

QUALIFICATION OF STABILITY CHAMBERS

BY

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THERMOLAB

QUALIFICATION OF STABILITY CHAMBERS

- Qualification of stability Chambers is critical as it is one of the most important equipments of quality control laboratory.

QUALIFICATION OF STABILITY CHAMBERS

- Why stability chamber is critical?

It is critical equipment because the samples kept in it for stability testing of a DS or DP will give unreliable result if the equipment is not well designed and maintained.

QUALIFICATION OF STABILITY CHAMBERS

Objectives

To discuss the principles of qualification of equipment, with specific focus on:

- The different stages of qualification
- Requalification and
- Qualification of stability chamber when it is “in use”

QUALIFICATION OF STABILITY CHAMBERS

Principle

- Stability testing chamber is a critical equipment
- It has direct effect on the product quality.
- Qualification ensures correct data evolving from samples kept under testing.

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Principle

- Stability chamber should be appropriately designed, located, installed, operated and maintained
- Correctly designed equipment should be qualified.
- Continued suitable performance needed
 - *Why? To ensure consistency in results on samples under study.*

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Scope

- Guidelines describe the general aspects of qualification for stability equipment
- Normally qualification is applicable to critical systems and equipment whose performance may have an impact on the quality of the product.
- Stability chambers mostly ignored and not subjected to stringent qualification provisions.

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General

- Stability chambers should be part of Qualification policy for systems and equipment
- To be included in programme devised for instruments used in production and quality control
- To be considered a part of New systems and equipment: All stages of qualification (DQ, IQ, OQ and PQ) should apply on this.

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General (continued)

- Stability testing Equipment: Qualified before routine use
- Systems and equipment: Periodic requalification, as well as requalification after all major changes.
- Certain stages done by the supplier.
- Maintain the relevant documentation, e.g.
 - *standard operating procedures (SOPs), specifications and acceptance criteria, certificates and manuals*

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General (continued)

- Qualification should be done in accordance with predetermined and approved qualification protocols
- The results of the qualification should be recorded and reflected in qualification reports

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Stability Chamber

- Discuss the approach of qualification of a newly installed stability chamber



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Stages of qualification

Design qualification

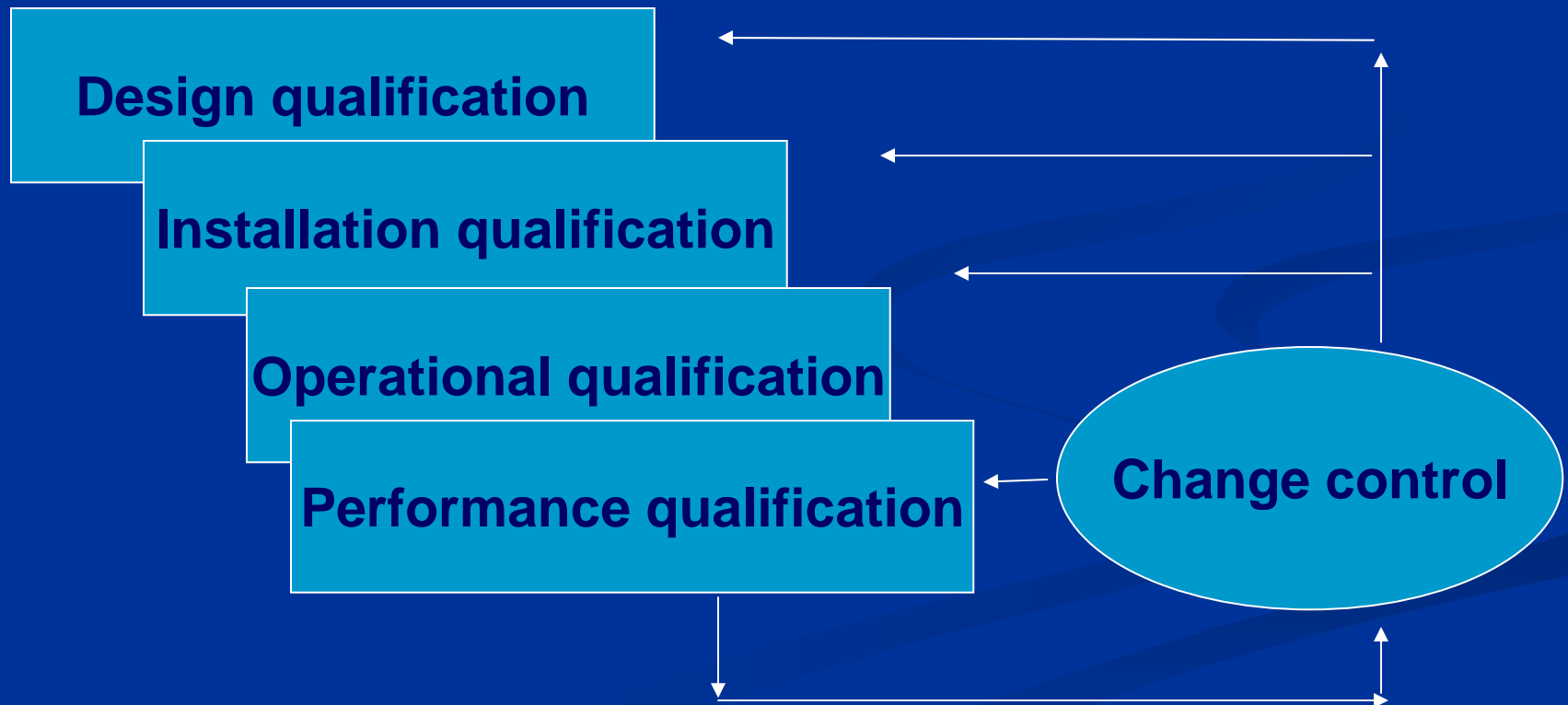
Installation qualification

Operational qualification

Performance qualification

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Stages of qualification



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Design qualification

- User requirements should be considered when deciding on the specific design of a stability testing equipment
- A suitable supplier should be selected for the appropriate system or equipment (approved vendor)
- Reputation of supplier very critical as correctly designed equipment will give credible trouble free service.

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Installation qualification

- Correct installation as per plan and protocol
- Normally advised to prepare requirements for calibration, maintenance and cleaning at this stage
- Identification and verification of all system elements, parts, services, controls, gauges and other components
- A well designed stability chamber normally has 70 to 80 components.
- Calibrate the measuring, control and indicating devices
 - *against appropriate, traceable national or international standards*

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Installation qualification (2)

- Documented records for the installation
 - *installation qualification report*
- Indicate satisfactory installation
- Include details, e.g.
 - *The supplier and manufacturer*
 - *System or equipment name, model and serial number*
 - *Date of installation*
 - *Spare parts, relevant procedures and certificates*

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"An installation qualification protocol / report"

- It is very important to prepare the protocol and report of installation after considering all components described in design qualification document by the vendor.
- Thermolab has most efficient qualification documents accepted by International Regulators.

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Operational qualification

- Stability testing equipment should operate correctly – operation verified as in the installation qualification protocol
- Studies on critical variable to include conditions encompassing upper and lower operating limits and circumstances (i.e. “worst case conditions”)
- To include verification of operation of all system elements, parts, services, controls, gauges and other components

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Operational qualification (2)

- Documented records (Operational qualification report)
- Finalize and approve SOP (operation)
- Training of operators provided – training records
- Systems and equipment released for routine use after completion of operational qualification, provided that:
 - *All calibration, cleaning, maintenance, training and related tests and results were found to be acceptable*

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"An operational qualification protocol / report"

- It reflects the information that should be included based in IQ document.
- Specific details need to be incorporated for every specific system or piece of stability equipment.

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Performance qualification

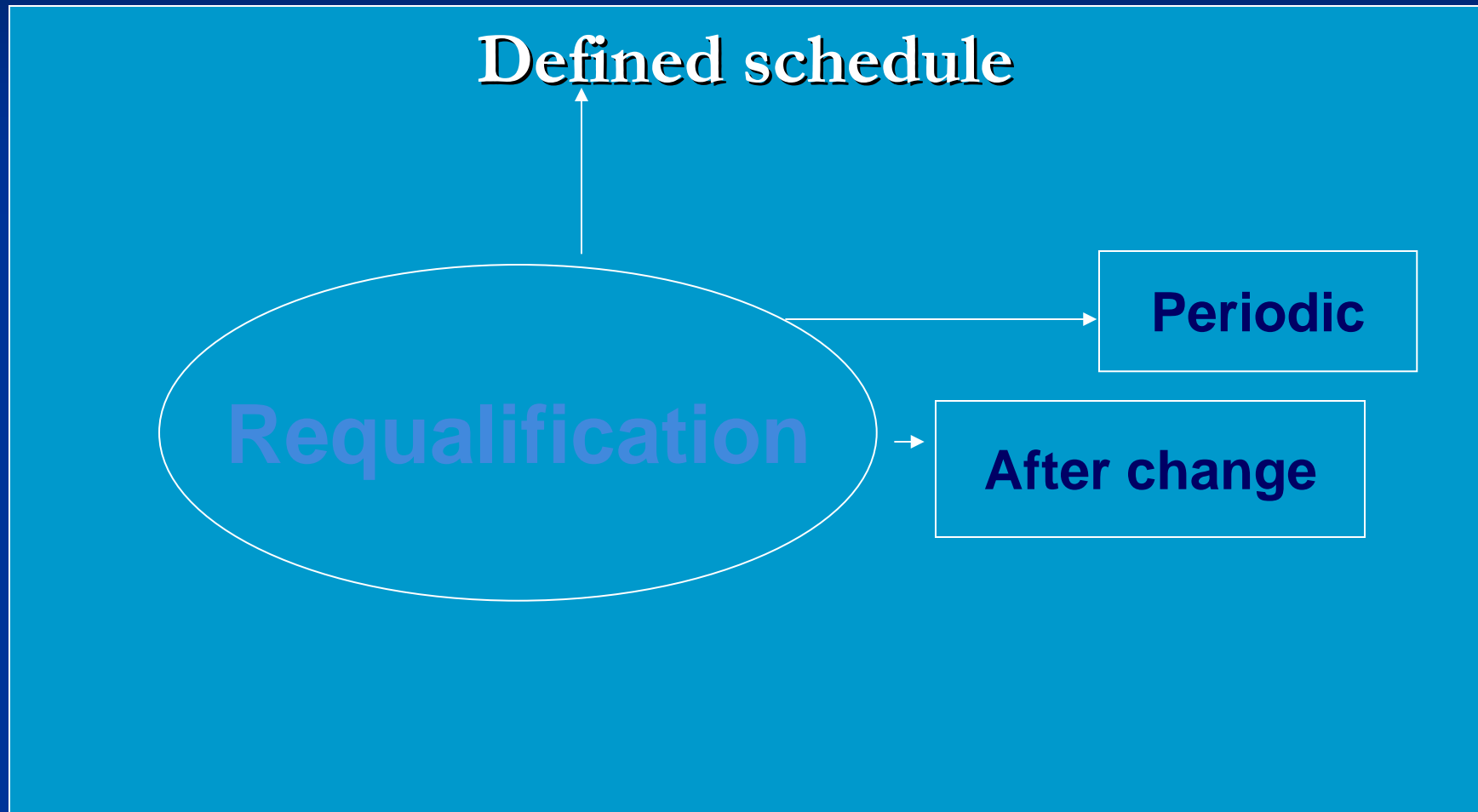
- Stability equipment should consistently perform in accordance with design specifications – verified in accordance with a performance qualification protocol
- Documented records – performance qualification report
- Show satisfactory performance over a period of time
- Users to justify the selected period

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"A performance qualification protocol / report"

- It reflects the minimum information that should be included
- Specific formats need to be designed for a every system or piece of stability equipment.

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Qualification of “in-use” systems and equipment

- Data to support and verify the suitable operation and performance of systems and equipment
- Should include operating parameters and limits for critical variables, calibration, maintenance and preventive maintenance, standard operating procedures (SOPs) and records

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- Periodic calibration and thermal mapping of stability chambers very critical.
- In use Qualification (Performance) should be done at specified interval.
- Out of calibration cases should be subjected to investigation
- OOC cases should be concluded to its logical end.

Services provided at Thermolab

- CALIBRATION, VALIDATION AND TESTING SERVICES OFFERED BY THERMOLAB:
- *Thermolab offers various after sales Services such as:*
 - Calibration during Installation and periodic Re-Calibration.
 - Validation during Installation and periodic Re-Validation. (DQ,IQ,OQ and PQ).
 - Documentation of standards acceptable to Indian and International Regulatory Agencies.
 - Re-Installation of chambers on to a new site.

Services provided at Thermolab

- Modifications and Up-Gradation of old chamber with latest features.
- Software Validation.
- Calibration and Certification of various parameters on site for all the equipments including process equipments for Temperature, Humidity, Pressure, Dimensions & Weight.
- AMC services undertaken. *Thermolab Offers a Total After Sales Solution to Pharma Industry.*
- Repairs and Servicing of equipments.

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THANKS