, CIMP, NPCB**
 - Dr. Kamaruzaman Saleh, Fadhilah Hasbullah, Poh Wen Tsin



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Malaysia joins OECD agreement on mutual acceptance of chemical safety data

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10/04/2013 - Malaysia has joined the OECD system for the [Mutual Acceptance of Data \(MAD\)](#) in the Assessment of Chemicals, ensuring that its non-clinical safety data related to the protection of human health and the environment will be accepted by all 40 countries adhering to MAD.

The MAD system – a multilateral agreement - allows participating countries to share the results of various non-clinical safety tests done on chemicals and chemical products, such as industrial chemicals and pesticides. This collaboration saves governments and chemical producers around [€150 million annually](#).

"Governments participating in the MAD system have confidence that chemical safety test data generated in other countries is of high quality and can be used for regulatory assessments. This reduces duplicative testing, saves laboratory costs, promotes work-sharing by countries assessing the same data and removes a potential non-tariff trade barrier," said OECD Secretary-General Angel Gurría. "Malaysia's participation in this system highlights the mutual benefit of the partnership between OECD and major emerging economies."

The first step towards participation in the MAD system is provisional adherence. During this time, non-members work with OECD countries to make their compliance monitoring programme on Good Laboratory Practice acceptable to all members. Provisional adherence to the OECD system means that the non-member must accept data from OECD and adhering countries generated under MAD conditions.

Participation in the MAD system requires that testing be carried out using OECD standards for test methods (OECD Test Guidelines) and data quality (OECD Principles of Good Laboratory Practice). Governments verify laboratory compliance using OECD procedures. At present, all 34 OECD countries as well as Argentina, Brazil, India, Malaysia, Singapore and South Africa adhere to the system. Thailand is currently a provisional adherent to it.

For further information, please contact [Richard Sigman](#) in the OECD Environment Directorate or telephone: +33 1 45 24 16 80.

Head of Division
Environment, Health and Safety Division
Environment Directorate

ENV/EHS/BD/jg/2013.114

Paris, 10 April, 2013

To: Heads of Delegations to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology

cc: Working Group on Good Laboratory Practice
Working Group of National Coordinators of the Test Guidelines Programme
Observer Countries
BIAC, TUAC, EEB
ENV Counsellors to OECD Permanent Delegations

Dear Sir/Madam,

Full adherence of Malaysia to MAD Council Decisions

I am pleased to inform you that on 29 March 2013, Malaysia accepted the invitation of the Council to become a full adherent to the OECD Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals and to join that part of the Chemicals Programme related to MAD, with all of the rights and obligations of member countries. This means that Malaysia – like Argentina, Brazil, India, South Africa and Singapore – now takes part as an Associate in that part of the Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology that concerns MAD, as well as in the Working Groups on Good Laboratory Practice and of National Test Guideline Co-ordinators.

In order for the MAD system to continue to function smoothly, I encourage you to inform all of the receiving authorities in your country of this agreement.

If you have any questions, please contact Richard Sigman (Richard.Sigman@oecd.org).

Yours sincerely,



Bob Diderich