National GLP programmes and implication of pharmaceuticals, pesticides and other chemicals Regulatory Authorities in Japan

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Number of monitoring authorities in OECD countries and non-OECD countries adhering to MAD Council Decision

AUS (1), AU (2), BE (1), CA (2), CZ (2), DK (2), FI (2), FR (3), DE (2), GR (2), HU (1), IR (1), IL (1), IT (1), JP (4), KO (3), NE (1), NZ (1), NR (1), PL (1), PT (2), SR (1), SL (1), SA (1), SP (2), SW (2), CH (3), UK (1), USA (2)

Ref: OECD document No.2、20th WG on GLP
# Overview of GLP Programmes in Japan

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<th>GLP Programme</th>
<th>Ministry</th>
<th>Related Organization</th>
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<tr>
<td>1 Pharmaceuticals and Medical Devices</td>
<td>MHLW</td>
<td>Pharmaceuticals and Medical Devices Agency</td>
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<td>2 Workplace Chemicals</td>
<td>MHLW</td>
<td>National Institute of Occupational Safety and Health</td>
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<td>3 Pesticides</td>
<td>MAFF</td>
<td>Food and Agricultural Materials Inspection Centre</td>
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<td>4 Veterinary Drugs</td>
<td>MAFF</td>
<td>National Veterinary Assay Laboratory</td>
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<td>5 Feed Additives</td>
<td>MAFF</td>
<td>Fertilizer and Feed Inspection Services</td>
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<td>6 Industrial Chemicals</td>
<td>MHLW</td>
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<tr>
<td>1) Toxicity</td>
<td>MHLW</td>
<td>National Institute of Health Sciences</td>
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<tr>
<td>2) Bioacc./Biodegr.</td>
<td>METI</td>
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<td>3) Ecotoxicity</td>
<td>ME</td>
<td>National Institute for Environmental Studies</td>
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Revised Guidance for the exchange of information concerning national programmes for monitoring of compliance with principles of Good Laboratory Practices
[Annex III to C(89)87(Final)Revised in C(95)8(Final)]

To facilitate international liaison and the continuing exchange of information, the establishment of a single GLP Monitoring Authority covering all good laboratory practice activities within a Member country has obvious advantages. Where more than one Authority exists, a member country should ensure that they operate in a consistent way, and have similar GLP Compliance Programmes. The Authority or Authorities with responsibilities for international contacts should be identified.
Experiences (Personal opinions)

[International Affairs]

- Contact point for OECD
- Flow of information
  - Information sharing/Confidentiality
- Policy arrangement and decision making

[Internal Affairs] (Especially for industry colleagues)

- Translation and interpretation
- Format
- Difference of inspection
Relationship among Ministries (Ministry of Health, Labor and Welfare [MHLW], Ministry of Environment [MOE], Ministry of Economy, Trade and Industry [METI], Ministry of Agriculture, Forestry and Fisheries [MAFF])

- Inter-Ministerial Meeting on Good Laboratory Practice
  - discuss the policy regarding GLP (esp. for OECD WG)
  - exchange the information regarding GLP

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Joint on-site evaluation (training) program in Japan

**Purpose**
1. Training for inspectors
2. Harmonization among programs
3. Preparation for OECD on-site evaluation

**Method**
The same procedure as OECD on-site evaluation (by using OECD Working template)
Joint translation program in Japan

OECD GLP Documents (No.1-No.15)
translated by JSQA

Draft Japanese translation of GLP Documents
checked by Ministries and Organizations

Common Japanese translation of GLP Documents*
posted at JSQA homepage

Available to the public, Various uses for government, industries and academia


* This is not official translation guaranteed by Japanese government

OECD Event, Villa Tuscolana, Frascati (Roma), Italy, April 10 – 11, 2008
Relationship among programs

- Relationship among GLP monitoring authority [MA] and receiving authority [RA]

- Both MAs and RAs are offices at the same organizations (sometimes at the same divisions)
- Close relationship through internal meetings
- Clear procedure for information exchange based on SOP etc
Relationship among programs

- Example: PMDA (MA → RA)
  - Send the list of the results of GLP status of test facilities (GLP compliance or GLP non-compliance) once a year
  - Inform the result of non-compliance with the detailed information urgently
  - Response the questions of GLP status

- Example: PMDA (RA → MA)
  - Request the information of GLP status
  - Request for-cause inspection
Relationship among programs

➢ Relationship among Ministries and related organizations

- Ministries

- Organizations (ex. PMDA)

- Clear relationship based on Laws, Notices and SOPs

- Close relationship through regular meetings and ad hoc meetings
Relationship among programs

- Relationship among Ministries and Industries (Example. GLP program for medical products)

- Information exchange (including opinions and requests)
- Training and Q & A
- Provide the information through the homepages

**JSQA:** Japan Society of Quality Assurance

**JPMA:** Japan Pharmaceutical Manufactures Association

**JEMDA:** The Japan Federation Association of Medical Devices
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Relationship among programs

Relationship between Japan and Other countries

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

MAD

Non-members (3 Countries)
South Africa 2003
Slovenia 2004
Israel 2005

Human resources


MOU with EC, Switzerland and USA*

India, Singapore, Brazil, Argentina (Provisional)

China, Russia, Chinese Taipei, Thailand etc.

Bilateral Cooperation

*Only pesticide program

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Examples of Bilateral Cooperation

1. China

2. Thailand
   PMDA supported 2 GLP symposiums organized by Ministry of Medical Science, Ministry of Public Health, Thailand (2007)

3. Chinese Taipei etc.
Relationship among programs

Summary of relationship with other entities

- Framework of OECD
- Bilateral agreement and/or cooperation

JP gov

MHLW (PMDA)
MAFF (FAMIC)
METI (NITE)
ME (NIES)

Other countries

Industry groups

Patients
Consumers
Others

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Proposal for future activities (Examples)

[Training program]
- Mutual visit training (the same system as OECD on-site evaluation program)
- Common training documents for non-member countries to join the OECD MAD framework
- Common training documents for GLP inspectors based on the OECD training for GLP inspectors

[OECD event]
- ‘2nd OECD event’ with industry colleagues
Mutual visit training program

Purpose
1. Training for inspectors
2. Harmonization among programs
3. Preparation for OECD on-site evaluation

Method
One country hosts and invites other countries (2 or 3 countries) to its inspection through the OECD internet. Participating countries pay their travel cost.

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Acknowledgment

[Ministries]
- Ministry of Health, Labor and Welfare (MHLW)
- Ministry of Economy, Trade and Industry (METI)
- Ministry of Environment (ME)
- Ministry of Agriculture, Forestry and Fisheries (MAFF)

[Other organizations]
- Pharmaceuticals and Medical Devices Agency
- National Institute of Occupational Safety and Health
- Food and Agricultural Materials Inspection Centre
- National Veterinary Assay Laboratory
- Fertilizer and Feed Inspection Services
- National Institute of Health Sciences
- National Institute of Technology and Evaluation
- National Institute for Environmental Studies

[Industry groups]
- Japan Society of Quality Assurance
- Japan Pharmaceutical Manufactures Association
- Japan Federation Association of Medical Devices

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Thank you for your attention