Implementing Good In Vitro Method Practices (GIVIMP) as a Quality Standard in a Laboratory

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Quality Standards

- Good Laboratory Practices (specifically OECD GLP #14 – Application of GLPs to In Vitro Studies)
- ISO 17025 and 90001
- Good Cell Culture Practices (GCCP)
- Good In Vitro Method Practices (GIVIMP) OECD Guidance Document #286

2018 Guidance Document on Good In Vitro Method Practices (GIVIMP) published

1) A detailed update on good practices for state-of-the-art *in vitro* methods applied to regulatory human safety assessment of a variety of compounds
2) Guidance to users and implementers of *in vitro* methods to help to ensure that SOPs are well-designed, robust, well-defined and well-described
3) Description of the key aspects that may impact the reliability and relevance of *in vitro* data
4) Description of the importance of reporting criteria, including establishing acceptance criteria and performance standards from *in vitro* data sets

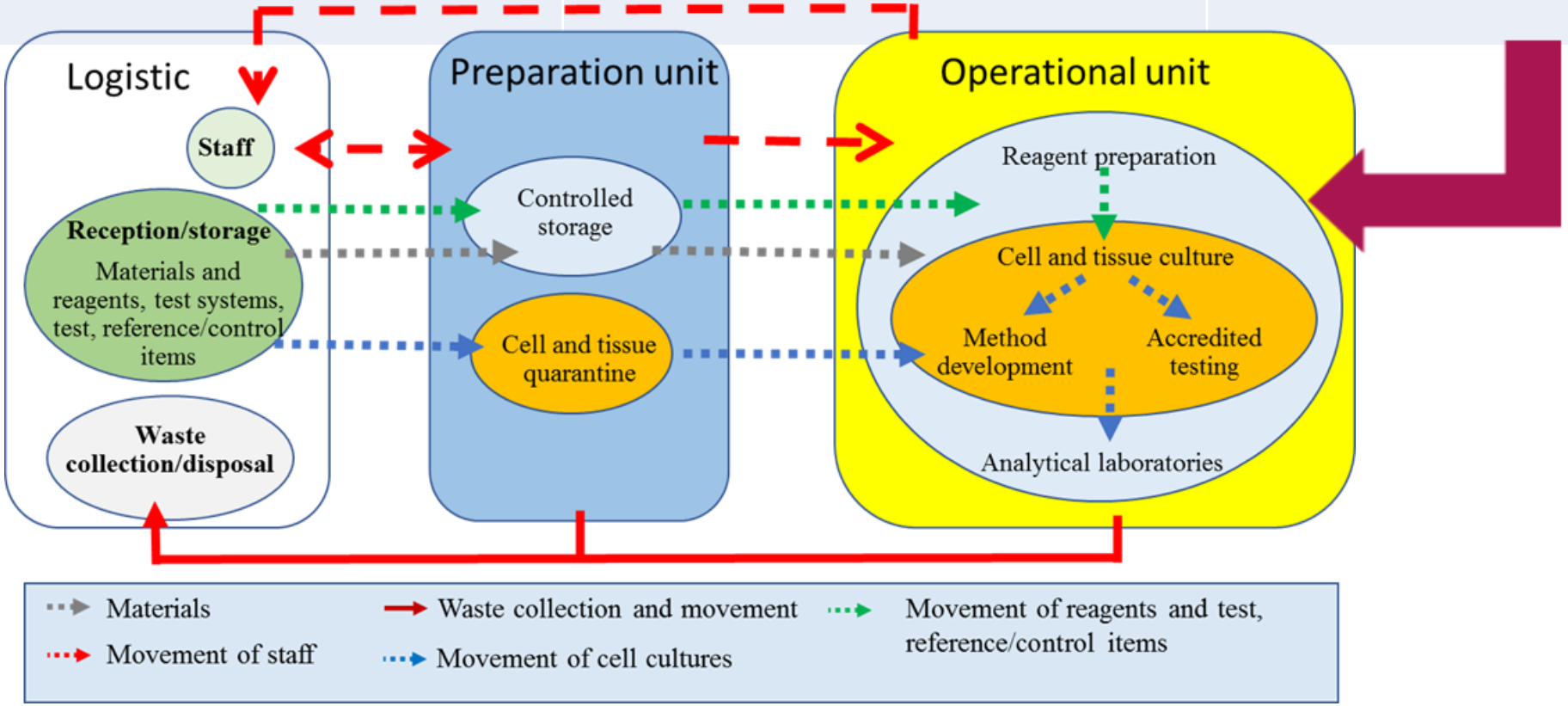
Available on OECD e-Library
https://doi.org/10.1787/20777876

Also available on the
OECD Series for Testing and Assessment No. 286

Download GIVIMP here

What the Guidelines Say re: Facility Design

GLP	GCCP	GIVIMP
OECD		
3.1.2. The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study 5.2.2. Newly received animal and plant test systems should be isolated…	Procedures should be performed in suitable facilities, according to local legal regulations.	3.1 Facility Design Figure 2 – Flow of staff and materials to show separation of processes.



Strategy for Implementing GIVIMP Recommendations

1. GIVIMP recommendations were grouped into topic areas that aligned with the chapters of GIVIMP: 1) Roles and Responsibilities, 2) Quality Considerations, 3) Facilities, 4) Apparatus, Materials, and Reagents, 5) Test Systems, 6) Test, Control, and Reference Items, 7) SOPs, 8) Performance of the Method, 9) Reporting of Results, and 10) Record Retention.
2. Within each chapter, items were categorized as either **Facility Related** or **Method Specific**.
3. Not all recommendations are applicable to every laboratory

Strategy for Implementing GIVIMP Recommendations

Adherence to GIVIMP recommendations was assessed by a QA professional.

- For facility related recommendations, Laboratory Management and/or Facility Management were consulted where processes and procedures needed to be put in place or modified.
- For method specific recommendations, scientists responsible for the performance of the method and/or Laboratory Management were consulted where processes and procedures needed to be put in place or modified.

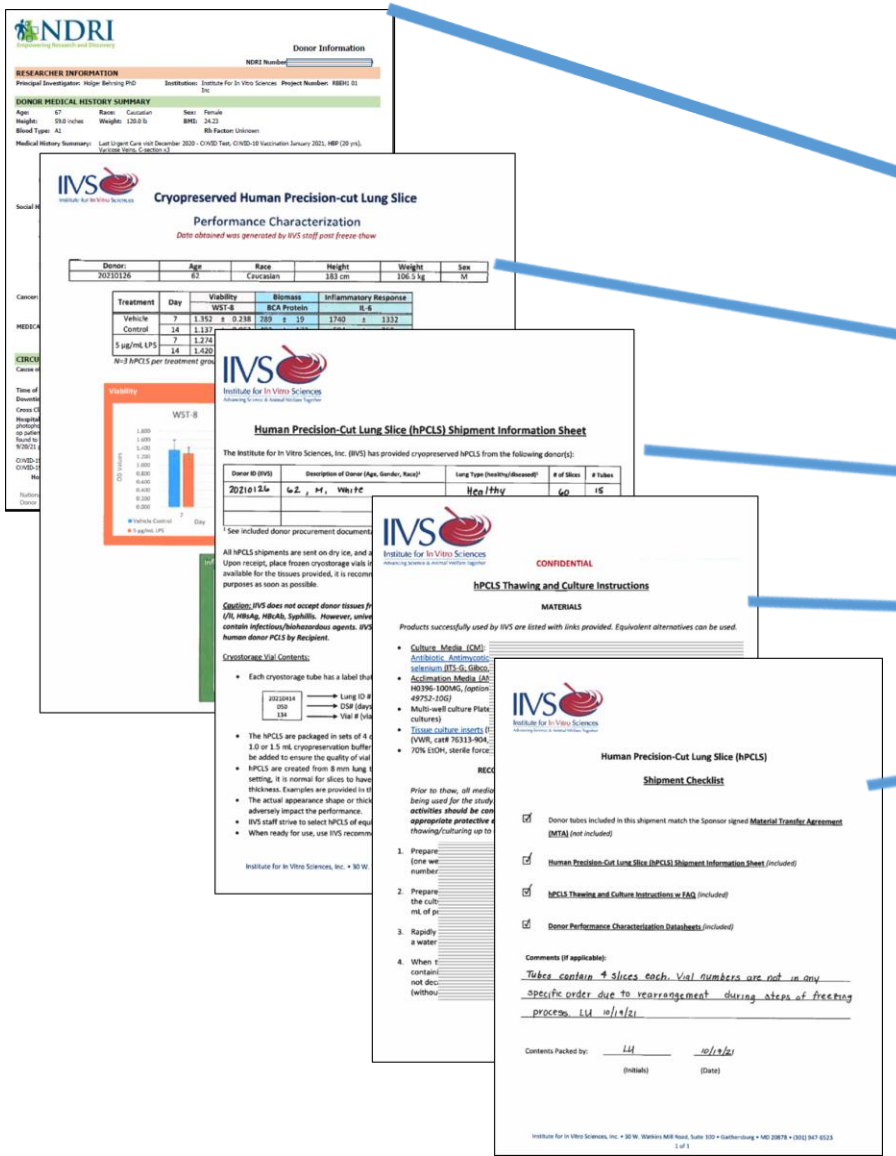
Examples from Our Own Implementation

- Material and Reagent Use
  - GIVIMP 2.5 – Are all consumables and reagents evaluated against fit for purpose?
  - GIVIMP 4.2 – Are materials and reagents from well established sources?

- SOPs for methods and general lab reviewed for inclusion of material and reagent specifications and suppliers
- Where substitutes are acceptable, “or equivalent” was written into SOPs

- Suppliers are divided into “critical” and “standard”
- “Critical” - part of the vendor assessment program
- “Standard” - substitutes for supplier and/or material are acceptable.

Examples from our own implementation



[Cryopreserved human Precision Cut Lung Slices (cryo hPCLS)]

- Donor information excluding all personal identifiable information
- Performance characterization results of the batch of hPCLS
- A shipment inventory sheet traceable to the IIVS processing batch records
- Thawing and general culture instructions for the hPCLS
- A shipping checklist to assure all required information is included and serving as a chain of custody document

Examples from Our Own Implementation

- Proficiency Chemical Reporting
  - GIVIMP 8.4 – Is there documented competency to perform work in compliance with existing OECD TGs where applicable?
- Organized transition from R&D to optimization to routine performance
  - E.g. GIVIMP 6.2 – Is the applicability domain of the method explained? And are the limitations and exceptions of the method explained?
  - E.g. GIVIMP 6.4 – Are an adequate number of concentrations tested for the test item?

Learnings and recommendations

- Assessing practices against GIVIMP is worthwhile for a laboratory, even if it is already compliant with Good Laboratory Practices (GLPs) since there are useful recommendations in GIVIMP that are not discussed in GLPs or other regulations and quality systems guidances.
- Partner with a quality assurance or quality system professional where expertise is lacking.
- Work through GIVIMP one topic area at a time and collaborate throughout the facility with the individuals responsible for each functional area.
- Consult test guidelines and affiliated protocols for method specific considerations where available. Where there are differences between laboratory procedures and these documents, the differences can be specified in the method Standard Operating Procedures (SOP)s and study plans.
- Consider the type of evidence you are creating to show proof that you are following GIVIMP as you are assessing your systems and creating new processes.

GIVIMP Resources

- Guidance Document on Good In Vitro Method Practices (GIVIMP)
- Free e-learning - EU-60: Developing in vitro methods and approaches for scientific and regulatory use
- Altertox Academy
- ASCCT and ESTIV meetings

Questions???

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