Singapore’s Progress on GLP and MAD

Submitted by: Singapore
Singapore’s Progress on Good Laboratory Practice (GLP) and Mutual Acceptance of Data (MAD)

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Outline

• Introduction to SPRING Singapore
• Overview of GLP Programme in Singapore
• Singapore’s Roadmap to MAD
• Singapore’s adherence to OECD Council Acts and MAD
Overview of SPRING (Standards, Productivity & Innovation Board)
**SPRING Mission & Roles**

**MTI Vision**
A leading global city of talent, enterprise and innovation

**SPRING Mission**
To Grow Competitive and Innovative Enterprises

- Enterprise Development
- Quality & Standards

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**Vision, Mission & Strategic Thrusts**

**Vision**
Dynamic and innovative Singapore enterprises

**Mission**
To enhance the competitiveness of enterprises for a vibrant Singapore economy

**Strategic Thrusts**

<table>
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<tr>
<th>Business environment</th>
<th>Industry</th>
<th>Firm</th>
<th>Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurture a pro-business environment that encourages enterprise formation and growth</td>
<td>Support and drive the development of key industries</td>
<td>Enhance productivity &amp; innovation and capabilities of enterprises</td>
<td>Increase access to markets and business opportunities</td>
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GLP Programme in Singapore

Why GLP for Singapore?

- Key infrastructure to support Singapore’s growth in the biomedical sciences and chemicals sector
  - Biomedical sector – target manufacturing outputs of S$ 25 billion by 2015
  - Chemical sector – target manufacturing outputs of S$ 75 billion by 2018
  - Attract and retain the world's top 10 biomed companies in Singapore

- Quality assurance framework for pre-clinical safety testing, it completes the value chain of product development from R&D to clinical trials to manufacturing
## Importance of GLP to Singapore

**Benefits**
- Eliminates non-tariff trade barriers
- Increases international market access
- Increases regulatory confidence in data
- Reduces time to market for new products
- Avoids testing duplication
- Saves resources especially time and money

## Singapore GLP Programme

- Established in Nov 2006 as a voluntary GLP Programme
- SPRING Singapore is the GLP Monitoring Authority. It is supported by a GLP Advisory Committee which comprises key stakeholders to provide advice on the GLP programme
- SPRING represents Singapore in the OECD GLP Working Group
- SPRING works in close partnership with 3 regulatory agencies (NEA, HSA and AVA) for the GLP programme
Relevant Regulatory Authorities

- **Agri-Food & Veterinary Authority (AVA)** – Food, Agricultural pesticides, Veterinary Drugs
  
  http://www.ava.gov.sg

- **Health Sciences Authority (HSA)** – Pharmaceuticals, Cosmetics
  
  http://www.hsa.gov.sg

- **National Environment Agency (NEA)** – Industrial Chemicals and Pesticides
  
  http://www.nea.gov.sg

SPRING Singapore is the National GLP Monitoring Authority

Scope of Registration

- **Non-clinical health and environmental safety studies of test items** in pesticide products, cosmetics, pharmaceutical products, veterinary drugs, food additives, feed additives and industrial chemicals
Areas for Registration

1. Physical-Chemical Testing
2. Toxicity Studies
3. Mutagenicity Studies
4. Environmental Toxicity Studies on Aquatic and Terrestrial Organisms
5. Studies on Behaviour of Water, Soil and Air
6. Residue Studies
7. Studies on Effects on mesocosms and natural ecosystems
8. Analytical and Clinical Chemistry associated with non-clinical studies
9. Others

Registration Process

• Advisory visit
• Application
• Documentation review
• On-site Inspection – Assessment of quality system, Review of records, discussions with key personnel, observation of relevant activities
• Assessment report with recommendations
• Approval decisions
• Registration of facility
• Annual on-site monitoring
Current Programme Status

- 3 facilities registered with 1 applicant
- 3 trained inspectors and 3 trainee inspectors
- Full member of OECD’s MAD for GLP since January 2010

Singapore’s GLP Journey to MAD
The Singapore’s GLP Journey

- Feb 2006: A multi-agency working group formed to develop the GLP Framework
- Sep 2006: SPRING designated as the national GLP Monitoring Authority by MTI
- Nov 2006: Launch of GLP Programme
- Development of procedures, processes & quality system
- Feb 2007: Participation at the OECD GLP WG Mtg in Auckland, NZ
- Mar 2007: Provisional member of OECD GLP WG
- Inspection and registration of test facilities for GLP

Singapore’s Roadmap to MAD

- May 2008: OECD GLP WG agreed to send a MJV team to Singapore at its meeting in Italy
- Mar 2009: OECD GLP WG reviewed and agreed to admission of Singapore to the MAD at its meeting in Paris
- May 2009: Singapore achieved full membership to the OECD MAD for GLP
- Jan 2010: OECD Mutual Joint Visit
- Capability Building & System Improvement Activities
Building Capabilities

**Industry**
- GLP Implementation Workshops (Jul 2007 & Jan 2008)
- GLP Sharing Sessions for QA and Study Directors
- Sharing sessions targeted at Archivists and other Study Personnel are planned
- GLP Talk to researchers of R&D institutions

**MA & Inspectors**
- Attachment trips to UK, Australia, Switzerland, Czech Republic (2006-2009)
- Consultancy
- Attendance at OECD GLP WG Mtgs (since 2007)
- Participation of OECD Inspector training course and workshops (since 2006)
- Inspector sharing sessions

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GLP Workshop in 2007
UK Attachment in 2006 for Inspectors
Attendance in OECD GLP WG Mtgs since 2007
Adherence to OECD Council Acts and MAD

Mutual Recognition

(GLP) Mutual Acceptance of Data

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

Non-OECD Member countries
- South Africa 2003
- Slovenia 2004
- Israel 2005
- Singapore 2010

Provisional
India, Brazil, Argentina, Malaysia

Ad-hoc Observers
China, Estonia, Chinese Taipei, Thailand etc
COUNTRY A

REGULATORY AUTHORITY

Requests Information on GLP Compliance Status of the Laboratory or Study Audit

Information

GLP MONITORING AUTHORITY

COUNTRY B

TEST FACILITY

Submits Data

Inspection and/or Study Audit

Information

Report

GLP MONITORING AUTHORITY

Requests Information

Source: OECD

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Closer Co-operations

GLP Visit by Chinese Delegation in Sep 2009

Thailand Delegation to Singapore on GLP

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Thank You