Editors' Comment “Three Times is not Even the Beginning” by Jerry Lanese, Ph.D., was originally published in the Journal of Validation Technology in early 2001. This paper was greatly influenced by the thoughts and writings of Ken Chapman. The philosophy and content of this 2001 paper are still valid today. Dr. Lanese’s examples and discussion provide perspective and insight into the lifecycle approach to process validation consistent with recent publications and presentations.

VALIDATION, YESTERDAY AND TODAY-THREE TIMES IS STILL NOT THE RIGHT ANSWER

“How many runs do we have to make to validate this process?” This question is asked every time there is a discussion about a validation project. “Three” is the stock answer. This response is misleading. It is a disservice to validation practitioners, the concepts of validation, and good science. And, it is naïve in light of recent US Food and Drug Administration guidance and statements. Since the beginning of the requirement for validation in the pharmaceutical industry, many have considered it to be a stopping point—a one—time effort to produce three closely supervised and controlled batches-between development and commercialization. Often corporate management, which is focused on the economic and marketing aspects of the overall operation, does not comprehend the increasing FDA expectation for process understanding. There is an impression that three times is all that validation is about. Our economic profit/stock performance business focus does not encourage executives to consider the long-term benefit of a thorough understanding of our processes. As firms try to shorten the time to market, good science is often short-changed, and experiments designed to develop sound process data are circumvented to meet unrealistic project deadlines. The FDA’s mission is to protect the health of the public, and the Agency believes that one way to decrease the risk to the public is to expect firms to consistently produce product that is suitable for its intended use. This can only be accomplished if the firm has a thorough understanding of the process and its critical parameters. Consistent product is a matter of luck without the clear understanding of the process and critical parameters, the limits of those parameters within which acceptable product can be produced, and controls to assure the process remains in those limits. To quote an FDA representative speaking at a August 2007 conference: “Making consecutive commercial scale batches without a level of process understanding does not provide adequate assurance that the process is capable of consistently delivering quality product.”(1) The FDA drive to encourage firms to develop quality into the process, and thus the product, is in direct conflict with industry efforts to shorten the time to market while reducing costs.

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VALIDATION, A DEFINITION
Validation is documented evidence that a system consistently performs as intended (2). Although few people believe that three successful runs demonstrate consistency of a process, it is a number that industry had settled on for practical reasons. The absence of any reference to three process validation (or conformance) batches in the recent (3) revision to the FDA Compliance Policy Guide on Process Validation (4) should be a strong message that the magic of three has come to an end. The number of runs used for process validation is acceptable today only if it is justified by knowledge of the process based on extensive studies during development, and the runs are used to verify that documented knowledge. It has been said that process validation, or process performance qualification (5), is really nothing more than verifying things we already know.

Validation does not begin or end with three runs. Consider a revision to the classical definition of validation: the accumulated documented evidence that a system consistently performs as intended.

The original, widely accepted definition, says nothing about three runs. The addition of “accumulated” makes it clear that the documentation includes much more than the information collected during the three runs. The accumulated documented evidence may fill a bookshelf or a file drawer. I refer to the accumulated documentation as the “validation reference library” or “validation library.” Ideally, the validation library should be a central location provided for the storage of all process-related records. In reality, the validation library may be a virtual source encompassing many locations. Whether central or virtual, the records must be well catalogued and readily retrievable. Today, that validation library would be a part of the Knowledge Management System. ICH Q10 identifies the knowledge management system as one of the enablers that facilitate product realization, state of control, and continual improvement (6).

VALIDATION, VALIDATION, AND ASSOCIATED TERMINOLOGY
In the late 1980s, I was a member of the PMA (now PhRMA) Computer System Validation Committee. We met on a monthly basis over a period of more than two years to develop the computer system validation concepts paper, which was eventually published in Pharmaceutical Technology (7). At this time in the history of validation, we talked about installation qualification (IQ) and operational qualification (OQ), but we were not using the term process qualification or performance qualification (PQ). We talked about validation and were confused about what the meaning of the term included. During one meeting, one of the committee members proclaimed: “Hey friends. We have been mixing up validation (with a small ‘v’) and VALIDATION (with a capital ‘V’).” We all looked at him and silently thought: “So what?” He went on to explain that validation (with a small ‘v’) includes those individual experiments in which we test the total process. For a complex system (process), validation was the testing conducted on the system (total process), when all of the modules of the system (process) are integrated, to demonstrate that the specific system or process performs as intended. We now call validation PQ. VALIDATION (with a capital ‘V’) is the total effort to demonstrate that the process or system performs as intended. It includes design qualification (DQ), IQ, OQ, PQ, and many other aspects. That revelation cleared up a lot of the confusion for me, and I believe that it helped the committee work through the several issues that we were confronted with in the preparation of that paper. Since that time, I have considered the evidence of VALIDATION to be the total documentation package reporting all the work that an organization performs to demonstrate that a system performs as intended, throughout its lifecycle. The collection of this information certainly begins long before those PQ runs and it continues long after. This is consistent with the process validation timeline for a new process (See Figure 1).

Since the introduction of the requirement for validation in the most recent revision of the pharmaceutical GMPs in 1978 (8), a family of terminology has developed that includes the word validation or qualification. Not all of the terms found in the references are consistent.

Inspectional guidance to FDA investigators (4) adds additional terminology when it states that conformance batches are sometimes referred to as validation batches and demonstration batches, and then introduces a specific category of conformance batches, the initial conformance batches (9).

Terminology in the medical device literature is also slightly different compared to that in the pharmaceutical industry—same content, but different words and different expectations for the various qualifications performed in device VALIDATION.

For the remainder of this discussion, validation, process validation, process qualification, or process performance qualification (PQ) will be interpreted as
Figure 1: Process Validation Timeline

the formal documented work to verify a process performs as intended. This is the magical "n" (often three) runs. VALIDATION will be interpreted as the umbrella system that yields VALIDATION data, or the total of the accumulated documented evidence that demonstrates that process has performed, and continues to perform, as intended.

**PHASES OF VALIDATION**
The concept that VALIDATION begins in product development and continues through the product lifecycle is supported by the following recent guidance.

ICH Q7A (10) states, “The critical parameters/attributes should normally be identified during the development stage or from historical data, and the necessary ranges for reproducible operation defined.”

ICH Q8 (12) goes beyond the Quality System Guidance (above) and states that, “Quality should be built into (the product) by design” (13). Q8 establishes the expectation that a firm develop a thorough understanding of the product and process during product development and define the product design space.

ICH Q10 (15) presents the expectation that the pharmaceutical quality system is effective through the product lifecycle that includes product development, process

“Quality should be built into the product, and testing alone cannot be relied upon to ensure product quality.”

The Annex to ICH Q8 (14) expands the concept of the design space. Appendices in this guidance make it very clear that the regulators are looking for a quality by design approach that will require more work, and quality systems in development.

ICH Q10 (15) presents the expectation that the pharmaceutical quality system is effective through the product lifecycle that includes product development, process
transfer, commercialization, and product discontinuance.

In a conference presentation (1), an FDA representative shared some of the following aspects of the lifecycle concept:

- Overall validation is not completed, but is ongoing
- Necessitates comprehensive process design to understand sources of variability and achieve process understanding
- Incorporates risk management
- Recognizes that more knowledge will be gained from commercialization.

That FDA representative further provided some insight into the pending revision of the process validation guidance. Within the product lifecycle, validation will include the following:

- Process design
- Process qualification
- Commercialization.

In the late 1990s, I was asked to review an article submitted to the Journal of Validation Technology, which discussed the validation of a very specific process. The author stated that there should be three validation runs. The author then stated that the validation data should demonstrate that the process performs as intended at the extremes of the five process variables. These statements present an oxymoron. They are not consistent among themselves, with good science, or current thinking. The magic three process qualification runs should not be for the purpose of learning new things. Experiments that demonstrate acceptable product can be produced at process limits and should not be conducted during process qualification. They are part of the work that goes into defining the design space. Not even the best set of designed experiments can challenge the target and two extremes for each of the five parameters in three runs. Process qualification (validation) runs must be at the target conditions to demonstrate that the process performs consistently as intended. If one deviates from the target values through the qualification experiments, how can one demonstrate that the process consistently performs as intended? The confusion results from applying the two different meanings to the term validation without clarification.

Someone once said to me that if validation were complete a successful PQ validation. Validation is the documentation of all knowledge, which provides assurance that the process performs as intended. That is an extensive, time consuming effort. Effective PQ validation requires a complete knowledge of the process before it is initiated. Because we understand the process and have identified the critical parameters, only a relatively short process qualification experiment will be required to demonstrate the key aspects of what you know. All of the information should be stored in the Validation library, or the knowledge management system encouraged within ICH Q10, so that it can be accessed by those needing it.

**ORGANIZING FOR VALIDATION**

Any Validation process (or system) requires some very basic policies or procedures that set the ground rules for Validation in the organization. These should be in place long before specific processes are even conceived. These policies or procedures include a corporate Validation policy and site Validation procedure(s). These policies and procedures identify the corporate philosophy covering Validation, establish a lexicon of Validation terms that will be used throughout the corporation to provide consistency, and provide guidance for Validation at the site. Since Validation encompasses activities through the lifecycle of the product in development and operations, and possibly other units in the corporation, the corporate policy or procedure defines what work each unit performs and what documentation each unit provides. The site procedure clearly identifies responsibilities for each of the various tasks required for complete Validation. From this procedure, it should be clear what unit will be coordinating Validation activities and what unit will be responsible for the final approval of all Validation documents. Validation is the responsibility of many units within a pharmaceutical firm. The contributions of each should be clearly defined. These corporate and site procedures are basic references in our Validation library. The proposed Validation standard, published in this journal approximately eight years ago (16), provides guidance on establishing a Validation program. There have been many changes in the past eight years and it is appropriate that an industry group redefine the concept of validation for the next decade.

The Validation effort for a specific process begins with product design when a group sits down and defines the intended use of the product. The group defines the functional requirements for the product and translates these requirements into proposed product...
specifications. These are the critical quality attributes (CQAs) that identify physical, chemical, and biological properties and assure the product is suitable for its intended use. CQAs are associated with the drug product as well as drug substance, excipients, and intermediates. Once the CQAs are identified, the product development team sketches a flow diagram, or begins a wish list for a system that will manufacture the designed product. Out of these humble and very theoretical beginnings of process design comes a formal, practical set of functional requirements for the process that document what the system is expected to do for the organization. The product design, product functional requirements, CQAs, process design, and process functional requirements constitute the first volumes on our system VALIDATION bookshelf. Since these documents have regulatory impact, and may be included in communications with the regulators, they should be controlled documents and subject to change control. They will change as the organization learns about the product and process. It is important that there be a clear history of each document and recorded justifications for any changes. As part of process design the developers will:(1)

- Propose process steps and operating parameters to be studied
- Identify sources of variability likely to be encountered
- Consider possible range of variability for each input into the operation
- Evaluate process steps and operating parameters for potential criticality
- Plan studies to identify multivariate interactions
- Plan studies to understand effects of scale
- Establish mechanisms to limit or control variability based on experimental data
- Plan designed experiments
- Outline lab scale, small scale, and pilot scale studies
- Develop representative models
- Evaluate the impact of commercial scale.

Periodically, the organization should compare the current product and process to the design criteria and verify that they perform as intended. This DQ was made a required part of the VALIDATION system for medical devices when the quality system regulation (17) was introduced in 1996. It should be no surprise if the regulatory investigators start asking questions about drug product and process design and design qualification. Functional requirements may be translated into functional specifications that are provided to suppliers in the form of a request for proposal (RFP) or a request for a bid. Often, the functional requirements are translated into statements that appear in a new drug application (NDA) or an amended new drug application (ANDA), becoming a contract with FDA and the public it represents. The functional requirements should become a reference document that the VALIDATION expert refers to as he or she writes the VALIDATION plan and the individual protocols. The VALIDATION plan documents the plan for the complete VALIDATION of the process, through and beyond the (three) PQ experiments. It describes the prospective validation efforts. The VALIDATION plan is another volume stored on the system VALIDATION bookshelf in the VALIDATION library. Each time the validation specialist prepares an IQ, OQ, or PQ protocol, he/she should go into that library and refresh his/her recollection as to what it is that the process is intended to do, the design space, and the critical process attributes.

PERFORMING VALIDATION

I often have someone approach me and ask: “I am responsible for the validation of a XXX process, how do I write the protocol?” The question is about validation with a little “v”. The individual has little knowledge of what went on in development. To this, I respond: “What do you or your company believe this process should be doing for you?” After a few silent moments during which the individual stares at me with a blank look, I ask: “Do you have functional requirements or critical quality attributes for the system?” The response is too often, “No.” Unless the organization takes the time to develop functional requirements, it will not know what the system is intended to do. It will not be able to begin to write any of the VALIDATION plans or validation protocols. Early in the process history (lifecycle), the process engineers define the process and then begin to “tinker” with it. They identify what is the best way to coat tablets or sterilize material or to do what is necessary to get to the defined end product. As the process matures, the engineers identify the critical process parameters and process limits, and they collect the early data that demonstrates the process performs as intended, and within the process limits. This is the beginning of the documentation to support the proven acceptable range (PAR) (18). Today, development must leap from the one-dimensional PAR concept to multi-dimensional design space. A discussion of this migration from one- to multi-dimensional development can be found in the article “From Proven Acceptable Ranges to Design Space” (19). Extensive development data is necessary so that the validation team can select appropriate, augmented (beyond rou-
tine in-process and finished product) testing and challenging acceptance criteria that should be included in the validation (PQ) protocol.

Who is responsible for identifying critical process parameters and demonstrating that the process performs as intended at the limits of these process parameters? Should it be development, process engineering, or production? FDA presentations at a 2001 American Association of Pharmaceutical Scientists (AAPS) chapter meeting gave a clear preview of FDA expectation that this information be developed during drug product development. There is no universal solution to this question; each firm is different. These responsibilities should be defined in the Validation procedures. However, there is universal agreement that during process development the following should occur:

- The critical process parameters must be identified
- Process limits for the critical parameters must be identified
- Data must be collected that demonstrates that the process performs as intended and within the process limits
- The experiments demonstrating that the process performs as intended at the limits should not be included in the PQ runs that demonstrate that the process performs consistently.

It is up to the firm to define how the information will be obtained and by which unit. The experiments should be defined in protocols and the information should be put into the Validation library.

**VARIABLES AFFECTING VALIDATION**

The process is a system that includes people, materials, equipment and procedures and control systems. In classical quality system discussions these are referred to as the 5Ms of a system: Men, Materials, Machines, Methods, and Measurements. Each of these elements must be qualified.

**People**

People are hired into job positions with defined responsibilities. These should be related to the process through the job description. Since job descriptions identify general categories of tasks and desired education and experience, which are elements found in the GMPs, they should be Quality System documents. The individuals are further qualified to perform a specific process through training and demonstrated performance. The qualification of personnel to perform assigned tasks is one of the items FDA investigators are instructed to review in the System Inspection Programs. (20,21).

Although data supporting the qualification of people are typically not bound and placed into the Validation library, the information should be maintained and available for reference, when required. Training information should be readily available through the knowledge management system.

**Materials**

Materials are qualified through studies to determine the best materials and the best material suppliers. Qualification is maintained through supplier audits and certification or qualification programs that provide evidence each supplier maintains quality systems that support the continuous supply of material meeting defined quality criteria. These efforts are recorded and reported, and the resulting documents are catalogued and placed in the knowledge management system and made available to the Validation library. We also challenge the individual lots of materials as they are received with acceptance testing. The records of these activities become part of the knowledge management system, and thus, reference documents for the Validation library. If we perform limited acceptance testing based on supplier qualification, all of the supporting records are reference documents for our Validation library.

**Equipment**

Before the process equipment is even purchased, each key equipment manufacturer is reviewed and possibly audited to verify that it has the ability and experience to manufacture the equipment and Quality Systems to support change, Validation, investigations and continuous improvement. Equipment specifications are reviewed, other users are interviewed, and reports are written that demonstrate that the identified equipment can perform as defined within the equipment functional requirements required by the process. These reports are added to the Information Management System and available to the Validation bookshelf.

When the equipment arrives, it is subjected to IQ and OQ. The protocols for the IQ and OQ are based on equipment specifications and functional requirements derived from process functional requirements and the Validation plan. The records of the completed protocols are then added to the Validation bookshelf.

Once the full-scale process equipment is in place, the ability to produce the product at the target and extreme parameters may be verified and recorded. Some Validation specialists are of the opinion that this step is not necessary. The verification will provide addi-
tional information for the Validation library and support for the proven acceptable range. Again, it is good science that validation (PQ) should not begin until the organization has sound scientific evidence that the process will perform as intended at the limits, as well as the target conditions. All of the evidence collected to provide that confidence should be documented and placed on the Validation bookshelf.

It is only after a company has the confidence and evidence that the process will perform as intended that it should consider process validation (PQ). The decision as to whether there should be three, more, or less runs to demonstrate that the process performs as intended should be based on a thorough knowledge of the process. There should be no surprises during the process qualifications experiments. If there are surprises, the organization has failed to identify the correct process parameters. When the magical runs do not demonstrate that the process consistently performs as intended, the organization must investigate the occurrence; learn from the experience; identify the cause of the unexpected; implement the corrective action and preventive action; document the experience; and, put the record into the Validation library so that those who follow may also learn. Then the validation team must prepare another protocol using the revised parameters. The Validation library must be complete and documented through development and validation.

The firm may choose to implement some statistical process controls to demonstrate that the process continues to perform in control, or as intended.

**Procedures**

Procedures are qualified through the document review process. Document history files are references in the knowledge management system and are available for the Validation library.

**Control Systems**

One of the more challenging validations to maintain is that of an analytical method. The life of an analytical method begins in the development area at the investigational new drug (IND) stage. Functional requirements for the test method are directly dependent upon the functional requirements and CQAs for the product. As the product matures, the requirements for method validation increase. As the method is refined, critical parameters and limits for the test method are identified and the development chemist collects data that demonstrate that the method performs as intended. Just before the method is submitted as part of an NDA/ANDA, the method development laboratory performs the formal test method validation. As with process validation, the formal test method validation should not be performed unless the laboratory has a thorough understanding of the method. Unlike process validation, test method validation is completed within the development area and submitted as part of the NDA/ANDA. Sometime before production process validation, the method is transferred to the control laboratory of the manufacturing unit. The method is either revalidated or verified in that environment; or, the original validation study is expanded by the development group to include the control laboratory. Most of the information is based on experiences in the development area. The documented evidence that supports the validity of the method is spread over at least two areas within a firm. Method development and the formal validation data are in the development area. Historical data from commercial production is retained in the operations quality assurance/quality control area. Each of the units is usually very territorial, and it is often difficult to pull together the total Validation package for a method and have it available in the knowledge management system.

**POST-VALIDATION MONITORING**

Surprises occur even after completely characterizing a process, demonstrating that it performs as intended at the process extremes, managing through three perfect qualification runs and then using the process for routine production. After running perfectly for months or years, something happens. There is a deviation from the expected. Any deviation challenges the validity of the process. Each deviation must be investigated, the cause identified, and corrective action and preventive action completed. Deviation investigations and records of related corrective and/or preventive action and change control are references for our Validation library. Unless the cause of the deviation is identified and appropriate actions taken, the process suddenly becomes invalid, our contract with the Agency and public is voided, and our Validation bookshelf becomes eligible for the recycle bin.

When the process continues to work well, we should be looking for a more effective method to do things, and it often becomes apparent that voluntary changes to the process are appropriate. Continuous improvement is an element of all contemporary quality systems including those covering the pharmaceutical industry such as the Quality System Guidance and ICH Q10. Unfortunately, there are times when equipment ceases to function as intended and must be repaired.
or replaced, and we must make a change. There must be a change control program in which it is determined if a planned or unplanned change impacts the Validation of the process. If the review determines that the changed process requires (RE)Validation, the original functional requirements, as well as all of the supporting information stored or referenced in the Validation library, become sources for the development of the validation protocol to demonstrate that the changed process continues to perform as intended. The change control documentation demonstrates that the process continues to perform as intended and it becomes a Knowledge Management System reference available in our Validation library.

Even if there are no deviations and no changes, the firm must actively demonstrate that the process continues to perform as intended. The mechanism for this is the annual product review (APR). The APR, or product review, is an existing requirement for drug products in the United States (22) and Europe (23), Active Pharmaceutical Ingredients (24), and medical devices (25). It should include a thorough evaluation of the data relating to the process, including a statistical analysis of the critical parameter(s) and key test data. The resulting report provides evidence that the process remains in control or in a state of Validation, or that there are problems, and the process does not meet the original functional requirements or the CQAs. A critical review of the data may support loosening (or tightening) of one or more of the elements within the proven acceptable range, or suggest a move within the design space. It is the FDA's intent that the APR provide a system for proactively identifying the potential process problems and the need for changes in manufacturing or control procedures. The European GMPs state the regulatory expectation that: “regular periodic or rolling quality reviews of all licensed medicinal products, including export only products, should be conducted with the objective of verifying consistency of the existing process, the appropriateness of current specifications for both starting materials and finished product, to highlight any trends and to identify product and process improvements” (23). Within the quality system philosophy outlined in the QS Guidance (26) and ICH Q10 (27) the APR is an ideal mechanism for identifying areas for continuous improvement. Unfortunately, many firms are afraid of a thorough review because it might reveal process problems. Once a problem is identified there is a regulatory risk if it is not corrected in a timely manner. Any preventive action will require resources. The contemporary Quality System Guidance places clear responsibilities on management to provide resources so that product quality and the quality system receive appropriate attention. The Quality System Guidance states that management responsibilities include the review of the quality system (28) and one of the desired outcomes is improvement to manufacturing processes and products. ICH Q10 also states that a management’s responsibility is the periodic review of process performance and product quality with a goal of product and process improvement (29). Changes can be handled as planned changes, in an orderly fashion, within the change control system. Deviations and reactive, disruptive changes can be avoided. If changes are not appropriate, a thorough APR demonstrates that the process continues to perform as intended. The APR becomes part of the knowledge management system and a reference available in our Validation library.

VALIDATION DOCUMENTATION AND THE VALIDATION LIBRARY

One of the significant challenges in maintaining a system in a state of validation is maintaining the documentation so that it is retrievable and meaningful. The Validation library is mentioned numerous times throughout this discussion. Even if a firm has all the information needed to understand, perform, and monitor validation, an individual who needs the information must be able to find the information quickly. This is best accomplished by the formation of a Validation library—either real or virtual. The Validation library is the accumulation of records demonstrating that all elements of the process system originally functioned and continue to function as intended. Retrieval of documents is of the utmost importance for responding to auditor inquiries, investigations of deviations, evaluation of proposed changes, and other applications. The importance of the Validation library cannot be emphasized enough.

In the typical firm, the Validation library is a virtual repository, spread throughout the organization. Validation (PQ) records covering the specific equipment IQs and OQs and process PQs are usually maintained by quality assurance (QA) within the operations unit of the organization. Manufacturing processes are implemented in the development area and are transferred to the operations area for scale-up to production scale. There should be a mechanism for the transfer of the development information to the operations environment. This information may be contained within the transfer report or product development report (PDR). The Pharmaceutical Quality System should include a
Knowledge Management element so that all personnel who need information about a product or process have easy access to it. In order for the knowledge management system to function, the information silos that result from the fiefdoms within the organization will have to be breached. In the view of FDA, the “lifecycle approach is a means to link product/process development to the commercial manufacturing process, and then maintain that process in a state-of-control during routine production.”1 The needs of the operations department must be clearly understood, and the responsibilities of the development unit for providing that information should be clearly defined. Information sharing must be two-way. Most of the process validation activities are performed within the operations environment and should be retained within that environment. The ultimate success of process validation is dependent upon information collected in the development phase. The accountability for that success must be shared between all of the parties in the product life cycle, management, development, and operations.

I have always said that if I were responsible for a QA program, the first person I would hire would be a librarian. Librarians are trained to archive and retrieve information. That is a skill necessary for maintaining the various validation bookshelves in the Validation library. The more contemporary approach is to develop an effective knowledge management system. To do this the organization will have to break down the barriers between the various units and disciplines and introduce an effective computerized information system that will facilitate searches so that the Validation library for a product or process can be easily created from the virtual information sources.

**VALIDATION—THE JOURNEY**

Validation is a proactive quality assurance tool. A Validation program is just one element of a contemporary pharmaceutical quality system. It must be effectively integrated with other quality system components such as documentation, records, change, corrective action/preventive action, and product review. When a process is developed, and there is an understanding of the critical parameters, the firm builds the quality into the product and process, and avoids frequent deviations. There is a statement that has been attributed to several individuals, but the name I hear the most is Ken Chapman. The statement reads: “Validation is not a destination, it is a journey.” Those three PQ runs are just one milestone along the way. It is time that we revise the definition of validation to: Validation is the accumulated, documented evidence that a process or system continuously performs as intended. To support this, we must accept that Validation is not a destination, it is a never-ending journey, and the accumulated documentation is the journal for the journey. Just as any journey requires a variety of disciplines working together so that the individual or group can take the journey, Validation requires the coordination and cooperation of individuals from all disciplines of an organization.

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ARTICLE ACRONYM LISTING

AAPS American Association of Pharmaceutical Scientists
ANDA Amended New Drug Application
APR Annual Product Review
CQAs Critical Quality Attributes
DQ Design Qualification
FDA United States Food and Drug Administration
GMPs Good Manufacturing Practices
IND Investigational New Drug
IQ Installation Qualification
NDA New Drug Application
OQ Operational Qualification
PAR Proven Acceptable Range
PDR Product Development Report
PQ Performance Qualification
QA Quality Assurance
RFP Request for Proposal

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