

Processing Notes (Not Part of the Mapping Report)

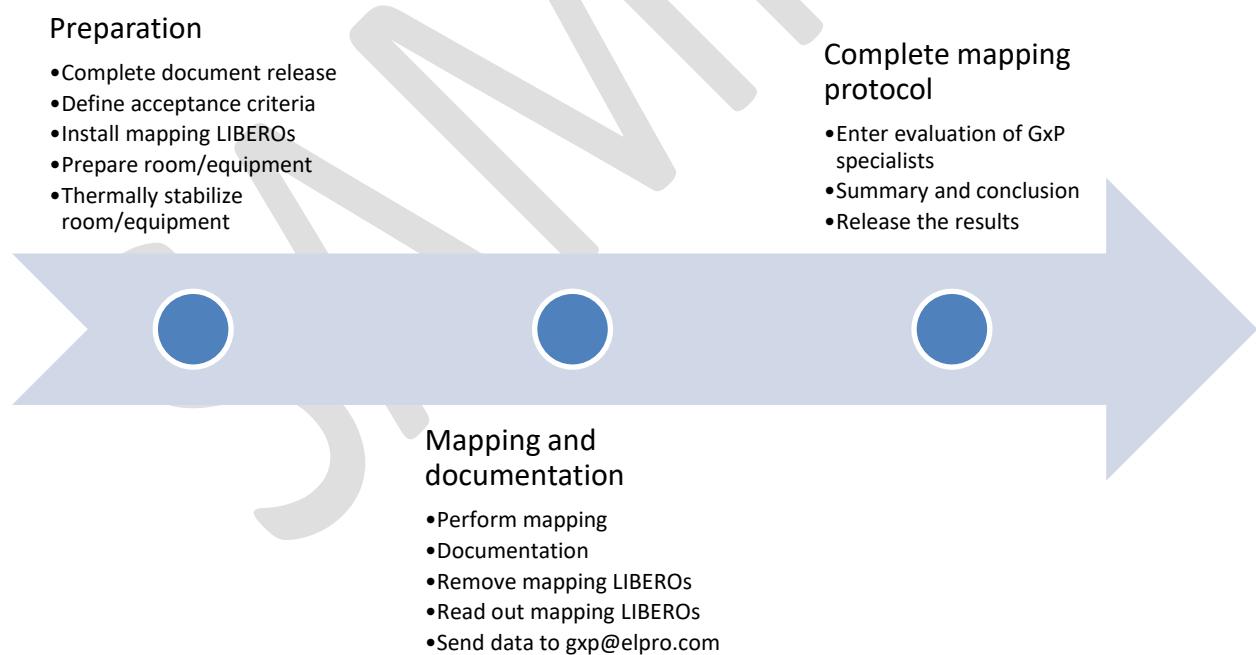
During mapping, uniform temperature distribution in your room/equipment is documented with the mapping LIBEROS contained in this mapping kit. If mapping is successful, this documentation qualifies your room/equipment as compliant with GxP storage of temperature-sensitive goods.

Please print this protocol, as handwritten notes are required and the ID labels of the mapping LIBEROS must be attached. You may then dispose of this first page containing processing notes.

“Room/equipment” refers to the room or device intended for mapping (e.g. storage room, large refrigerator). Always enter the same (unique) room/equipment ID throughout the document (serial number, internal reference).

Company	Name of the company at which mapping is performed
Location	Location of the room/equipment at the company (e.g. storage room xy)
Equipment ID	Short, unique identification of the room/equipment (e.g. serial number, internal reference)

Mapping workflow:



102308-MAP-EN

Temperature Mapping Protocol/Report for Rooms and Equipment

Company	
Location	
Room/equipment	

Version History

Version	Date	Author	Description
1.0	14.Sep.2020	Larissa Fricke	Initial version
2.0	17.Feb.2021	Patrick Herburger-Rauter	Revision

The “Release” field should be checked by a second person. If this is not possible, it may be checked by the person who performed the review.

	Author
Name	Larissa Fricke Qualification Engineer ELPRO

	Review	Release
Name		
Title/function		
Company		
Date		
Signature		

Table of Contents

1.	Definitions.....	3
2.	General Notes	4
2.1	Documentation Practices	4
2.2	Mapping LIBEROs.....	5
2.3	Calibration Certificates	5
2.4	Basis for Placement of the Mapping LIBEROs.....	5
2.5	Internal and External Heat Exchange	5
3.	Mapping.....	6
3.1	Defining Acceptance Criteria	6
3.2	Starting and Attaching the Mapping LIBEROs	7
3.3	Preparing the Room/Equipment	8
3.4	Performing and Documenting Mapping	9
3.5	Removing the Mapping LIBEROs	10
3.6	Reading Out and Sending the Mapping LIBEROs	10
4.	Results.....	11
5.	Summary/Conclusion	12
6.	Acceptance of Results.....	13
7.	Further Steps.....	13
8.	Annexes.....	13
9.	References	14
	Annex A: Information Sign	15