Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

SPAQA Meeting November 2008

OECD on-site evaluation visits
EU GLP WG December 2007

olivier.depallens@bag.admin.ch

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

MAD

Mutual acceptance of test data (MAD) [OCD Council Decision 1981] is a basic benefit of the application of GLP principles.

Experience showed that MAD is only possible if genuine mutual confidence exists in the manner in which inspections and study audits are carried out.

This mutual confidence can only be obtained through the transparency resulting from site visits by teams of experts.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Mutual Joint Visits (MJV)

Experience from MJV

Between 1998 and 2001, all OECD GLP monitoring programmes were reviewed through the Mutual Joint Visits (MJV) pilot project.

It was recognised that the MJV programme increased harmonised monitoring procedures and sustained mutual confidence between monitoring authorities.

All OECD compliance monitoring authorities agreed to accept compliance decisions from authorities who passed an MJV.

MJV required for all new monitoring programmes to be accepted by the OECD GLP working group.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

On-site evaluation visits

Continuing programme

To maintain confidence obtained with the MJV, the OECD GLP working group proposed a “continuing programme” taking into account improvement proposed during the MJV pilot programme.

OECD Joint Meeting agreed for a continuing programme under the condition to reduce resources needed.

► **Periodic on-site evaluation programme**

→ rounds on a ten years basis
→ teams of two inspectors
→ centralised funding of travel costs

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

On-site evaluation visits

Overall planning

Actually **44 monitoring programmes** in the OECD GLP working group (some countries have more than one programme, e.g. USA with EPA and FDA monitoring programmes)

Complete cycle of **10 years** to evaluate all programmes.

→ 4 to 5 on-site evaluation visits per year

Team of 2 inspectors.

→ each monitoring programme will participate in 2 on-site visits

OECD secretariat establishes the on-site visits plan (schedule, teams)

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

On-site evaluation visits

2008

1) Japan – Medical Products and

2) Japan -Workplace Chemicals * 1- 11 September
Team: Belgium/Korea

3) Czech Republic 14-20 September
Team: Italy/South Africa/ (Singapore) (Secretariat)

4) Germany * 20-24 October
Team: Ireland/Switzerland (Turkey

2009

5) Norway *
Team: Netherlands/Israel

6) US – Medical Products
Team: Denmark/Australia

7) France – Medical Products *
Team: US (Chemicals and Pesticides)/Greece (Chemicals and Pesticides) 18-22 May

8) Denmark - Medical Products *

9) Denmark – Chemicals and Pesticides *
Team: Japan (Medical Products and Workplace Chemicals)/Finland (Thailand) November?

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

On-site evaluation visits

Switzerland

The Swiss GLP compliance monitoring programme was inspected (visited) in 2000

On-site evaluation visit: 2014

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

On-site evaluation visits

Organisation

Pre-visit documentation review

On-site visit (normally one week)
day 1: presentation and discussion of the programme
day 2-4: team observes an inspection conducted by the monitoring authority
day 5: final discussion
→ emphasis on observation of inspection / study audit
→ emphasis on relation between monitoring and receiving authorities

Visit report

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

On-site evaluation visits

Decision

On the basis of the team visit report, the GLP working group has to decide if the visited monitoring programme correctly implements:

Revised Guides for Compliance Monitoring procedures for GLP (Doc. No 2)

Revised Guidance for the Conduct of Laboratory Inspections and Study Audits (Doc. No 3)

Guidance for the preparation of GLP reports (Doc. No 9)

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

On-site evaluation visits

Follow-up

Remedial actions can be recommended by the Working Group:
- Timetable established with the visited programme
- Follow-up of corrective actions by the inspection team
- Eventually follow-up on-site visit

Evaluation of remedial actions at Working Group meeting

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

EU GLP Working Group (December 2007)

Technical issues (questions asked by Switzerland)

Are the notes of a QA-inspector during a GLP-inspection considered as raw data – are these notes to be archived?

The group underlined that the original QA notes are important and should be archived

What is an acceptable interval to archive training records ?

In some member States training records have to be archived annually. In general, when a person leaves the facility his/her training records should be archived

11

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

EU GLP Working Group (December 2007)

Cooperation with receiving authorities

EMEA: good working relationship with GLP working group. Different study audits required based on procedure in place.

EFSA: actually no contact with the GLP WG despite various tentative from the WG coordinator

Study audit from US-FDA

US-FDA requested to conduct a study audit in a test facility in Belgium. Announced as a follow-up inspection, US-FDA conducted a full inspection based on FDA GLP regulation and not OECD GLP regulation.

12

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

EU GLP Working Group (December 2007)

Statistics on inspection findings

DE presented a statistic on findings based on 200 inspections:

% deviations	*related GLP principles*
27%	study conduct
17%	organisation & personnel
10%	SOPs
9%	QA
5%	IT
4%	archive
4%	facilities

Trend: increasing number of new types of studies → area of expertise "others"

13

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

EU GLP Working Group (December 2007)

GLP programmes in EU Countries

Estonia, Lativa, Lithuania: have a responsible GLP contact point but will work with other EU monitoring authorities in case of application for inspection

Bulgaria: work in progress

Turkey (candidate country): twinning programme with Slovakia

14