ThermoFisher SCIENTIFIC

VALIDATION OR QUALIFICATION

WHAT'S THE DIFFERENCE?

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- CLINICAL TRIAL SOLUTIONS
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

patheon

TABLE OF CONTENTS

INTRODUCTION

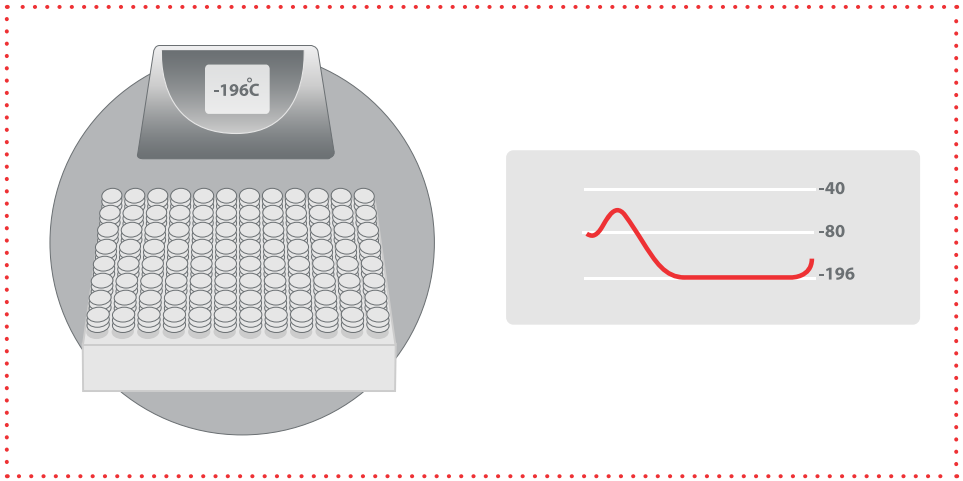
For those studying, manufacturing, or experimenting with delicate pharmaceuticals and biological samples, the importance of sample storage and accurate temperature monitoring is well known.

From a qualification and validation perspective, the equipment and processes used for shipping, storing (whether refrigerated storage or ultra-cold storage), and other services must comply with the products' requirements throughout the chain of custody. The terms "validation" and "qualification" are used interchangeably and loosely at times. In this eBook, learn the true difference between the two, and why they are both important components in managing valuable biological material.

VALIDATION

Validation is best described as the process of "establishing documented evidence" which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes. Simply put, it is the act, process or instance to substantiate something on a reliable basis.

What are the examples for validation? Some include design validation, sterilization validation, process and software validation.



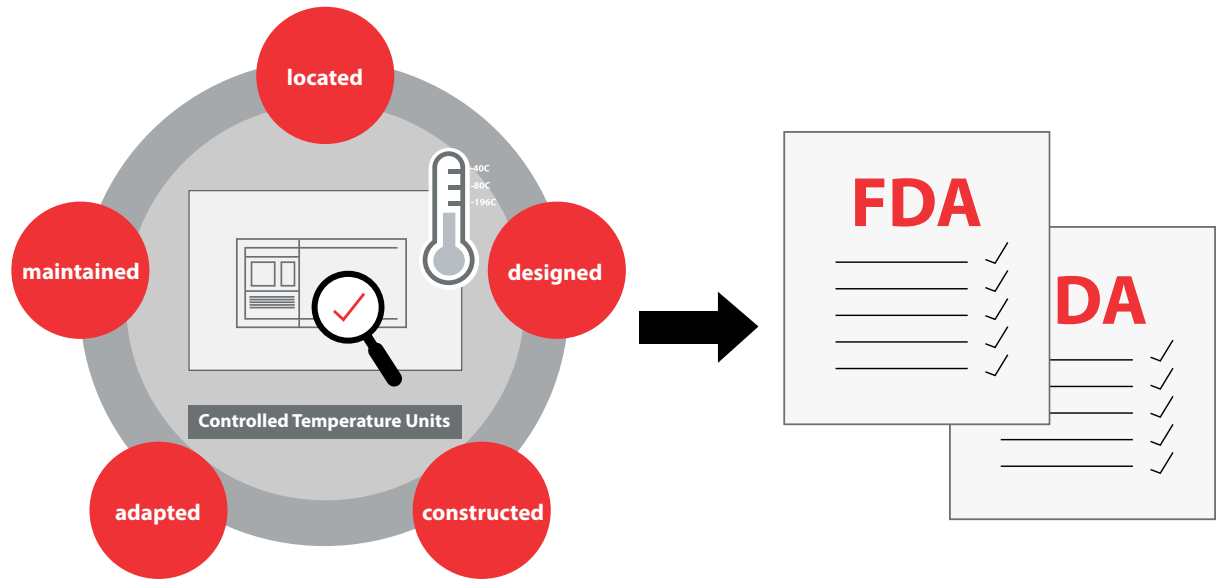
QUALIFICATION

Qualification is described as the action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. It is the process used to establish confidence that the equipment is capable of consistently operating within established limits and tolerances. Qualifications tend to be smaller in scope, more static in nature and are usually subsets for a greater validation initiative.

Qualification allows for conduction of tests to be performed on one element or component of the process to be validated against a specified outcome. Simply put, it is the act or process to assure that something complies with an expected outcome, standard or a set of specific requirements.

Examples of the various types are: installation qualification, operational qualification, and performance qualification. All of these tests are normally used to qualify equipment for their intended use. A good example would be a controlled temperature unit (CTU) qualification study.

It is commonly understood that Controlled Temperature Units used for storing biological samples must be located, designed, constructed, adapted and maintained to suit the operation. Equipment qualification allows for testing and documentation of these expectations. The FDA requires that sufficient documentation be provided to show that the environment a product is exposed to will not affect the safety, quality, purity, identity, or strength of the product. Current good manufacturing practices (cGMP) regulations 21CFR parts 210, 211 and 820 detail this further. Compliance should not be the only reason why it is important to qualify Controlled Temperature Units. The ability to test and document the evidence of equipment performance provides the operational confidence needed as the expected outcome is known.

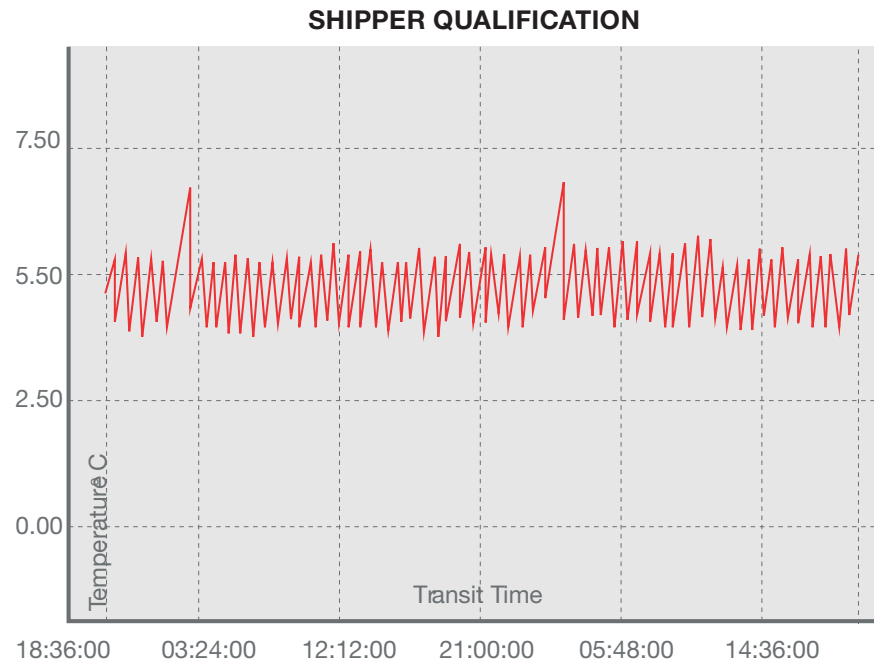


HOW DO QUALIFICATION AND VALIDATION WORK TOGETHER?

Validation incorporates the concept of qualification. Validation is used to asses something dynamic that is bound to change. A validation study is larger in scope and incorporates various qualifications to reach the end result.

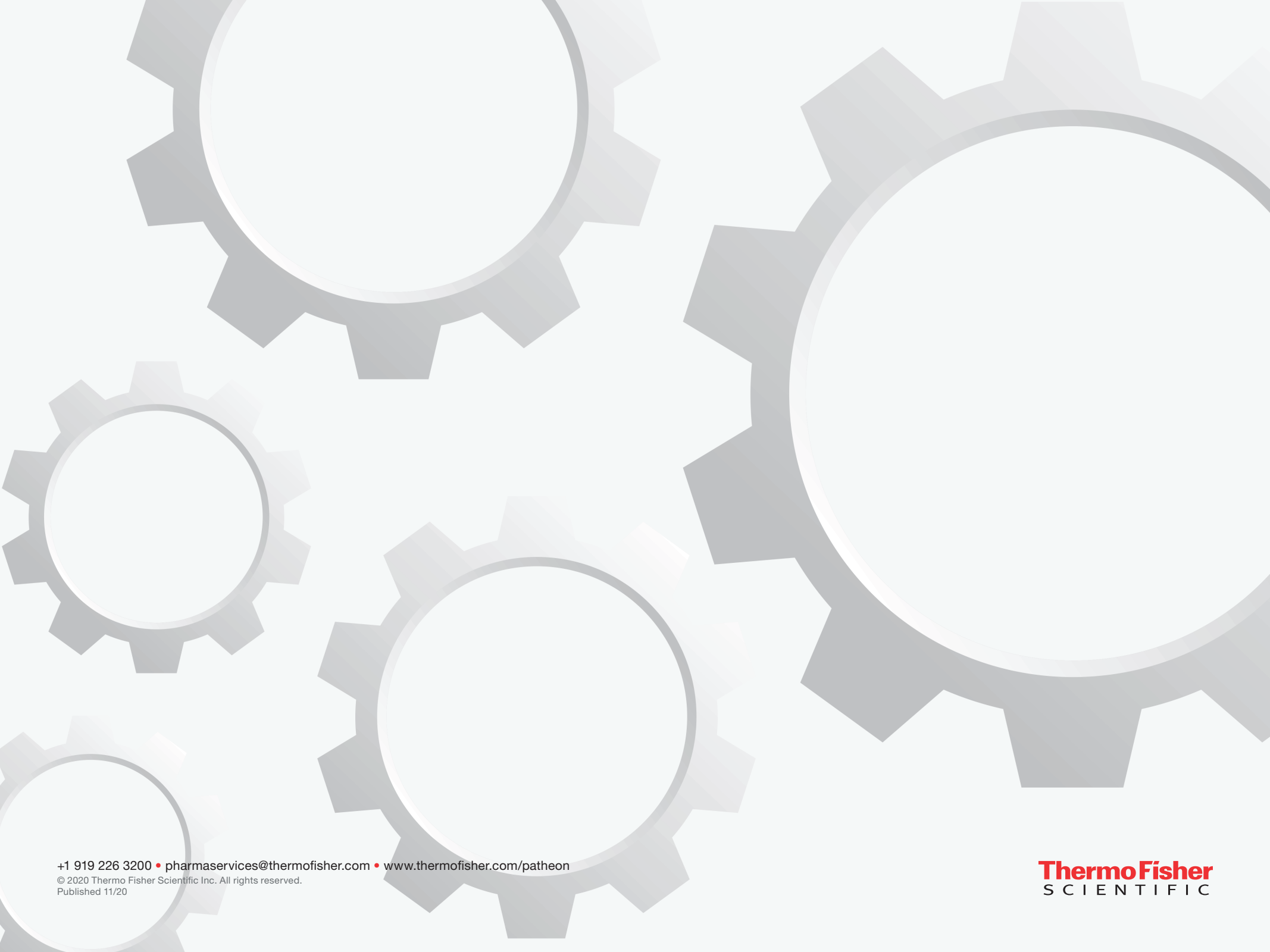
So how important is the name? The name of the activity isn't nearly as important as the nature of the activity.

Validation or qualification, the requirement for establishing documented evidence is imperative. The documented evidence is derived through testing. The qualification study details the process of testing, instrumentation used and recording the evidence against predetermined criteria, which shows that the Controlled Temperature Unit meets its intended quality attributes.



ABOUT US

Thermo Fisher Scientific provides industry leading solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With unwavering commitment to service, science and process engineering, our clinical services team is powered by people with an exceptional commitment to quality and unrivaled expertise. We are exclusively focused on serving the packaging and distribution requirements of clinical trials across the world. Whether planning, packaging, labeling, storing, or distributing the important supplies needed to perform clinical research, we are committed to delivering the highest level of quality, performance, reliability and sustainability standards through our Patheon Thermo Fisher Scientific[SM] offerings.



+1 919 226 3200 • pharmaservices@thermofisher.com • www.thermofisher.com/patheon

Published 11/20

ThermoFisher
SCIENTIFIC