

Good In Vitro Method Practices (GIVIMP) Certification: A Roadmap for Implementation and Harmonization

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ABSTRACT

The Organization for Economic Cooperation and Development (OECD) guidance document on Good In Vitro Method Practices (GIVIMP) details a set of quality standards to improve both the quality of and confidence in newly developed, and routinely executed *in vitro* methods. Currently a practical guide to implement GIVIMP standards is missing; leaving organizations to define the best approach for themselves. Given the broad range of scientific and quality topics in GIVIMP, there is the potential for varying interpretations of the guidance and thus significant differences in implementation. The Institute for In Vitro Sciences, Inc. (IIVS) has created a business to business certification program to help commercial and academic institutions achieve the best value from this guidance document. The certification program harmonizes GIVIMP interpretation and standardizes “claims” of compliance with the document among participating laboratories. GIVIMP certification can be useful for academic and commercial facilities already functioning under other quality standards such as Good Laboratory Practices (GLPs) and ISO since GIVIMP provides unique recommendations for *in vitro* work not covered under those standards. A pilot certification between IIVS and BASF SE toxicology laboratories (Ludwigshafen, DE) has been launched to provide proof-of-concept for the program. This poster discusses the need for the GIVIMP certification program and provides details on its structure and administration.



The aim of GIVIMP is “to reduce the uncertainties in cell and tissue-based *in vitro* method derived predictions by applying all necessary good scientific, technical and quality practices...” (OECD, 2018)

How a Certification Program Helps Implement GIVIMP

GIVIMP is internationally harmonized guidance, but it is not a regulatory standard. No government authority is responsible for overseeing its implementation, which could lead to various interpretations of the guidance. Standardization of the assessment provides harmonization in the understanding of concepts within the document across many laboratory types.

The certification program is a consistent, meaningful process that results in practical steps toward quality improvements based on the guidance for participating laboratories. Having this process for using the guidance ensures that the important principles discussed in GIVIMP are not overlooked, but put into practice by the intended audience.

The IIVS GIVIMP Certification Program is structured to be flexible so that it is feasible for all sizes and types of *in vitro* laboratories and suppliers to participate in the program. Not all guidance is applicable to each method or laboratory – The program provides a fast way to sort through recommendations and capture all those that are applicable based on the pre-determined scope. Participation in the certification program decreases time and resources spent, even for experienced laboratories, determining the most relevant principles to follow and the best course of action for their implementation.



The certification program transforms the sizable GIVIMP document into a manageable, systematic approach for improving laboratory processes and creating a quality framework for *in vitro* laboratories.

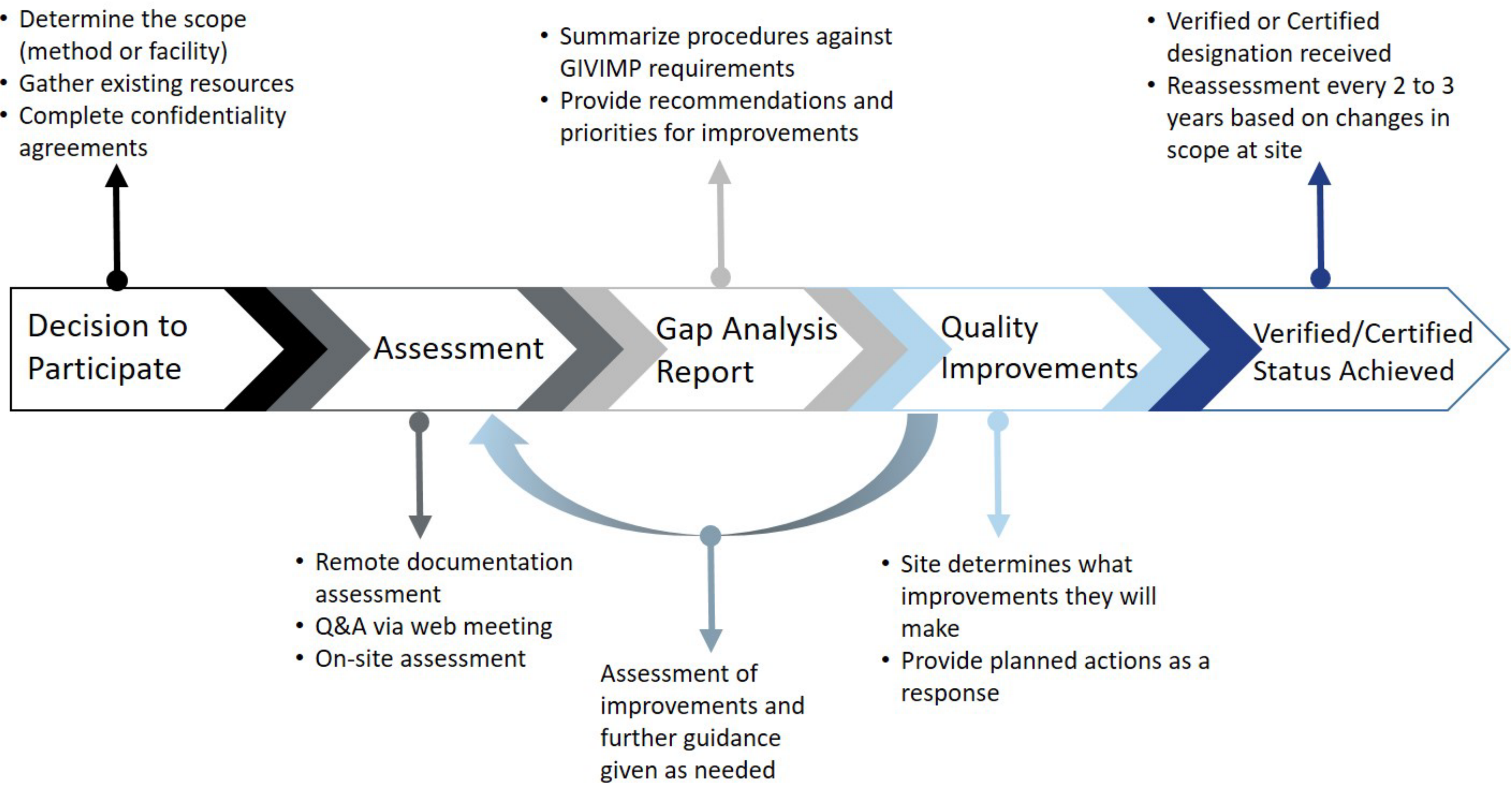
Why IIVS

- This activity aligns with IIVS’ mission. IIVS is a non-profit organization with a mission to increase the use and acceptance of *in vitro* methods worldwide.
- IIVS has been compliant with Good Laboratory Practices (GLPs) for 25 years and is familiar with auditing and applying quality standards to *in vitro* methods.
- IIVS participated in a consortium that created e-learning modules on developing reliable and relevant alternative, non-animal approaches for regulatory use. Explaining GIVIMP was a large part of that training module.



The IIVS GIVIMP Certification program combines IIVS’ technical understanding of *in vitro* methods with its quality and auditing expertise.

This timeline shows the order of events within the IIVS GIVIMP Certification Program. The length of time each section takes is dependent on the scope of GIVIMP activities defined by the site.









How it Works

Given the breath and depth of the GIVIMP guidance, this program is designed to assist laboratories in efficiently applying the recommendations to their work.

- Laboratories determine the scope from single test method, specific laboratories or departments, or the full facility.
- Key elements or “Core Competencies” of the program have been identified for each of the chapters in a collaborative effort between the scientists and QA professionals of IIVS and BASF. The core competencies are applicable to both the development of a single method and the overall organization of laboratory operations.
- An assessment against the core competencies and additional applicable recommendations will be performed by a trained GIVIMP auditor. The outcome of the assessment will be a Gap Analysis Report intended to help prioritize improvement efforts.
- GIVIMP certification is a process, not a pass/fail determination. Continuous improvements can be made by laboratories over time.
- If after an assessment a laboratory is not ready for verification, their report will provide specific recommendations to improve adherence to the standards. Re-assessment can be conducted once the facility has had time to follow the recommendations.
- When a laboratory demonstrates adherence to the core competencies, they will be considered “GIVIMP Verified” for the laboratory or the method(s) assessed.
- When further appropriate recommendations from GIVIMP are implemented the laboratory or method(s) will be considered “GIVIMP Certified.”
- Participants in the program can continue to make quality improvements and request additional assessments until their desired level of Verification or Certification is achieved.
- Periodic reassessment will be performed to maintain Verification or Certification status.

A method(s) or laboratory can be assessed and determined to be either GIVIMP Verified or Certified depending on adherence to defined core competencies

	TEST METHOD	SUPPLIER & LABORATORY
 Audit evaluates adherence to appropriate core competencies of GIVIMP <ul style="list-style-type: none">Re-assessment if Certification is desiredRe-verification assessments to minimize drift from compliance		
 Audit evaluates adherence to additional applicable standards in GIVIMP <ul style="list-style-type: none">Re-certification assessments to minimize drift from compliance		

References

OECD (2018), “Guidance Document on Good In Vitro Method Practices (GIVIMP)” OECD Series on Testing and Assessment, No. 286, OECD Publishing, Paris, <https://doi.org/10.1787/9789264304796-en>

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