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

HASENAH ALI, PHD
NATIONAL PHARMACEUTICAL CONTROL BUREAU
MINISTRY OF HEALTH

NATIONAL REGULATORY CONFERENCE
7-9 MAY2013

CONTENT

1. Good Laboratory Practice

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

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

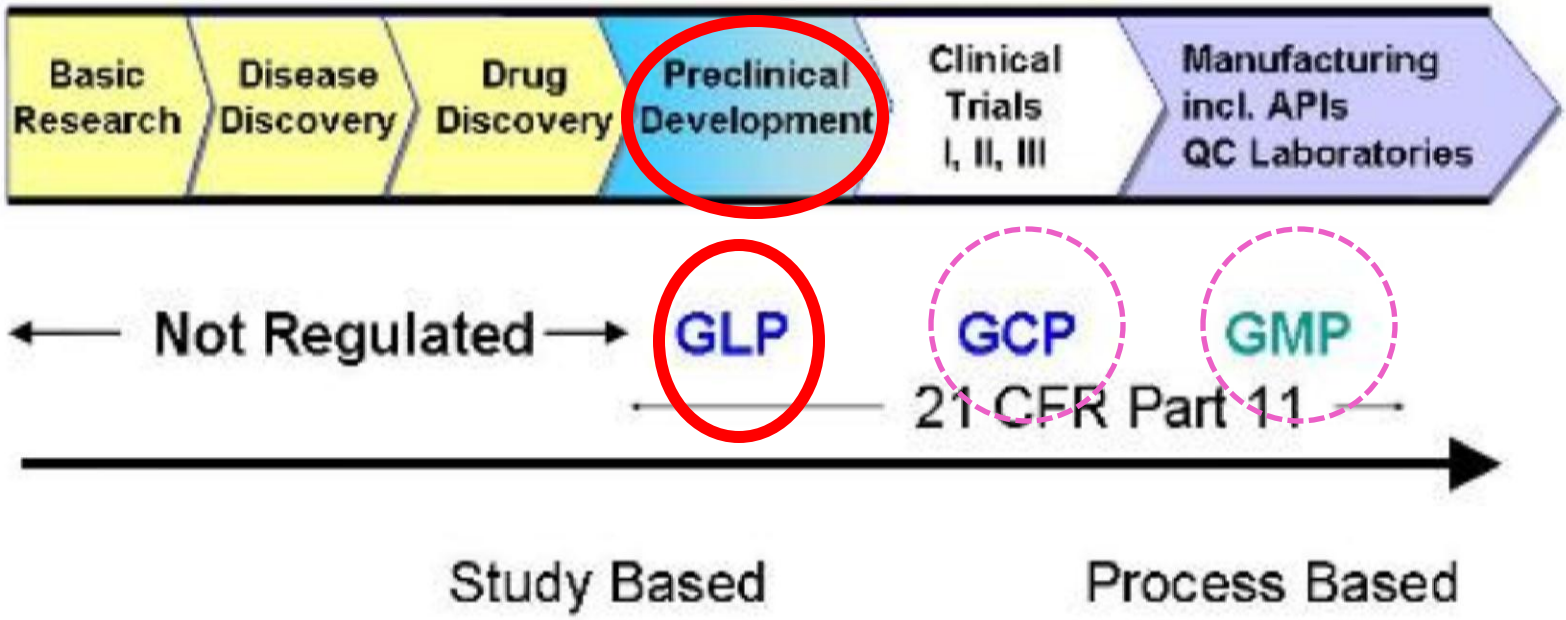
- Should be applied to the non-clinical safety testing of test items contained in:

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

- 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



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

1. Good Laboratory Practice – Registration flow

TEST FACILITY

FINAL REPORT OF NON CLINCAL STUDIES

REGULATORY AUTHORITY

1. Good Laboratory Practice – WHY ?

- 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 ?

- 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 ?

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 ?

- >>>> 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 ?

- ✓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

- 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

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

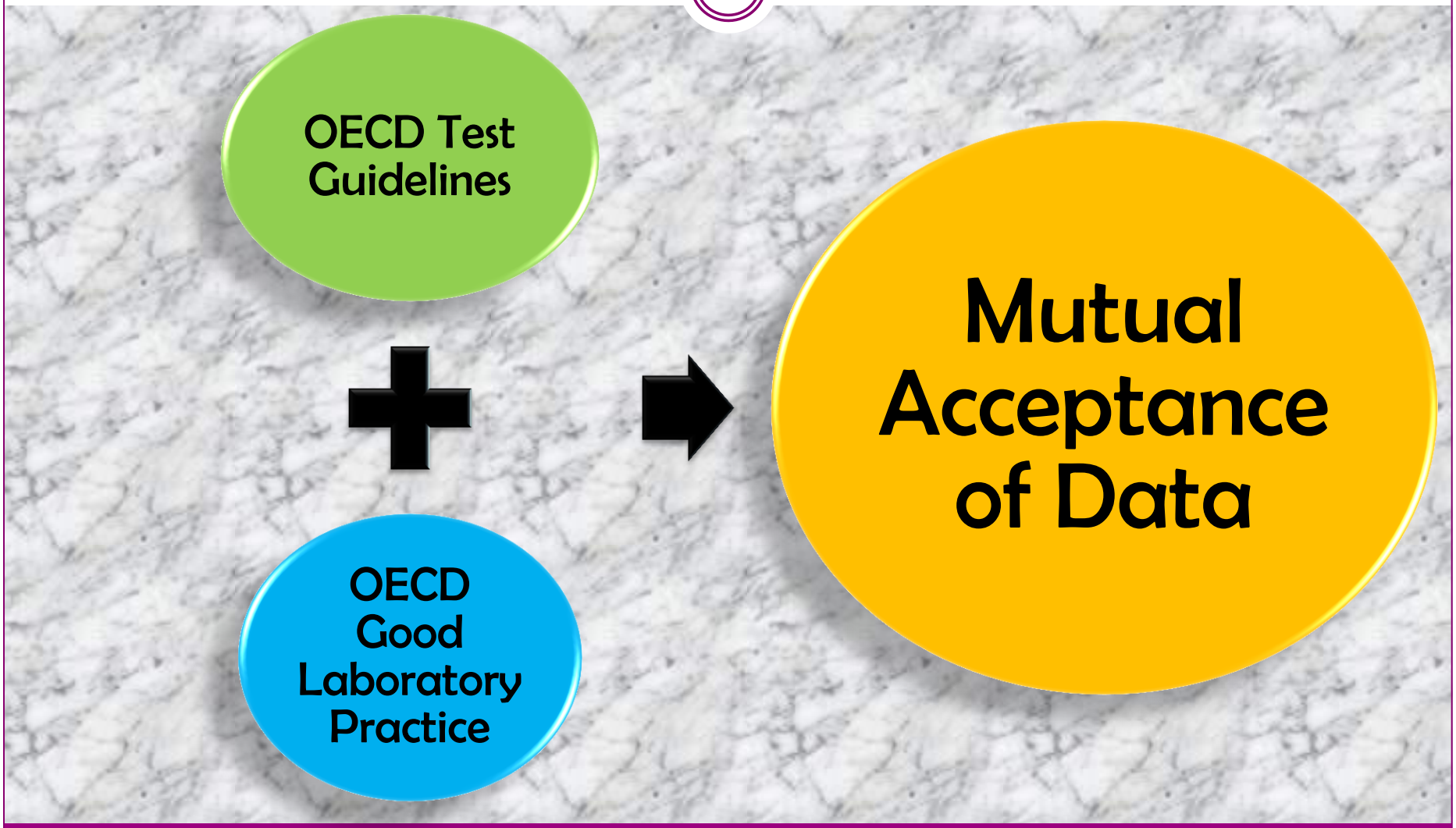
- Australia
- Japan
- New Zealand
- South Korea

3. 1981 "MAD" Council Decision

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

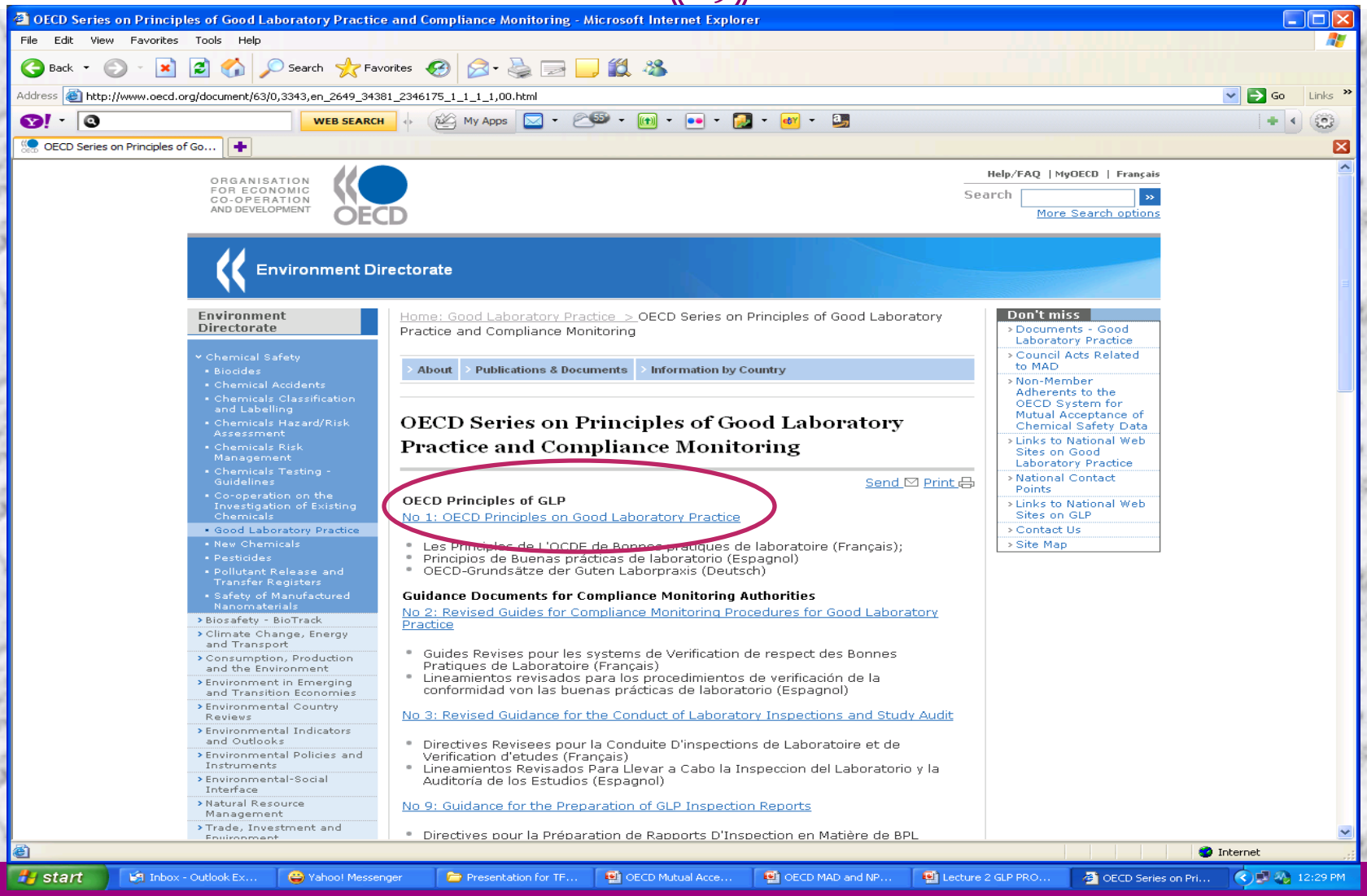


3. 1981 "MAD" Council Decision

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



3. OECD Series on Principles of GLP

OECD GLP PRINCIPLES:

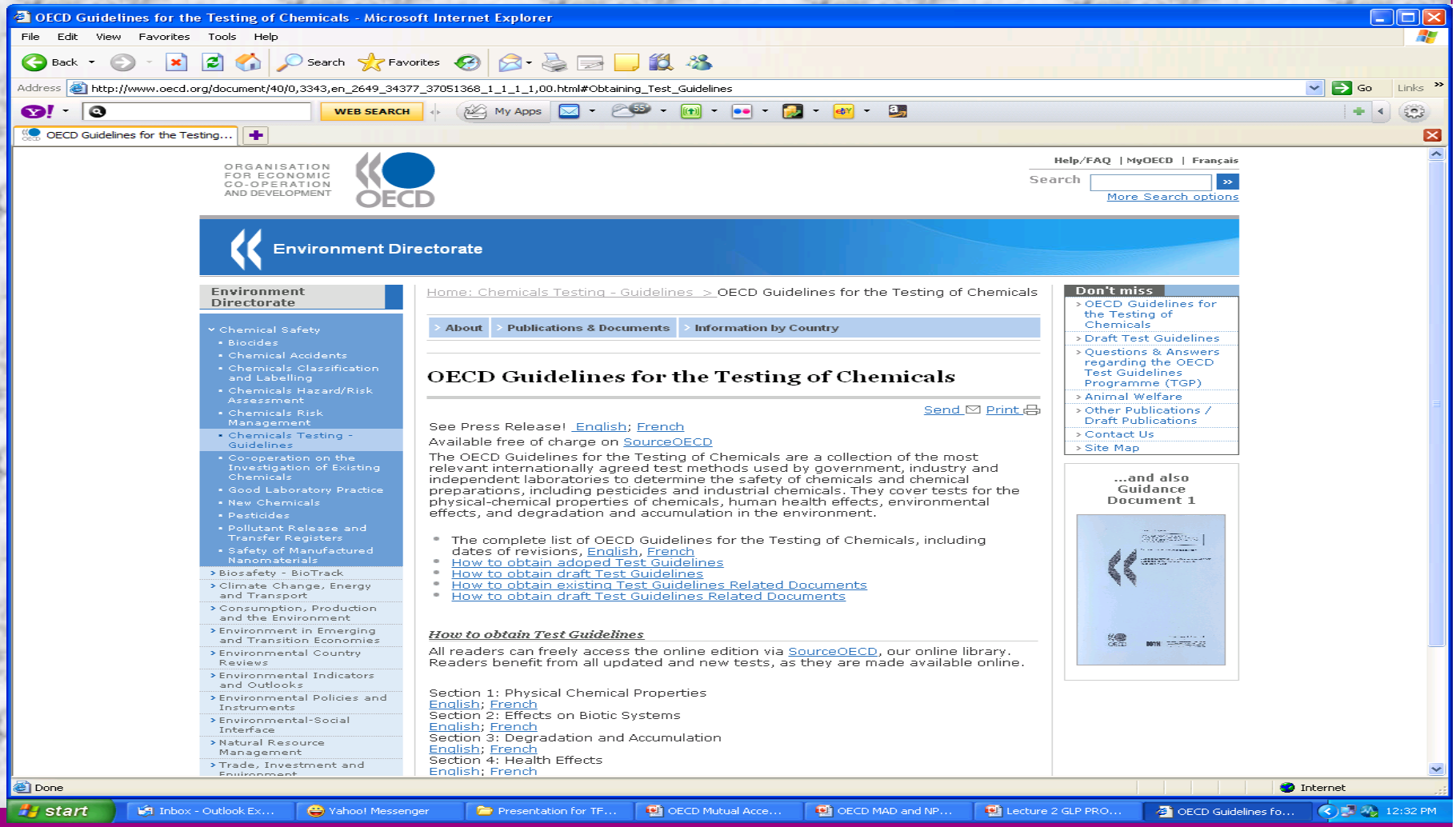
1. Organization and Personnel
2. Quality Assurance Programme
3. Facilities
4. Apparatus, Material and Reagents
5. Test system
6. Test and Reference Items
7. Standard Operating Procedures
8. Performance of the Study
9. Reporting of Study Results
10. Storage & Retention of Records and Materials

3. OECD GLP Test Guidelines

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



3. 1997 Council Decision

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

- 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)

China
Russia
Chinese Taipei

Provisional Member

- Malaysia (2008)
- Thailand (2010)

4. Malaysia's actions

Memorandum of Cabinet was prepared by MOH & MOSTI (End of 2007)

Cabinet Approval with implementation of OECD GLP in Malaysia

13th Feb 2008

Letter of intention to OECD was sent by Minister of Health, Malaysia.

17th April 2008

Letter of invitation given to Malaysia to be Provisional member by OECD

2nd July 2008

Minister of Health sent a letter accepting the invitation

28th July 2008

On 2nd Oct. 2008 OECD written to Malaysia to nominate an observer to:

i) Working group on GLP
ii) Working group of National Coordinator of the Test Guideline Program

Provisional members (2-3 years)

Mutual Joint Visit (14-19 Nov 2011)

Full Adherence

4. Malaysia's status in OECD

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

4. Malaysia's status in OECD

- 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

TEST FACILITY IN MALAYSIA

FINAL REPORT OF NON CLINCAL STUDIES

REGULATORY AUTHORITIES IN OECD & NON-OECD ADHERING TO MAD

5. Compliance Monitoring Authorities

MINISTRY OF HEALTH
COORDINATOR FOR GLP COMPLIANCE MONITORING PROGRAM IN MALAYSIA

NATIONAL PHARMACEUTICAL CONTROL BUREAU
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

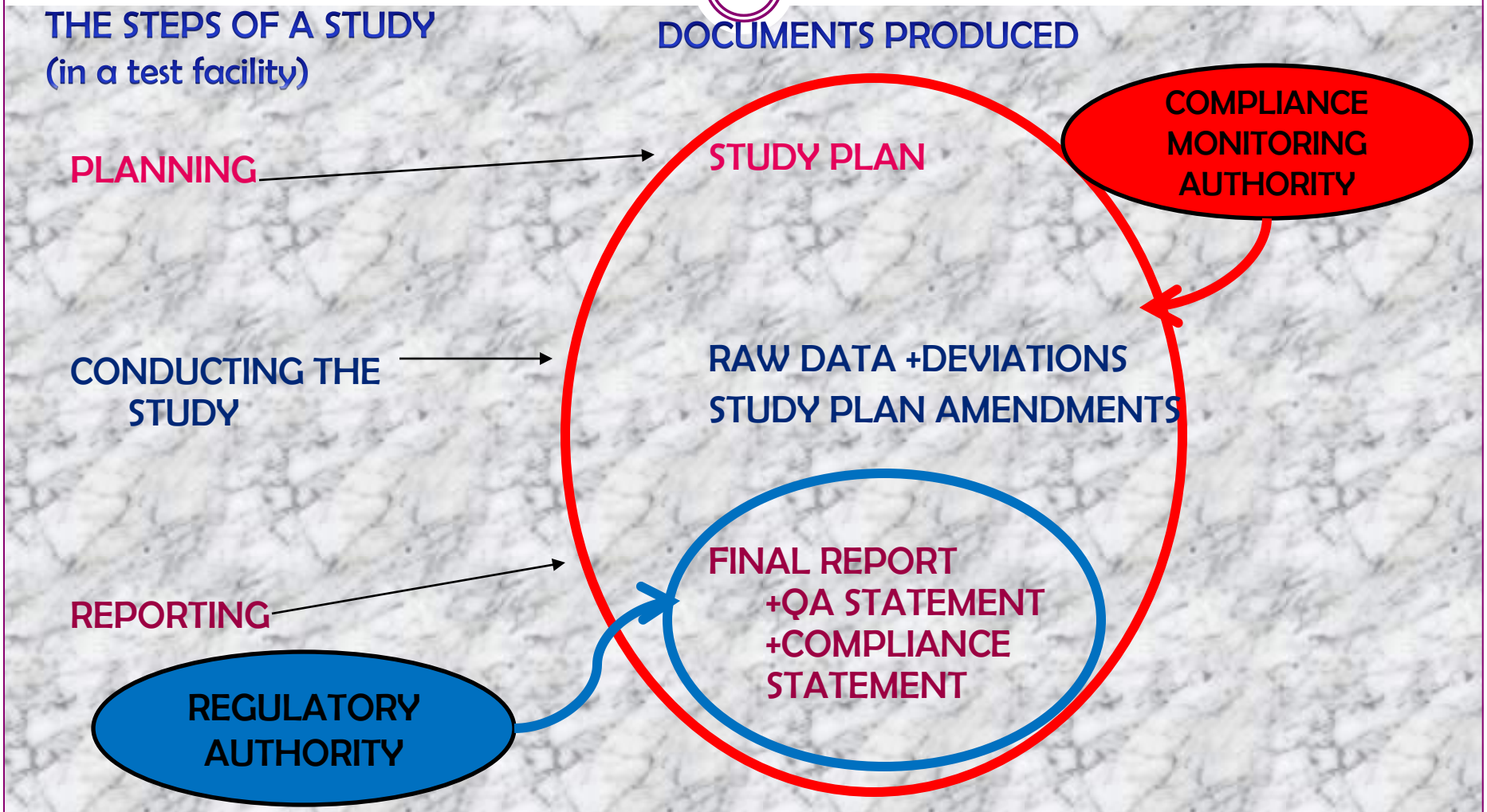
TEST FACILITY

FINAL REPORT OF NON CLINCAL STUDIES

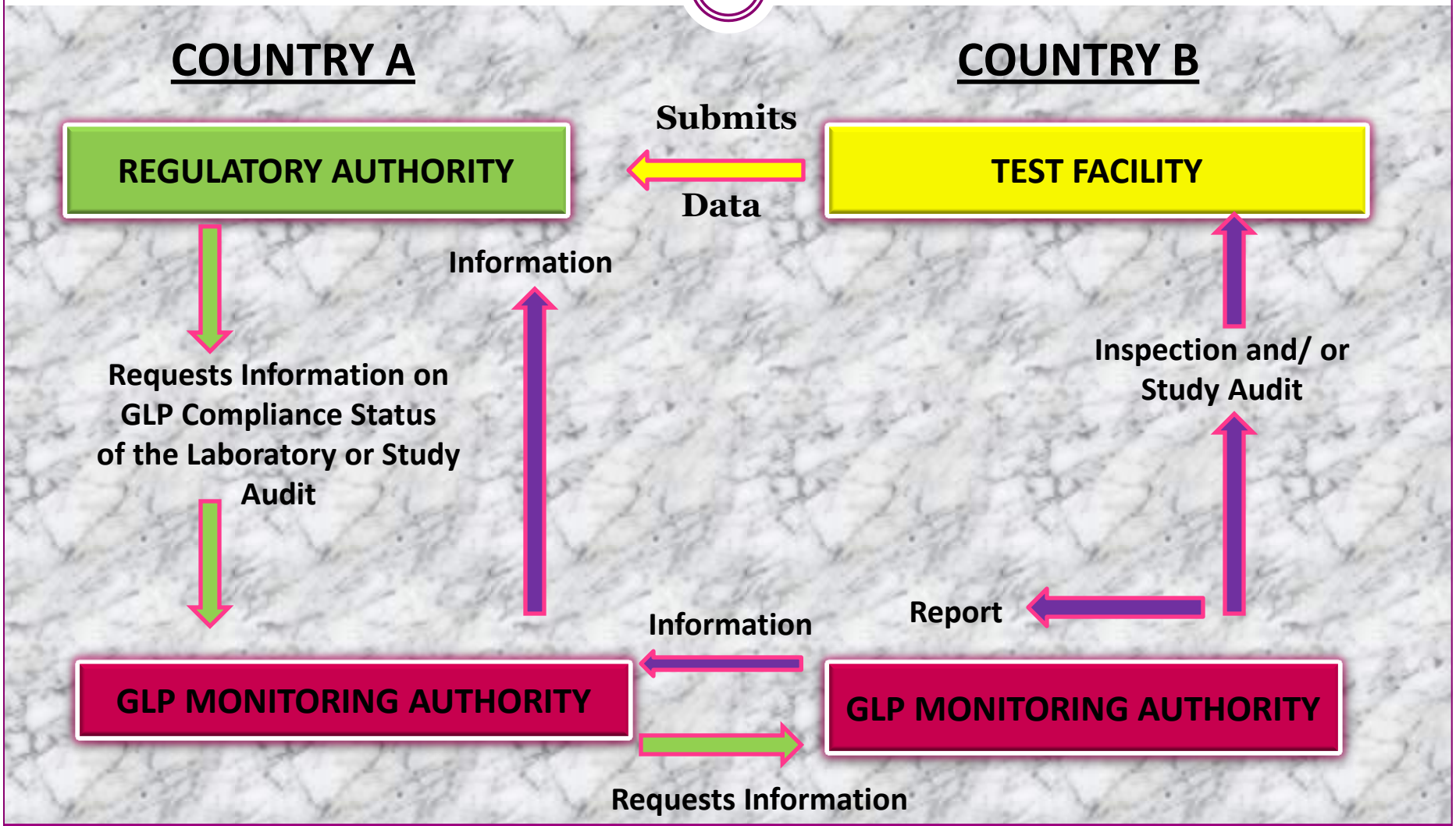
REGULATORY AUTHORITY

COMPLIANCE MONITORING AUTHORITY

5. Compliance Monitoring Authorities



5. Compliance Monitoring Authorities



6. NPCB GLP Compliance Monitoring Programme

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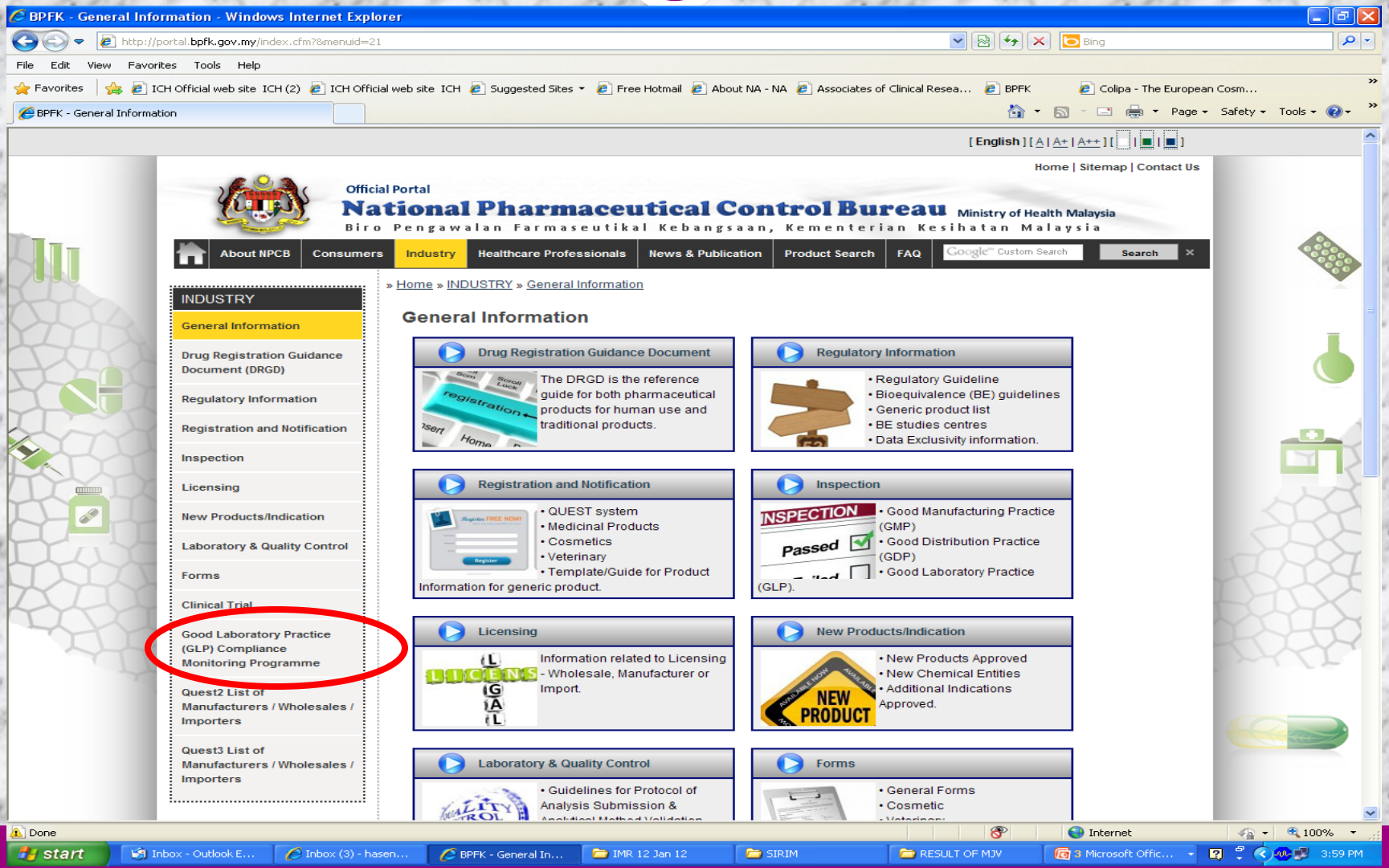
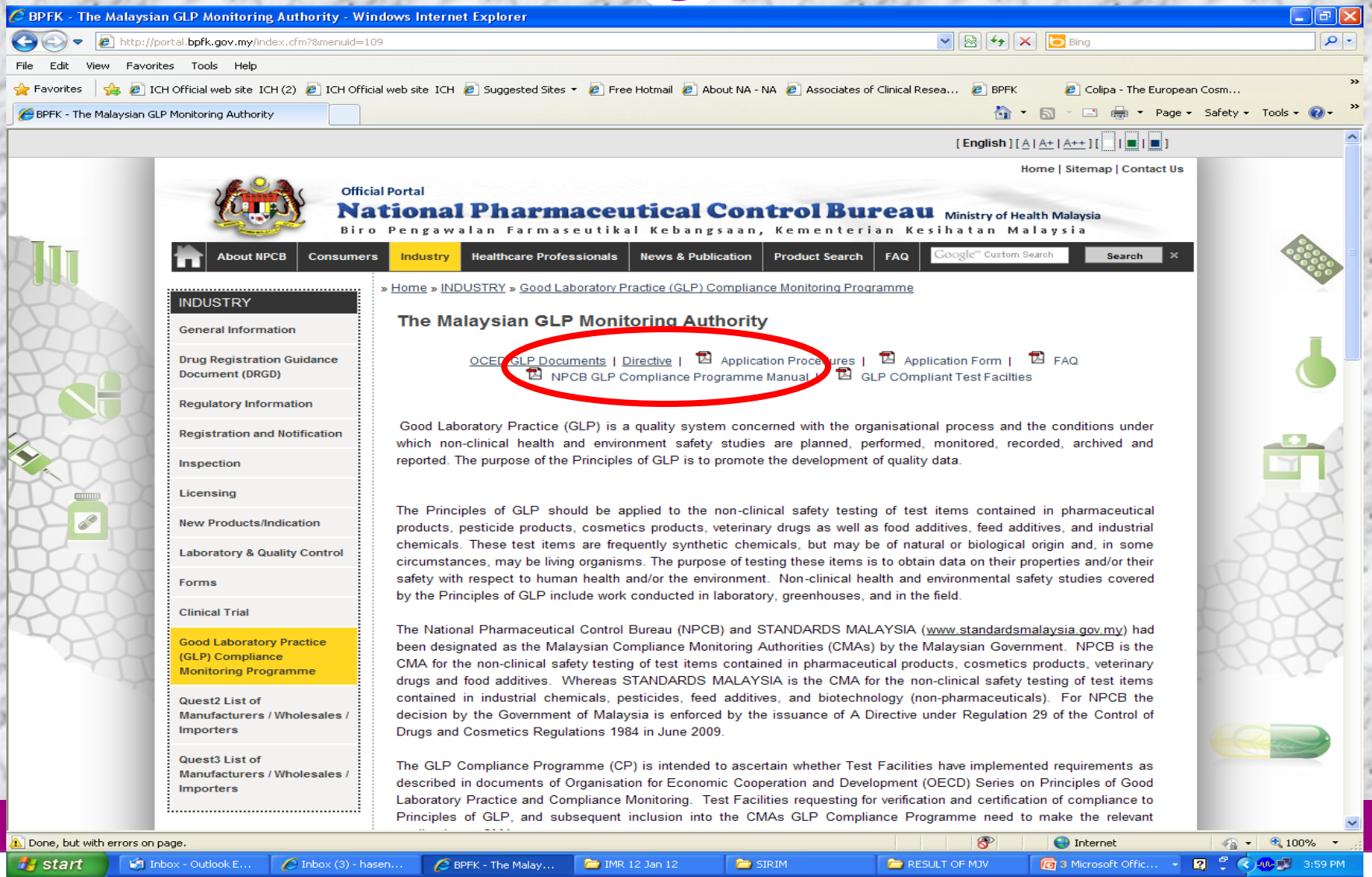


6. NPCB GLP Compliance Monitoring Programme



6. NPCB GLP Compliance Monitoring Programme

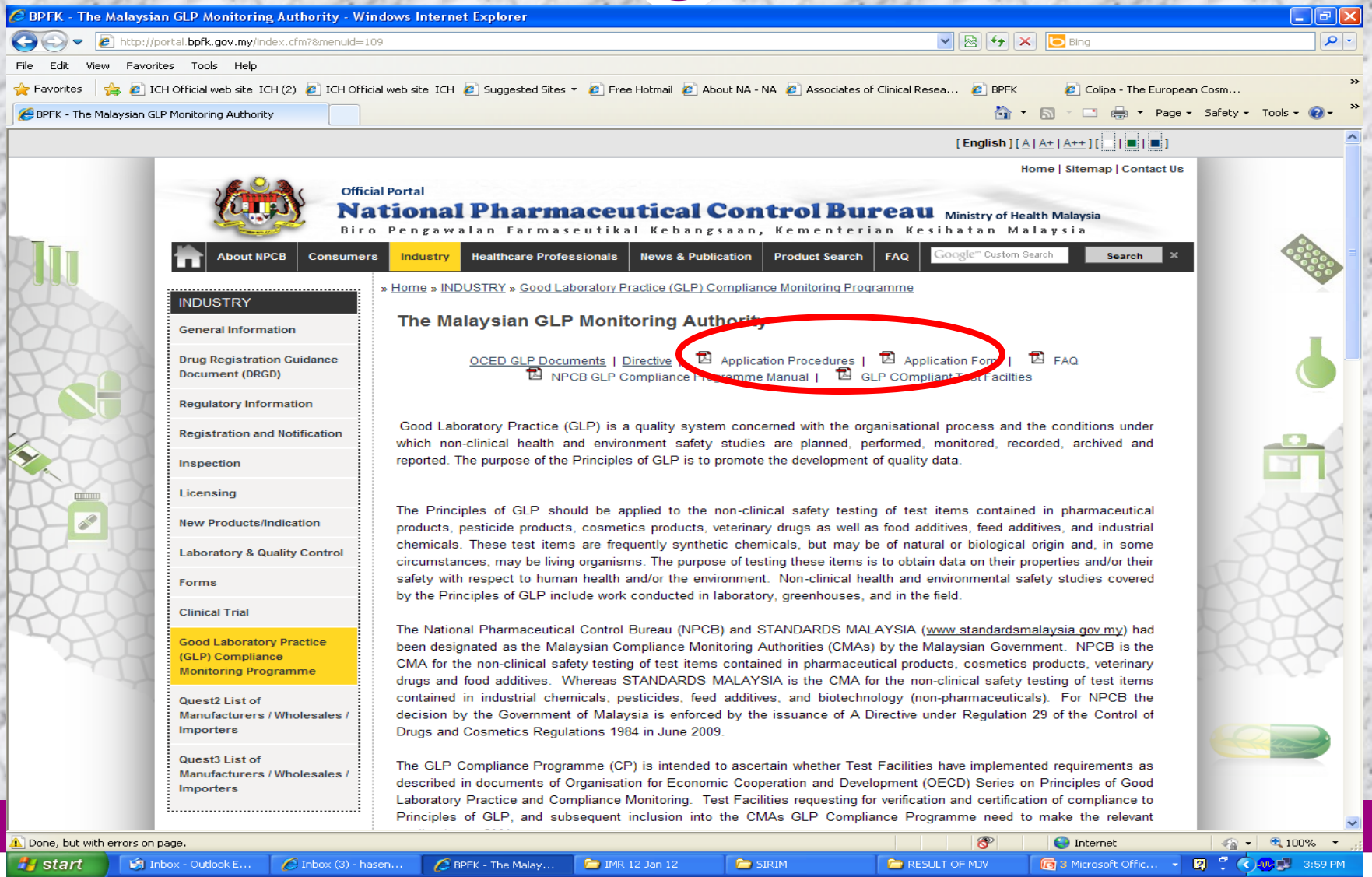
bpfk	NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB) GOOD LABORATORY PRACTICE (GLP) COMPLIANCE PROGRAMME MANUAL	Document Number: NPCB/GLP/100	
		Edition	3
		Page number	1 of 22

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

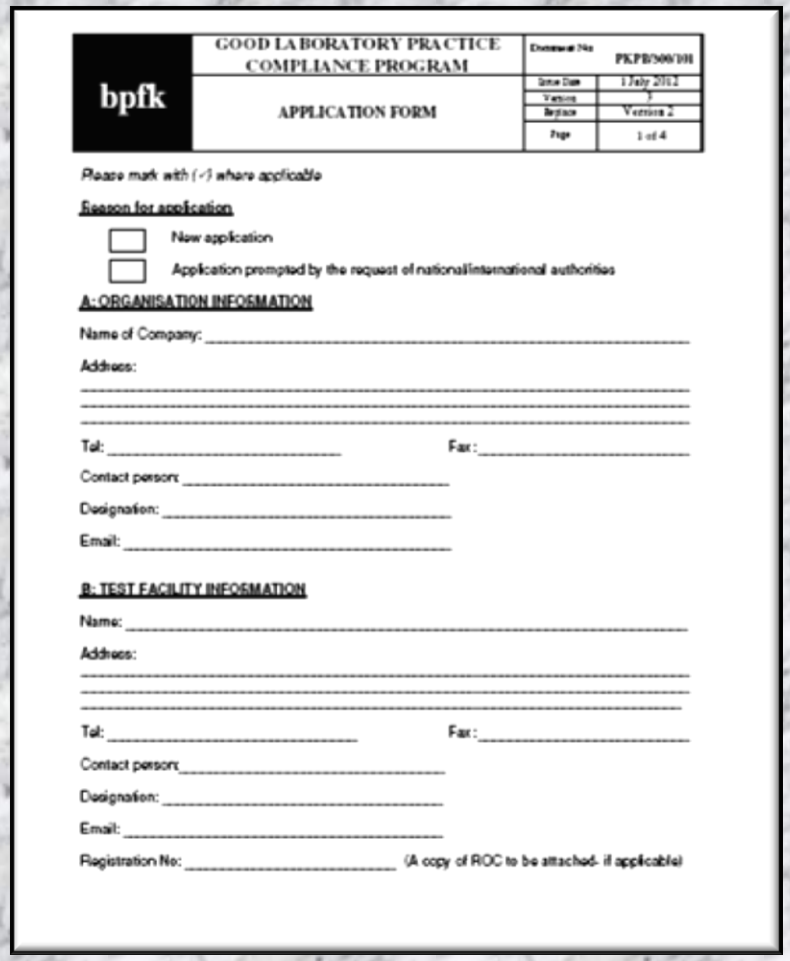
Tel: 603-7883 5400
Facsimile: 603-7955 1030
Website: www.bpfk.gov.my

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

6. NPCB GLP Compliance Monitoring Programme



6. NPCB GLP Compliance Monitoring Programme



bpfk	GOOD LABORATORY PRACTICE COMPLIANCE PROGRAM	Document No	PKPB/500/101
		Issue Date	1 July 2012
	APPLICATION FORM	Version	3
		Replace	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)

6. NPCB GLP Compliance Monitoring Programme

- Complete application submit (post/by hand) to:

  Deputy Director

  Centre for Investigational New Product

  National Pharmaceutical Control Bureau

  Ministry of Health Malaysia

- Fee : FREE

6. NPCB GLP Compliance Monitoring Programme

6. NPCB GLP Compliance Monitoring Programme

4 types of Inspections:

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

6. NPCB GLP Compliance Monitoring Programme

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

6. NPCB GLP Compliance Monitoring Programme

Inspection

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

6. NPCB GLP Compliance Monitoring Programme

Surveillance Inspection

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

6. NPCB GLP Compliance Monitoring Programme

Extra-Ordinary Inspection

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

6. NPCB GLP Compliance Monitoring Programme

6. NPCB GLP Compliance Monitoring Programme

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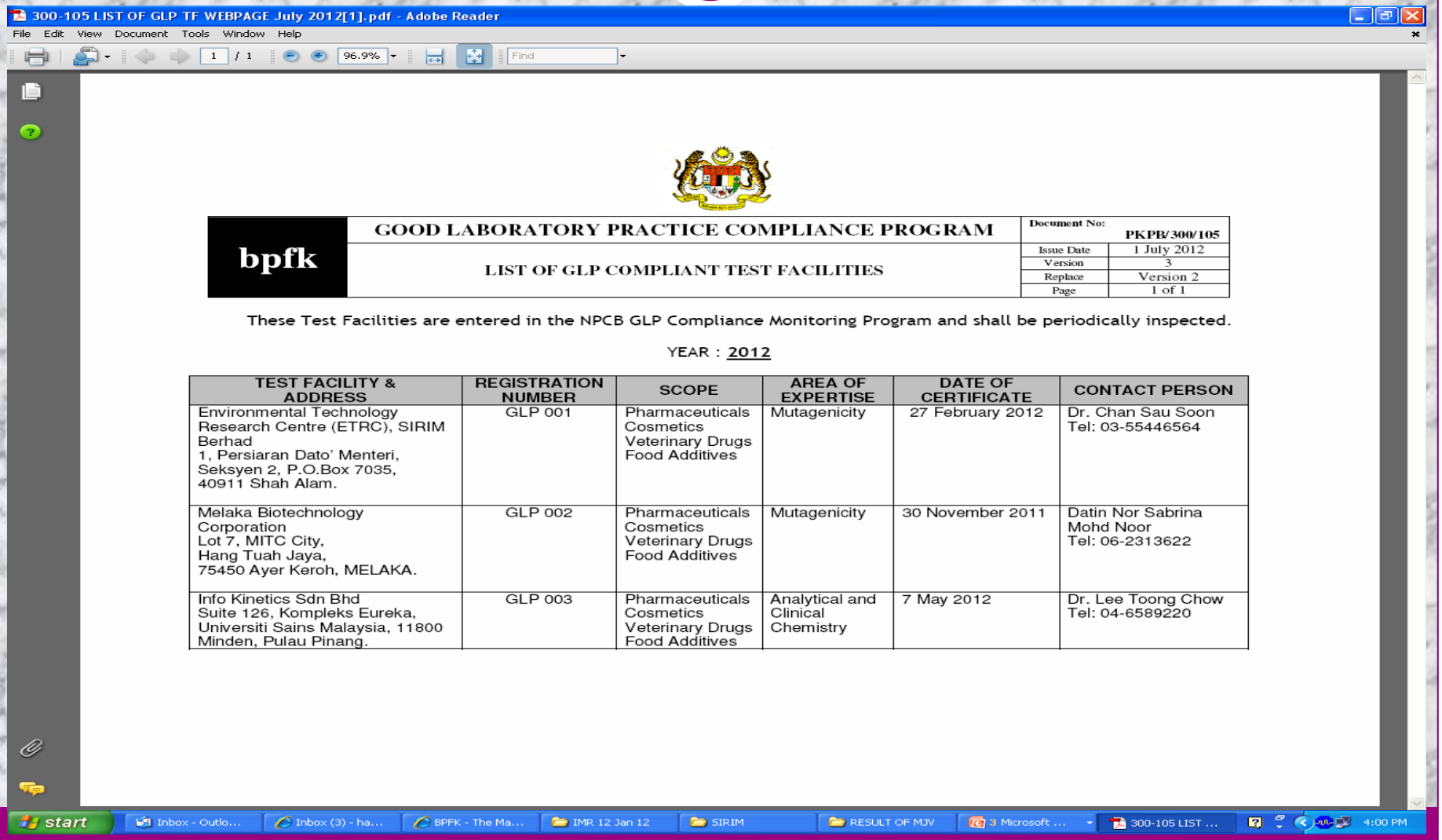


6. NPCB GLP Compliance Monitoring Programme

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

6. NPCB GLP Compliance Monitoring Programme

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

6. NPCB GLP Compliance Monitoring Programme

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

6. NPCB GLP Compliance Monitoring Programme

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

- 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

This will then:

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

7. Benefits

It will also:

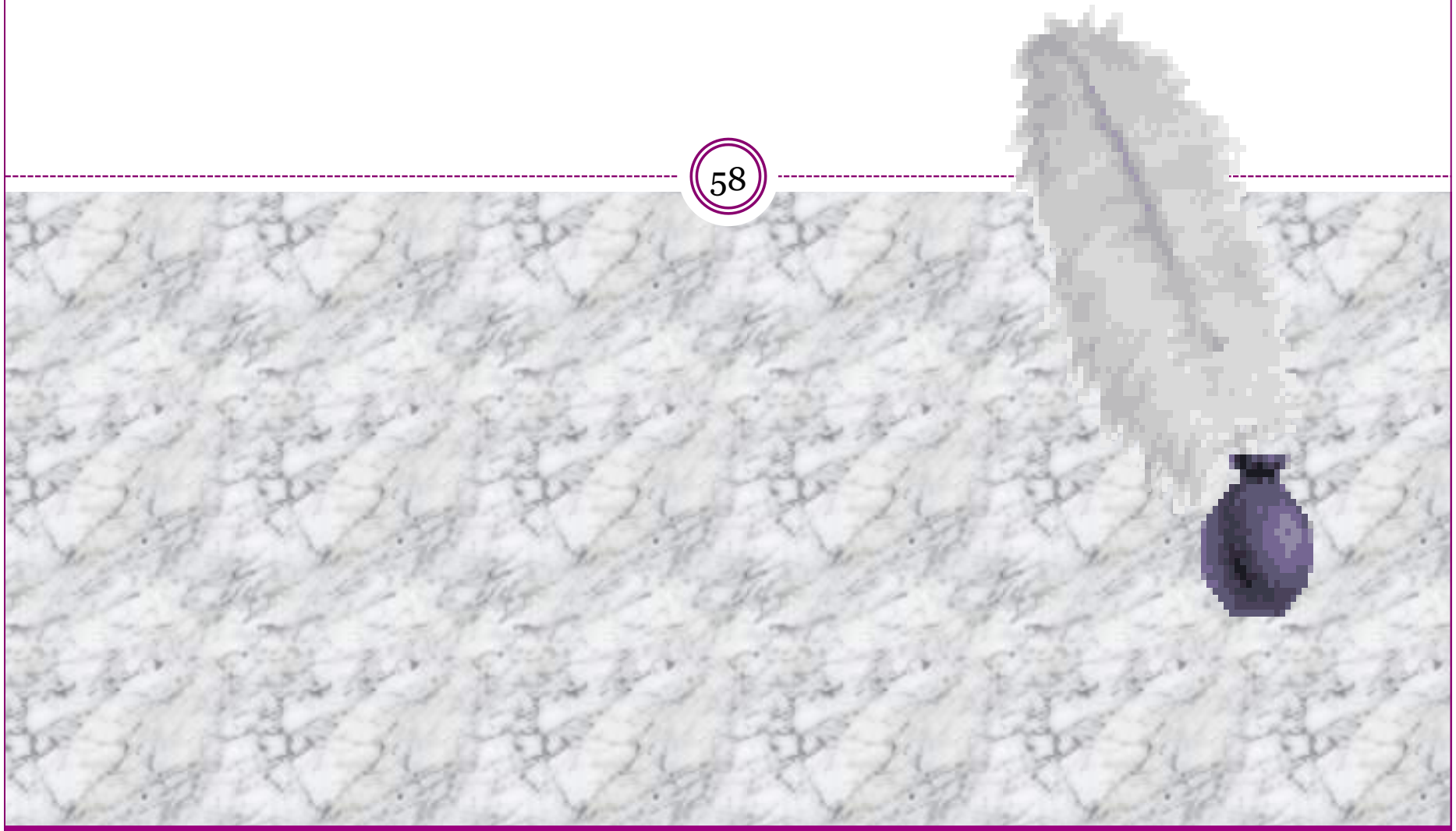
- ✓ Create new business opportunity for GLP laboratories in Malaysia – increase country economy
- ✓ Create new carrier move to
  - Study Director
  - Principle Investigator
  - QA
  - Archivist.

8. Impact

- 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

- 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, CINP, NPCB
  - Dr. Kamaruzaman Saleh, Fadhilah Hasbullah, Poh Wen Tsin



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Malaysia joins OECD agreement on mutual acceptance of chemical safety data

Send Print Tweet

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

Direct line
Tel.: +33 (0) 1 45 24 14 85
Fax.: +33 (0) 1 44 30 61 80
Bob.Diderich@oecd.org

www.oecd.org/ehs
www.oecd.org/env
ORGANISATION FOR ECONOMIC
CO-OPERATION AND DEVELOPMENT

2, rue André-Pascal
75775 Paris CEDEX 16
France