

## **Update from the OECD GLP Industry Discussion Group (IDG) Q1 2026**

Hello GIQAR Members,

I'm Ilaria Enrietto, and I am your GIQAR GLP representative for the OECD GLP Industry Discussion Group (IDG). In this article you can read more about the IDG and the member's responsibilities. I have also included information about a recent meeting with the IDG and a sub-group from the OECD GLP Working Party on 9 February 2026. During this meeting, several topics were discussed including the outcome of the survey that was distributed to GIQAR GLP members in December 2025. This survey asked Industry the following questions:

- Is there any need for updating OECD GLP Advisory/Consensus documents and if so, why?
- Are there any other topics that require guidance?
- Have you encountered any issues with GLP certificates or routine inspection programs by your GLP Compliance Monitoring Authorities (CMA)?
- Have you ever encountered issues when collecting information from Sponsors / CMO to support test item characterisation?

The sub-group of the OECD GLP Working Party (WP) has also shared new training material relating to Test Item in GLP studies. This training was originally prepared for the GLP CMA but the IDG members have been asked to distribute the training to the Industry. For that reason, the GIQAR GLP Team will organize a dedicated webinar session on this topic.

### **Background OECD GLP Industry Discussion Group (IDG)**

The OECD GLP Industry Discussion Group allows industry organisations and test facilities to communicate concerns that may impact their business. Any issues identified either during the inspection process, or otherwise, should first be discussed with the relevant National GLP Compliance Monitoring Authority.

The members of the IDG represent sectors of industry that are involved in the management and conduct of GLP studies.

Membership is limited to organisations who have been nominated by their respective government representative (member of OECD Working Party on GLP).

Feedback from test facilities is typically via quality assurance professional societies that make up the majority of the IDG, including the GIQAR GLP Team.

The IDG members meet periodically with the subgroup of the OECD GLP WP to discuss:

- Issues of perceived lack of harmonisation of GLP processes across the OECD GLP Community.

- Potential advances in technology or other issues that may impact the ability of test facilities to adhere to the current GLP Principles.

## **Summary of meeting 9 Feb 2026 between the OECD GLP IDG and Subgroup of the OECD GLP WP.**

### 1. IDG Survey

#### ***Is there any need for updating OECD GLP Advisory/Consensus documents?***

Responses were received from 11 countries with >70 individual responses.

There were detailed answers from Sweden, France, Netherlands, Spain, Germany, Switzerland, Italy, Canada and US with summarized data (yes/no) from South Korea and Japan. Responses had not yet been received from India, UK and Belgium. The top 3 documents to be updated based on the responses provided to date were:

- Compliance of Laboratory Suppliers with GLP (1999) Consensus Document OECD No 5
- The Application of the OECD Principles to the Organisation and Management of Multi-site studies Consensus Document OECD No 13 (2002)
- Establishment and Control of Archives that Operate in Compliance with the Principles of GLP Advisory document OECD No 15 (2007)

It will be up to the OECD GLP WP to make the final decision on documents to be updated and when.

#### ***Are there any other topics that require guidance?***

Here is a summary of topics mentioned:

- New Approach Methodologies (NAMs) including models such as organ-on-a chip or organoids testing.
- GLP Application to AI/Machine learning tools
- Advanced therapy medicinal products (ATMP)

#### ***Have you encountered any issues with GLP certificates or routine inspection program by your GLP Compliance Monitoring Authorities (CMA)?***

There was a number of points raised that indicated that there are differences in the approach of CMA in some countries.

#### ***Have you ever encountered issues when collecting information from sponsors / CMO to support test item characterisation?***

Issues included:

- Incomplete certificates of analysis

- Poor knowledge of the sponsor about GLP requirements and understanding of OECD advisory No 19
- Sponsors with holding key characterisation data to protect intellectual property risking study validity and safety
- Lack of shipping records with temperature controls to confirm test item stability on arrival.

## 2. Test Item Training

The OECD GLP WP has released training material about Test Item (“Characterisation of test items” and “Analysis of test item in vehicle”). The training can be used by both GLP CMA and Industry. This training material reminds study personnel, especially Study Directors, of the requirements about test item as stated in the GLP Principles and clarified in OECD Document No 19.

The training covers the following elements:

- The GLP requirements and OECD Advisory no 19
- What is the test item?
- What characterisation is required?
- What do we need to know for the test item in vehicle?
- Specific case of Field Trials and analysis of test item diluted
- Some examples of text submitted in study reports (both bad and good)
- Some common questions received from industry

Plenty of examples are given to give a better understanding of the expectations relating to what needs to be known and what documentation is required. It also covers GLP deviations and the necessity to perform impact analysis when data is missing.

**The training will be shared in a dedicated Webinar session organized by the GIQAR GLP Team.** It will also be an opportunity for attendees to ask questions about the training supplied by the OECD GLP WP. The actual date of this event will be posted on the GIQAR website.

## 3. Other discussion points at the meeting

- The IDG presented areas for consideration relating to Data integrity (Advisory document No 22) and IT security (Position paper No 25).
- Chinese Test Facilities assessment by industry QA and Compliance Monitoring authorities for GLP compliance.

The OECD GLP Working Party will meet for their annual meeting in April 2026. Here there will be further discussion with all OECD GLP Working Party Members, including key items that have been brought to their attention during the February meeting with the IDG.

**Finally.... *Let your voice be heard!***

If you know of any areas that you think require harmonisation, or gaps where you consider there is a need for more guidance on GLP, let me know and I will make sure that they are brought to the monthly IDG meetings.

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