ProjectNumber-2 Master Qualification Plan

Depot	**Depot XXXXX**
Customer	**Customer Long**

1. Approval

	Author
Name	Sean Merrill Validation Engineer ELPRO-BUCHS AG
Date	
Signature	

	Release	**Release**
Name	Customer Long	Customer Corporate
Date		
Signature		

2. Version History

Version	**Date**	**Author**	**Description**
1.0	03.Apr.2014	Sean Merrill	First Version

3. Content

4. Objective

This document is intended to define the general strategy, responsibilities and requirements for the qualification of the controlled storage areas of the depot of Customer Long (in the following called Customer Short) at Customer Address.

5. Scope

This plan covers the qualification of the controlled storage units at the depot of Customer Short (ambient storage, cold storage and freezer storage).
The related infrastructure of the facilities (HVAC and cooling systems) will not be qualified, but implemented according to good engineering practices (GEP). The central monitoring system (CMS) will be qualified by ELPRO in a different project. The availability of qualification documentation and the verification of the alarm functions will be checked during operational qualification (OQ).
The GMP-/GDP-critical storage components have been identified previously in a quality risk assessment (ProjectNumber-1).

6. Project Description

Customer Short is planning to implement controlled storage facilities in its depot facility at Customer Address. The main purpose of this building shall be receipt, storage, and dispatch of temperature controlled products and materials, later possibly also secondary re-packaging and labeling. The general requirements for this project are outlined in the user requirement specifications (Depot User Requirement Specification) of the individual storage areas. In order to fulfill the different storage requirements of the pharmaceutical components, six separate environmentally controlled storage areas are to be implemented, details see chapter 7.

7. GMP/GDP-Critical Components/Areas

The risks to product quality and requirements for qualification of these areas have been addressed in a quality risk assessment (ProjectNumber-1) performed prior to the implementation of this master plan.The following components/units have been identified as GMP-/GDP-critical:

Unit No.	Name	Remarks
E001	Ambient controlled temperature area (15°C..25°C)	temperature controlled (HVAC)
E002	Returns Room (15°C..25°C)	temperature controlled (HVAC)
E003	Controlled Substances Room (15°C..25°C)	temperature controlled (HVAC)
E004	Labeling Room (15°C..25°C)	Redundant cooling system
E005	Walk-in Cold Room (2°C..8°C)	Redundant cooling system
E006	Freezer Units (-25°C..-15°C)	4 Freezers

Table 7-1

Kommentiert [TP1]: Room #/Unit # to come from customer

8. Organization / Responsibilities

The project team is responsible for the coordination and control of all qualification activities:
Michael Röhrig (ELPRO): Project Management ELPRO, Creation of Documents, Qualification Work
Tina Pfaffe (ELPRO): Creation of Documents, Qualification Work
Customer 1: Review and Release of Documents
Customer 2: Qualification Work, Project Management
Customer 3: Qualification Work, Review and Release of Documents

9. General Qualification Requirements

All qualification activities will follow the relevant national and international pharmaceutical legislation. The general requirements of Customer Short regarding qualification and validation are outlined in the procedure SOP Qualification.
All relevant internal, national and international regulatory references are listed in chapter 19 of this document.

10. Change Control

The general requirements regarding change control are outlined in the SOP Change Control. All changes in all phases of the qualification have to be formally documented according to this procedure.

11. Deviations

The general requirements regarding deviations are outlined in procedures SOP Deviations and SOP CAPA. All deviations from the predefined acceptance criteria in the qualification protocols will be documented in the corresponding qualification reports. A CAPA plan will be implemented as applicable, including responsibilities and timelines for completion of each task. A list with pending actions is generated as required. All pending actions need to be completed before the final qualification report can be approved.

12. Qualification Strategy

Quality critical components of the Customer Short depot are outlined in chapter 7 of this document. The scope of qualification covers the storage units. All relevant energy utilities are not within the scope of this qualification project, function and performance will be tested indirectly during the OQ and PQ phases for the storage units.
The HVAC systems for all units will be documented and installed based on GEP requirements. The function and performance will be tested indirectly through the ability to maintain the acceptable temperature range. The correct design and installation will be checked during the DQ and IQ phases.
For the DQ and IQ phases, one set of qualification documents (protocols and reports) will be generated (each phase) covering all six units.
Each unit in this document forms a qualification system that will be fully qualified including individual qualification reports for the OQ and PQ qualification phases. The Freezer Module consisting of four freezers can be summarized in one OQ and PQ protocol and report.
The finalization of each qualification unit will be documented in individual qualification reports.
Each qualification phase will be formally reviewed and approved. The next phase can only be started if the previous has formally been completed and approved by Customer Short operations and QA.

12.1 User Requirement Specification (URS)

The purpose of the URS is to provide a full description of the required system performance, as well as define performance criteria, critical parameters, and operating range. The URS should also include cleaning, maintenance, training, documentation, and security requirements. The URS will be generated by Customer Short and a copy given to ELPRO.

12.2 Design Qualification (DQ)

The intent of DQ is to provide documented assurance that the design of the storage unit in the Customer Short depot meets all user and GMP requirements.
Activities include collection and verification of existing engineering and vendor documents (functional and design specifications) and their comparison with the user requirement specifications. All documents will be assigned an “as built” status. The verification will be performed using predefined checklists with all required documentation.

12.3 Installation Qualification (IQ)

During the IQ phase, the correct installation of the units provided in chapter 7 will be reviewed based on the “as built” documentation. Specific testing requirements and acceptance criteria will be defined in the pre-approved IQ Plan. The verification will be performed using predefined checklists with all required documentation and tests to be performed.

12.4 Operational Qualification (OQ)

Kommentiert [ME2]: needs to edited per customer project

During the OQ phase, the correct function of the Customer Short depot storage units in chapter 7 will be tested. The qualification activities will be performed under static conditions (all installations complete, HVAC systems operating, all required equipment such as racks, tables, and shelves in place, no materials stored; no operators present during testing). All data loggers used will be calibrated.
The following tests are required/planned:

12.4.1 CMS Qualification all Units

Verification of the alarm functions. The tests will be performed in the separate qualification of the central monitoring system (CMS). The test involves review and verification that the alarm tests have been successfully performed for each unit. The following documents will be used for qualification of the CMS including software:

Document Number	Document	Component / Software
SE3221Ep	Installation Qualification Protocol	elproLOG ANALYZE QLS
SE3222Ec	Operation Qualification Part 1	elproLOG ANALYZE QLS
SE3223Eg	Operation Qualification Part 2	elproLOG ANALYZE QLS
SE3224Ec	Operation Qualification Part 3	elproLOG ANALYZE QLS
SE3225Eh	Operation Qualification Part 4	elproLOG ANALYZE QLS
SE3226Ee	Operation Qualification Part 5	elproLOG ANALYZE QLS
SE3231Eb	Operation Qualification Part 6	elproLOG ANALYZE QLS
SE3233Ec	Operation Qualification Part 7	elproLOG ANALYZE QLS
SE3239Ed	Operation Qualification Part 8	elproLOG ANALYZE QLS
SE3244Ea	Operation Qualification Part 9	elproLOG ANALYZE QLS
SE3248Ed	Operation Qualification Part 10	elproLOG ANALYZE QLS
SE3256E	Operation Qualification Part 10	elproLOG ANALYZE QLS
SM3251Ek	Installation Qualification Protocol	elproLOG MONITOR
SM3252Eg	Operation Qualification Protocol	elproLOG MONITOR
SM3253Eb	Configuration	elproLOG MONITOR
SV3251Eb	Installation Qualification Protocol	elproEVENT
SV3252Eb	Operation Qualification Protocol	elproEVENT
SU3251Eb	Installation Qualification Protocol	elproLOG USER
SU3252Eb	Operation Qualification Protocol	elproLOG USER
S-ID-5136Ee	Installation Qualification Protocol	ECOLOG-NET
S-ID-5137Ed	Operation Qualification Protocol	ECOLOG-NET

Table 12-1

During the OQ phase, all documents will be reviewed to ensure completion and that they have been released.

12.4.2 Ambient storage (E001), Returns Room (E002), Controlled Substances Room (E003), and Labeling Room (E004) (15°C..25°C)

1. Generator/UPS and emergency door alarm tests will be documented in the report for the ambient unit E001.
2. Verification of the temperature uniformity by performance of a temperature mapping study (under static conditions/without any loads): a predefined number of loggers will be placed at predefined locations within the storage unit (static). The logger placement must ensure a three-dimensional covering of the entire volume of the area where pharmaceutical materials are intended to be stored. According to ELPRO SOP PB3.13 "Temperature Mapping", for rooms with a length of more than 30 m (E001) and less than 5 m height, the loggers have to be placed in two vertical levels with a horizontal space of at most 10 m. For the smaller rooms E002, E003, and E004, horizontal space between the loggers should not exceed 5 m.
   The temperature will be recorded for a predefined period at any seasonal variation.
   Acceptance criteria: 15°C..25°C during the entire mapping period at all logger locations
3. Verification of the relative humidity: the relative humidity will be recorded at a minimum of one predefined logger position for a predefined period at any seasonal variation.
   Acceptance criteria: Monitor humidity during the entire mapping period at least one measuring point. The relative humidity is specified to <60% for personal comfort reasons only. For the qualification, the humidity data are collected for information only.
4. Definition of the provisional positions for the sensors of the permanent monitoring system based on the results of the mapping (critical points like hot and cold spots, maximum and minimum average temperatures)

12.4.3 Walk-in cold storage area (E005) (2°C..8°C)

1. Verification of the temperature uniformity by performance of a temperature mapping study (under static conditions/without any loads): a predefined number of loggers will be placed at predefined locations within the storage unit (static). The logger placement must ensure a three-dimensional covering of the entire volume of the area where pharmaceutical materials are intended to be stored. According to ELPRO SOP PB3.13 "Temperature Mapping", for rooms with a length of less than 30 m and less than 5 m height, the loggers have to be placed in two vertical levels with a horizontal space of at most 5 m
   The temperature will be recorded for a predefined period at any seasonal variation.
   Acceptance criteria: 2°C..8°C during the entire mapping period at all logger locations
2. Stress test: Open door / recovery test: each entrance door to the walk-in cold storage will be opened for a predefined time (5 minutes). After closing the door, the temperatures within the cold store shall recover to the required temperature limits (2°C..8°C) within 20 minutes. This test will be performed immediately after the mapping study has been completed (using same logger setup).
   Acceptance criteria: 2°C..8°C at all logger locations after maximum 20 minutes after the door has been closed.
3. Stress test: power failure. The power supply for the cold storage area will be interrupted for a predefined time (5h). This test will be performed using same logger setup as for the mapping study. The duration the cold storage area is able to maintain temperatures below 8°C will define the duration the cold unit can maintain temperature during a power outage.
   Acceptance criteria: Monitor the temperature at all logger locations for minimum 5h after the power supply has been switched off.

4. Verification of the redundant function of the cooling units: the correct switch between the two redundant systems will be verified.
   Acceptance criteria: switch between the units is functioning according to the predefined settings
5. Definition of the provisional positions for the sensors of the permanent monitoring system based on the results of the mapping (critical points like hot and cold spots, maximum and minimum average temperatures)

12.4.4 Freezers

Each of the four (4) freezers will undergo the following testing:

1. Verification of the temperature uniformity by performance of a temperature mapping study (under static conditions/without any loads): a predefined number of loggers will be placed at predefined locations within the storage unit (static). The logger placement must ensure a three-dimensional covering of the entire volume of the area where pharmaceutical materials are intended to be stored. According to ELPRO SOP PB3.13 "Temperature Mapping", for chambers with a volume of less than $2m^3$, 8 loggers have to be placed in the corners of the freezers, and one in the center.
   The temperature will be recorded for a predefined period at any seasonal variation.
   Acceptance criteria: -25°C..-15°C during the entire mapping period at all logger locations
2. Stress test: Open door / recovery test: the freezer door will be opened for a predefined time (5 minutes). After closing the door, the temperatures within the freezer store shall recover to the required temperature limits (-25°C..-15°C) within 20 minutes. This test will be performed immediately after the mapping study has been completed (using same logger setup).
   Acceptance criteria: -25°C..-15°C at all logger locations after maximum 20 minutes after the door has been closed.
3. Stress test: power failure. The power supply for the freezer storage area will be interrupted for a predefined time (5h). This test will be performed after the mapping study has been completed (using same logger setup). The duration the freezer storage area is able to maintain temperatures below -15°C will define the duration the cold unit can maintain temperature during a power outage.
   Acceptance criteria: Monitor the temperature at all logger locations for minimum 5h after the power supply has been switched off.
4. Definition of the provisional position for the sensor of the permanent monitoring system based on the results of the mapping (hot spot).

12.5 Performance Qualification (PQ)-needs to be edited per customer project

Objective of the PQ is to demonstrate that the storage units of the Customer Short depot consistently operate according to the required ranges under defined loads. The qualification activities will be performed “in operation“ (all installations completed, HVAC systems operating, all required equipment (e.g. racks, tables, shelves) in place, materials stored (minimum 50% loaded), normal operational conditions (dynamic testing to include operators entry and loading/unloading activities)).
The following tests are required/planned:

12.5.1 Ambient storage (E001), Returns Room (E002), Controlled Substances Room (E003), and Labelling Room (E004) (15°C..25°C)

1. Verification of the temperature uniformity by performance of a temperature mapping study (in operation/with min. 50% load): a predefined number of loggers will be placed at predefined locations within the storage unit (in operation). The logger placement must ensure a three-dimensional covering of the entire volume of the area where pharmaceutical materials are intended to be stored. According to ELPRO SOP PB3.13 "Temperature Mapping", for rooms with a length of more than 30 m (E001) and less than 5 m height, the loggers have to be placed in two vertical levels with a horizontal space of at most 10 m. For the smaller rooms E002, E003, and E004, horizontal space between the loggers should not exceed 5 m.
   The temperature will be recorded for a predefined period at each seasonal variation (summer and winter). The test can be performed using either pharmaceutical materials or dummy loads
   Acceptance criteria: 15°C..25°C during the entire mapping period at all logger locations for both seasonal variations
2. Verification of the relative humidity: the relative humidity will be recorded at a minimum of one predefined logger position for minimum 1 week at any seasonal variation.
   Acceptance criteria: Monitor humidity during the entire mapping period at least one measuring point. The relative humidity is specified to <60% for personnel comfort reasons only. For the qualification, the humidity data are collected for information only.
3. A routine calibration program with defined intervals must be in place for each instrument before release of the unit.
4. Definition of the final positions for the sensors of the permanent monitoring system based on the results of all mappings after last seasonal mapping (critical points like hot and cold spots, maximum and minimum temperatures).

12.5.2 Walk-in cold storage area (E005) (2°C..8°C)

1. Verification of the temperature uniformity by performance of a temperature mapping study (in operation/with minimum 50% load): a predefined number of loggers will be placed at predefined locations within the storage unit (dynamic testing to include operators' entry and loading/unloading activities). The logger placement must ensure a three-dimensional covering of the entire volume of the area where pharmaceutical materials are intended to be stored. According to ELPRO SOP PB3.13 "Temperature Mapping", for rooms with a length of less than 30 m and less than 5 m height, the loggers have to be placed in two vertical levels with a horizontal space of at most 5 m.
   The temperature will be recorded for a predefined period at any seasonal variation.
   Acceptance criteria: 2°C..8°C during the entire mapping period at all logger locations
2. Definition of the final positions for the sensors of the permanent monitoring system based on the results of the OQ and PQ mappings (critical points like hot and cold spots, maximum and minimum temperatures)

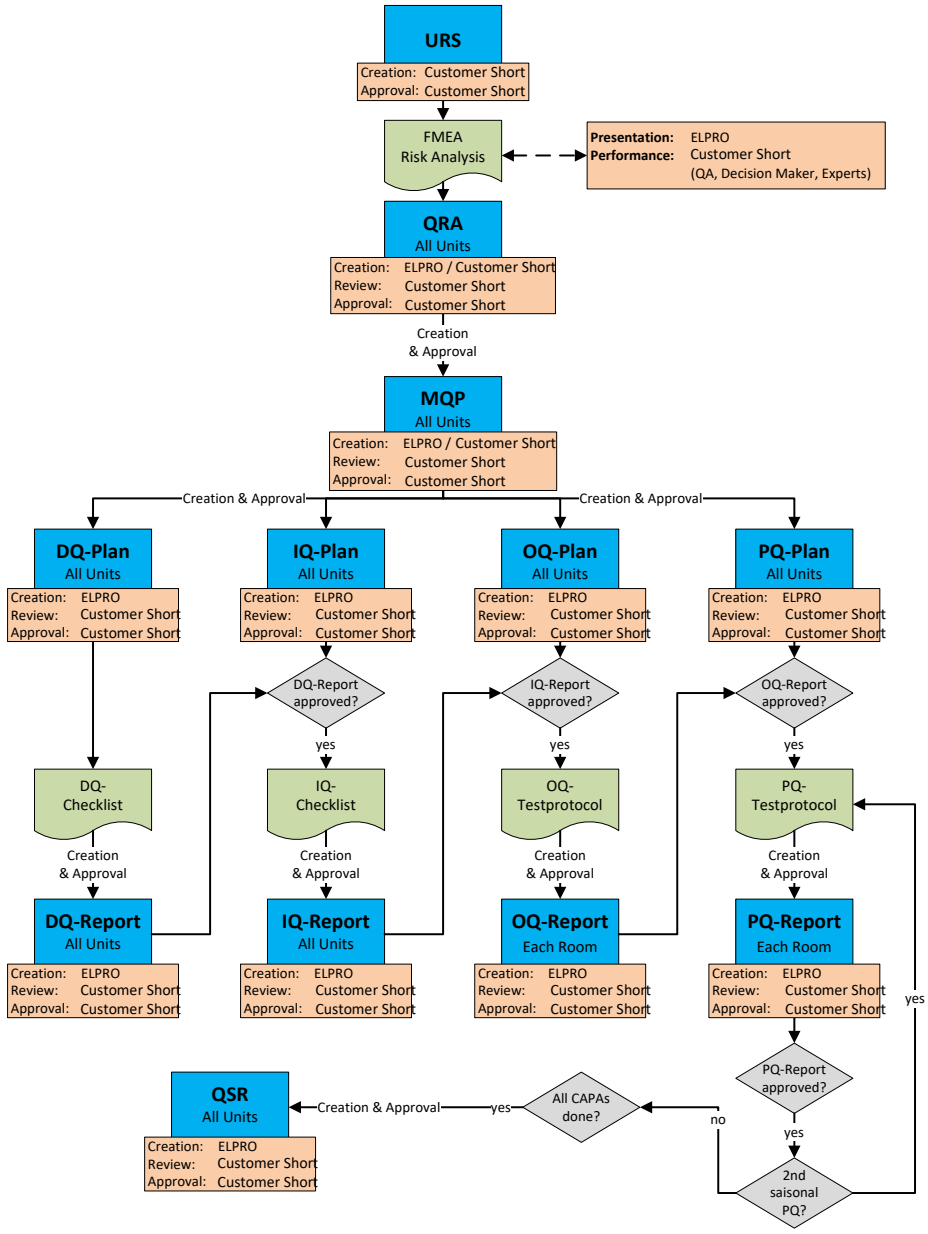
12.5.3 Freezers (E006) (-25°C..-15°C)

1. Verification of the temperature uniformity by performance of a temperature mapping study (in operation/with minimum 50% load): a predefined number of loggers will be placed at predefined locations within the storage unit (dynamic testing to include operators' entry and loading/unloading activities). The logger placement must ensure a three-dimensional covering of the entire volume of the area where pharmaceutical materials are intended to be stored. According to ELPRO SOP PB3.13 "Temperature Mapping", for chambers with a volume of less than $2m^3$, 8 loggers have to be placed in the corners of the freezers, and one in the center.
   The temperature will be recorded for a predefined period at any seasonal variation.

   Acceptance criteria: -25°C..-15°C during the entire mapping period at all logger locations
2. Definition of the final positions for the sensors of the permanent monitoring system based on the results of the OQ and PQ mappings (hot spots, maximum temperatures)

13. Qualification Documentation

Document hierarchy



14. List of qualification documentation

All qualification relevant documents are listed in the table below:

Document code	Document description	Remarks
ProjectNumber-1	Quality Risk Assessment (QRA)	All Units
ProjectNumber-2	Master Qualification Plan	All Units
ProjectNumber-3	DQ-Plan	All Units
ProjectNumber-4	IQ-Plan	All Units
ProjectNumber-5	OQ-Plan	Each Unit
ProjectNumber-6	PQ- Plan	Each Unit
ProjectNumber-7	DQ-Report	All Units
ProjectNumber-8	IQ-Report	All Units
ProjectNumber-9	OQ-Report	Each Unit
ProjectNumber-10	PQ-Report	Each Unit
ProjectNumber-11	Qualification Summary Report (QSR)	All Units

Table 14-1

All required forms and checklist will be included in the relevant plans and reports of the various qualification phases.

For DQ, IQ, and the qualification Summary Report, one set of qualification documents will be provided. For OQ and PQ, a discrete set of qualification plan and report will be provided for each room..

Kommentiert [ME3]: adapt project specifically

All new documents need to be approved by QA and operations representing the Customer Short depot.

After all pending actions have been implemented, the qualification summary report can be issued and approved by QA representing the Customer Short depot. With this approval the depot will be released and transferred to operations.

15. Acceptance Criteria

The system(s) / units will be accepted and approved for operations when all tests have been performed as required in the qualification protocols, all acceptance criteria have been met, all deviations have been assessed to ensure no impact to following phases, all pending actions have been implemented and all qualification documents have been approved by QA.

An assessment of the locations of the permanent monitoring should be made based on the results of the temperature mapping studies. The locations for the routine monitoring should represent the worst case situation. At minimum the hot and cold spot of each storage unit should be defined as a location for the permanent monitoring.

16. Calibration

All quality critical instruments/devices of the storage units as well as all instruments used for testing during the qualification phases (e.g. for temperature mapping studies) have to be within calibration. A routine calibration program with defined intervals must be in place for each instrument prior to conducting the first PQ mapping.

17. Maintenance of the Qualified State

Preventive maintenance

For each qualified unit a preventive maintenance plan or contract should be in place to prior to conducting PQ mapping. In this document all activities with regards to preventive maintenance are specified:

- Scope of maintenance work to be performed
- Responsibilities
- Frequencies for all required maintenance activities, including calibration
- Documentation / protocols

The detailed requirements for preventive maintenance are outlined in the procedures SOP Maintenance and SOP Calibration.

18. Requalification

Requalification of a storage unit might be required after the implementation of a modification / change to the existing qualified status of each qualified unit (e.g. replacement of a part which is not a like-to-like replacement). A risk assessment will be conducted to determine if additional qualification work is necessary in conjunction with the change control process.
Details for the routine requalification of qualified units are documented in SOP Qualification.

19. Associated Documents

- User requirement specification: Depot User Requirement Specification
- Quality risk assessment: ProjectNumber-1
- FDA 21CFR Part 210, 211
- USP 1079, Good Storage and Shipping Practices
- WHO good distribution practices for pharmaceutical products, WHO Technical Report Series, No. 957, 2010, Annex 5
- WHO Guide to good storage practices for pharmaceuticals, WHO Technical Report Report Series No. 908 2003, Annex 9
- Annex 15 to the EU Guide to Good Manufacturing Practice
- ICH Harmonized Tripartite Guideline Quality Risk Management Q9
- WHO Technical Report Series No 96, Annex 9: Temperature Mapping of storage areas (Jan 2014)
- Local Regulations: Buenas Practicas de almacenamiento y distrubucion para droguerias ydepositos de productos farmaceuticos de uso humano, Norma Tecnica No. 147, Instituto de Salud Publica de Chile, Agencia nationale de Medicamentos
- SOP Calibration
- SOP CAPA
- SOP Change Control
- SOP Deviations
- SOP Maintenance
- SOP Qualification

Kommentiert [ME4]: will be specific to the project/location. US is covered by USP, FDA, WHO guidlines