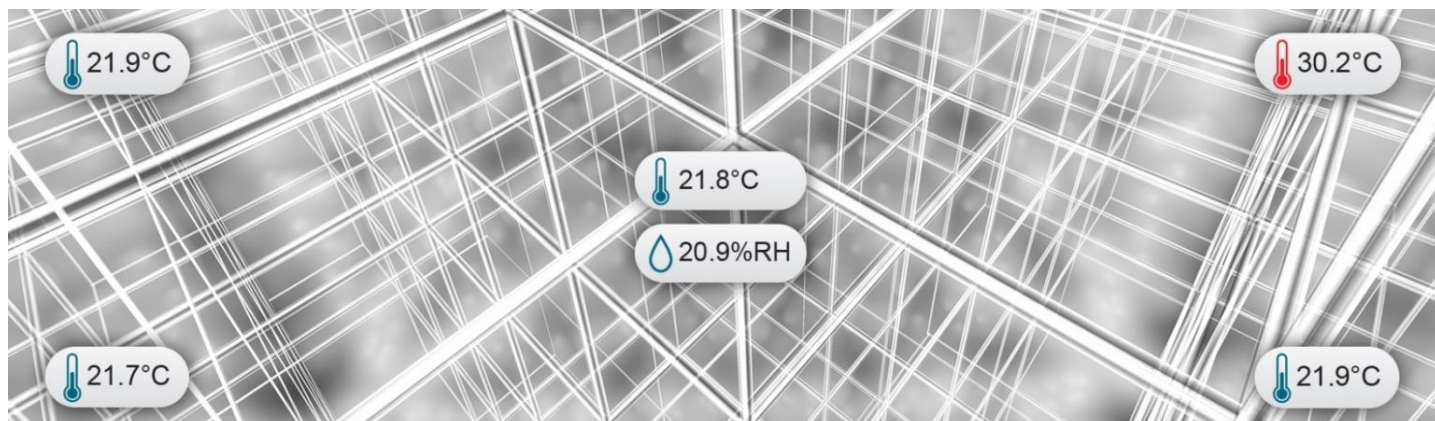




VALIDATION

Project management, calibration, qualification
and thermal validation



GxP-requirements of the health authorities regarding product quality and patient safety means that companies operating in the life science sector are forced to perform validation

All critical aspects in touch with production, laboratory and distribution processes must go through quality assurance by execution of tests documenting, that the equipment, process plant or climate facility etc. in question with a high degree of probability is suitable for the intended use

OUR VALIDATION SERVICES

Element Metech is the preferred partner within:

- ▶ **Non-sterile validation** of the physical conditions obtained by the use of various storage equipment and climate facilities
- ▶ **Sterile validation** of the physical conditions obtained by the performance of a given sterilization process, including sterilization processes performed by the use of special sterilization equipment and sterilization processes in connection with sterilization of process plants

Element Metech presents a valuable umbrella of services, which covers handling of the total validation package. Thus Element Metech has a group of skilled and specialized validation consultants with expertise within:

- ▶ **Project management**
- ▶ **Calibration**
- ▶ **Qualification**
- ▶ **Thermal validation**

PROJECT MANAGEMENT

Element Metech always ensures an accurate project management in relation to both smaller and larger complex validation projects.

This provides you with a better chance to achieve the project success that you naturally want.

Element Metech holds the full responsibility for planning and managing the project. Element Metech not only pays close attention to reach the goals on time, but also to reach them in the best possible way in terms of quality and costs.



For instance, Element Metech's validation consultants can take the responsibility for:

- ▶ Determination of purpose, goals and deliveries
- ▶ Planning and scheduling
- ▶ Project execution including handling of corrective actions, communication to stakeholders and reporting

We facilitate your project in a way that is convenient for you, where we ensure, that the project is clearly defined, that all project members know the direction, that the communication is clear and that risks are identified, addressed and solved as early as possible.

CALIBRATION

Calibration of the following instruments is usually performed in connection with ensuring of correct functionality of equipment, process plants and climate facilities etc.:

- ▶ Controlling and monitoring operations-related instruments
- ▶ Instruments for use during test execution

Element Metech determines the accuracy of a given instrument by a measurement documenting the difference between the instrument in question and a traceable reference instrument.

Element Metech offers a wide range of ISO/IEC 17025 accredited calibration options within several physical parameters and with an impressive measuring range and accuracy both:

- ▶ In-house at our own laboratories
- ▶ On-site at customer sites

In connection with validation and especially in connection with preparing validation equipment for use during thermal validation this means, that we can offer calibration in exactly the calibration points, that you need, and with a particularly short delivery time.



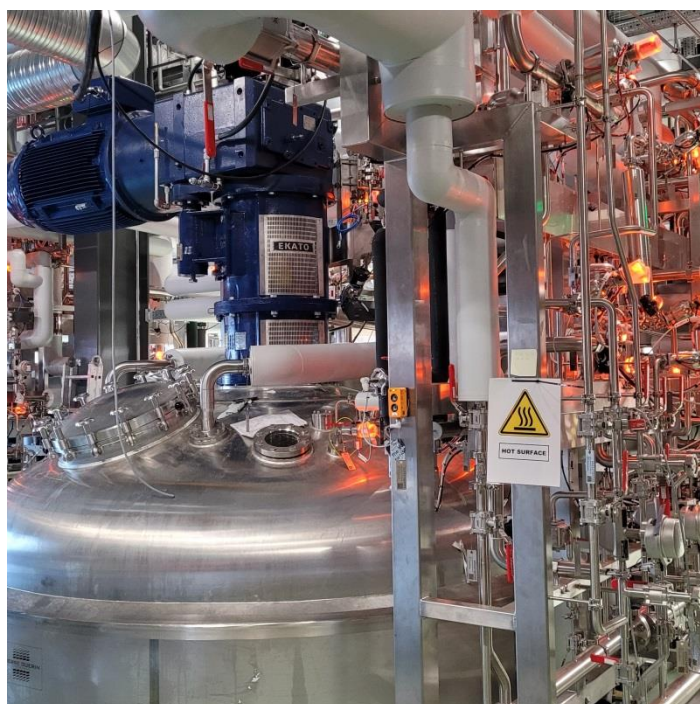
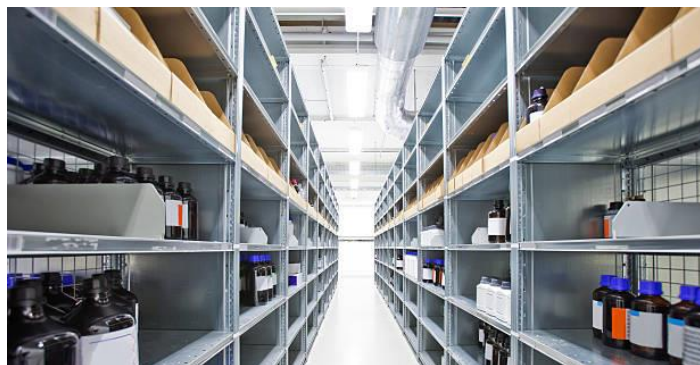
QUALIFICATION

Upon qualification, it is ensured through execution of tests both before and after installation, that the actual equipment, process plant or climate facility etc. is able to meet requirements concerning design, installation and functionality, including expectations for the accompanying documentation.

Element Metech presents a value-creating handling of all relevant qualification activities:

- ▶ Design qualification (DQ)
- ▶ Installation qualification (IQ)
- ▶ Operational qualification (OQ)
- ▶ Performance qualification (PQ)





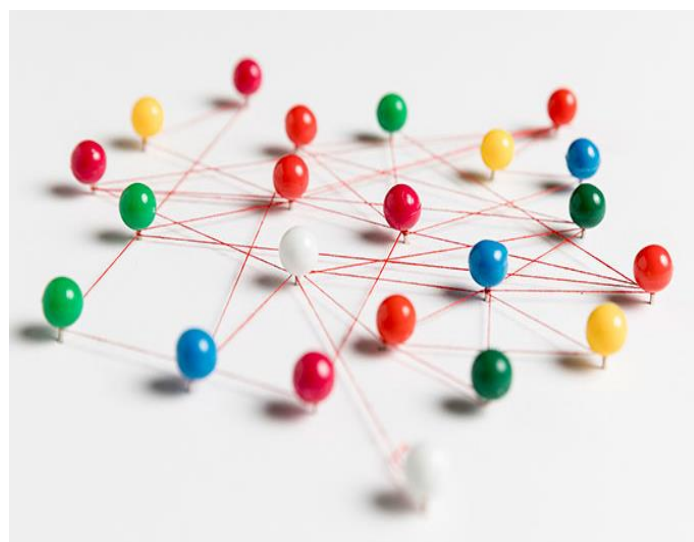
THERMAL VALIDATION

When performing thermal validation it is examined, whether a given volume is able to maintain the limit values of the desired physical conditions by measuring one or more of the following parameters:

- ▶ Temperature
- ▶ Humidity
- ▶ Pressure
- ▶ Carbon dioxide (CO₂)

A fixed number of sensors / data loggers are distributed throughout predefined measurement locations in order to log the selected parameters for an appropriated period of time.

If needed, we can perform and document the thermal validation as a DANAK-accredited test (valid for temperature measurements).



OUR CORE COMPETENCES

Element Metech is the strong and flexible validation resource both in relation to individual tasks and long-term partnership. We possess significant and professional competencies, which through our high degree of customer focus; guarantee a successful and optimal solution in compliance with regulatory GxP-requirements, guidelines and trends as well as special internal customer requirements.

Keep focus on your core business and use us for what we are good at, namely adding expertise and experience to the validation. We are the close and supportive partner, who ensures you an optimal process and a successful result.

CONSULTANT SERVICES

Element Metech's validation consultants have a considerable knowledge and a deep understanding in relation to:

- ▶ Preparation of validation master plans and/or validation plans
- ▶ Preparation of user requirement specifications
- ▶ Execution of risk assessments
- ▶ Preparation of validation protocols including test plans
- ▶ Test execution and data handling
- ▶ Preparation of validation reports

In this context we would also like to provide further assistance by handling of:

- ▶ Change control
- ▶ Corrective and preventive actions
- ▶ Deviations

As well as of course professional discussion and advice in general.

We can use your validation setup. In addition, we offer the possibility to use Element Metech standard documentation.

Element Metech would also like to introduce competencies in relation to further administrative challenges, e.g. design of validation strategy as well as preparation of instructions and document templates.



RENTAL OF VALIDATION EQUIPMENT

Element Metech provides rental of a wide range of validation equipment such as:

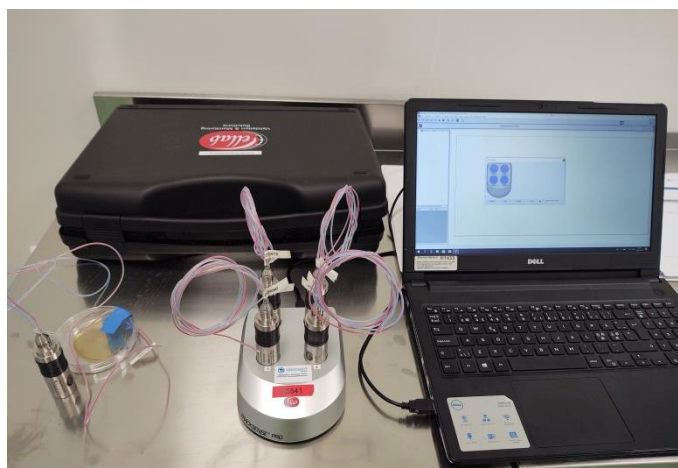
- ▶ Wireless data loggers
- ▶ Validator systems with connected sensors

Element Metech's validation equipment covers measurement of all physical parameters related to thermal validation:

- ▶ Temperature
- ▶ Humidity
- ▶ Pressure
- ▶ Carbon dioxide (CO₂)

Measuring range, logging frequency and MPE-values depend on the selected validation equipment.

All validation equipment is of course tested by performance of qualification in accordance with regulatory GxP-requirements, including guidelines for computer systems such as FDA 21 CFR part 11 and Eudralex volume 4 annex 11.



Element Metech serves the full handling of validation equipment including:

- ▶ Calibration
- ▶ Programming
- ▶ Physical placement/replacement
- ▶ Reading out data and data handling
- ▶ Preparing of data report eventually as a DANAK-accredited test report

Our validation equipment is always calibrated at our own DANAK-accredited laboratories allowing the calibrations to be performed at the calibration points specially chosen by the customers and with an optimal short delivery time.

We have already supported several customers by validation of:

- ▶ Storage equipment such as incubators, refrigerators and freezers
- ▶ Climate facilities such as storage facilities, cold rooms and freezing rooms
- ▶ Sterilization processes performed by use of special sterilization equipment such as autoclaves and dry sterilizers
- ▶ Sterilization processes associated to sterilization of process plants

We have taken care of:

- ▶ Design of validation strategy
- ▶ Preparation of instructions
- ▶ QA-authorization of validation documents
- ▶ Preparation and approval of documents
- ▶ Project management
- ▶ Test execution

We are your responsible, conscientious and reliable partner, who delivers the proper solutions in relation to validation of equipment, process plants and climate facilities etc.

We naturally put you at the center and listen to your needs

No order is too small or too large

How can we support you?



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