

Qualified or Validated?

January 2013

When two words do not mean the same thing

As winter closes further on the northern hemisphere it is often quoted that the Inuit have 100 words for snow. This may have been disproven, but the fact it is believable demonstrates that there is often a necessity for different words to reflect sometimes subtle differences.

The English language can offer dazzling arrays of words which are based upon a similar meaning, but the use of these different words can offer a very big difference. In conversation the words validated and qualified can be used pretty much interchangeably, but when dealing with cold chain they have very specific meanings.

A look in the dictionary provides the following definitions when the words are used in this context;

Qualified: having complied with the specific requirements or precedent conditions

Validated: to support or corroborate on a sound or authoritative basis i.e. experiments designed to *validate* the hypothesis.

When even this fails to provide clarity to the situation you can understand how confusion arises.

In the temperature controlled packaging industry everyone offers qualified solutions. The meaning is very lightweight, if you request a system that can offer a duration of 96hrs they will give you a system qualified to that. However this solution could range from a plain envelope up to an actively controlled refrigerated lorry.

This occurs because to say something is qualified to 96 hrs you just need to have tested it to maintain temperature for that duration. The envelope can work because if you want a 96hr 2-8°C solution, the supplier can put the envelope in the fridge for 4 days and say that under those conditions it is qualified.

This is a product qualification and is often not worth the paper it is written on. These basic off the shelf qualifications do not even allow for direct comparison between systems due to differing methodologies and the results shown are often not repeatable.



We do things differently at IntelSius. We believe in providing transparent results.

The key to selecting a qualified system which meets your requirements is in selecting the correct conditions with which the shipper complies. At IntelSius we work with our customers from the very beginning of the product selection and design processes to make sure that when offering a solution the product is suitable for the end user.

Design Qualification, Performance Qualification, Operational Qualification

For our qualified systems we work through three processes:

Design Qualification assesses the design of the solution to ensure appropriate properties such as; dimensions, mass, temperature range, preparation time and facilities required meet the customer's satisfaction. In this stage Intelsius makes use of a range of tools to determine the most suitable product or begin work on a new solution. The most valuable of these is the in house, proprietary software **ATMOS™**. (Analytical Thermal Modelling Software)

This software can simulate the thermal exposure by analyzing thermal flows into and between the components of the packaging system, determine the performance characteristics of the proposed solution and whether the protection selected is sufficient to meet the challenges expected.

Using ATMOS can save up to 70 percent in packaging development time and costs when bringing a new drug to market, moving drugs through a new route or preparing for a new clinical trial.

Performance Qualification assesses the performance of the solution, often by means of a controlled extremes/worst case simulation, in an environmental chamber. These tests often demand specific scenarios such as payloads (minimum, maximum, typical, empty), durations (minimum hours, within range, until failure) and temperature exposures (off the shelf, 3rd party, customer specific).

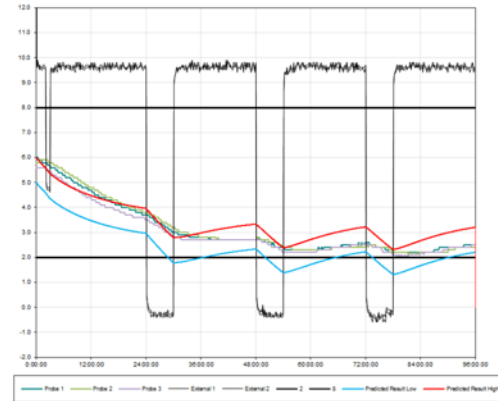
The ISTA certified laboratory at Intelsius can provide rigorous thermal testing of temperature control solutions with full reporting of the results to give the customer confidence that the solution proposed not only meets their requirements but exceeds expectations.

A validated solution incorporates a third stage, **Operational Qualification**. This is a test of the solutions' real world performance. This part of the process begins by assessing the performance of the solution in an operational situation with either dummy or real product. This involves monitoring of performance, (often with data loggers) to determine the correct operation of component storage and preparation, solution dispatch and receipt to SOP, performance in the real world and third party adherence to SOP.

Intelsius' technical services capability will guide and assist any customer through this process. The support offered can range from supplying data loggers up to full guidance with data analysis and report writing.

The temperature control experts at Intelsius are here to help guide you through Qualification and Validation just as an Inuit guide takes one over a "qengaruk" and away from a "navcaq"*.

*snow bank and snow cornice respectively



TIME vs. Temperature Graph Showing Experimental data and simulated data lines showing high (+0.5°C) and low (-0.5°C) simulated values. With image of system packing configuration simulated.



Temperature-Controlled Packaging and Cold Chain Solutions

When shipping biological and pharmaceutical materials, a minor temperature excursion could compromise your payload's integrity.

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