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Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment



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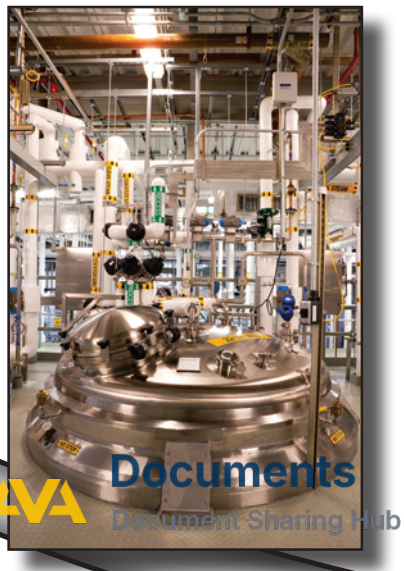
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This Guide is intended to provide direction to industry on the implementation of a science- and risk-based approach for demonstrating that pharmaceutical and biopharmaceutical facilities, systems, equipment, and associated automation are suitable for intended use. The ISPE cannot ensure and does not warrant that a system managed in accordance with this Guide will be acceptable to regulatory authorities. Further, this Guide does not replace the need for hiring professional engineers or technicians.

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ISBN 978-1-936379-09-5

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Foreword

The global pharmaceutical industry and regulators are responding to the challenge of significantly improving the way drug development and manufacturing is managed. New concepts are being developed and applied including science-based risk management approaches, a focus on product and process understanding, and the application of Quality by Design concepts.

This Guide provides direction to industry on the implementation of a science- and risk-based approach for demonstrating that pharmaceutical and biopharmaceutical facilities, systems, equipment, and associated automation are *fit for intended use*.

ISPE seeks close involvement of international regulators, including the US FDA, in the development of the ISPE Guides, which cover many important aspects of pharmaceutical development and manufacturing. These Guides are excellent examples of how ISPE, regulators, and industry can work cooperatively for public benefit.

Any uncertainty about the requirements for regulatory compliance may drive up costs and discourage innovation and technological advance. Neither of these outcomes benefits public health. ISPE Guides describes current good practice with the aim of providing an approach that is effective, cost-efficient, and in compliance with existing regulations and related guidance.

The Guides are solely created and owned by ISPE. They are not regulations, standards, or regulatory guideline documents, and facilities built in conformance with the Guides may or may not meet FDA or other regulatory requirements.

A continued working relationship between ISPE and international regulators will be fruitful for regulators, industry, and most importantly for public health.

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Acknowledgements

This Guide was produced by a Task Team led by Guy Wingate, GlaxoSmithKline, Bob Adamson, RBQ Services, Ltd., and Steve Wisniewski, Commissioning Agents, Inc. The work was supported by the ISPE Commissioning and Qualification (C&Q) and Good Automated Manufacturing Practice (GAMP) Communities of Practice (COPs).

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The Team Leads would like to express their grateful thanks to the many individuals and companies from around the world who reviewed and provided comments during the preparation of this Guide; although they are too numerous to list here, their input is greatly appreciated.

Regulatory Input and Review

Particular thanks go to the following for their review and comment:

CDER/Office of Compliance, FDA, USA
Karl-Heinz Menges, Regierungspräsidium Darmstadt GMP-inspectorate, Germany
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Cover photos: Left photo courtesy of Merck & Co., Inc., www.merck.com. Right photo courtesy of Novartis, www.novartis.com.

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1 Introduction

This Guide is a key part of the validation life cycle approach to quality assurance to ensure the manufacture of safe and effective products. It presents a structured approach to the delivery of GxP regulated facilities, systems, and equipment. It supports the latest industry and regulatory initiatives, including science-based risk management approaches, a focus on product and process understanding, and the application of Quality by Design concepts.

The Guide is designed to improve the way in which the industry delivers regulated manufacturing capacity: improving the ability to meet documented process requirements, control risks within the manufacturing process, producing high quality products, and consistently operating to meet product and process requirements.

An important aspect of this approach is the need for early and consistent application of the key concepts and principles throughout the life cycle in order to establish and demonstrate *suitability for intended use*.

1.1 Background

The successful delivery of manufacturing facilities (including small, large, new, expansion, or renovation type projects) regulated by various authorities, poses significant challenges to manufacturers, engineering professionals, and equipment suppliers. These facilities are required to meet all applicable GxP regulations, and to comply with all other relevant local and international governing codes, laws, and regulations.

As well as these applicable regulations, this Guide is intended to be compatible with:

- ICH (International Conference on Harmonisation) Guides ICH Q8(R2), Q9, and Q10 (References 3, 4, 5, Appendix 6)
- ASTM Standard E2500-07: Standard Guide for the Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment (Reference 15, Appendix 6)

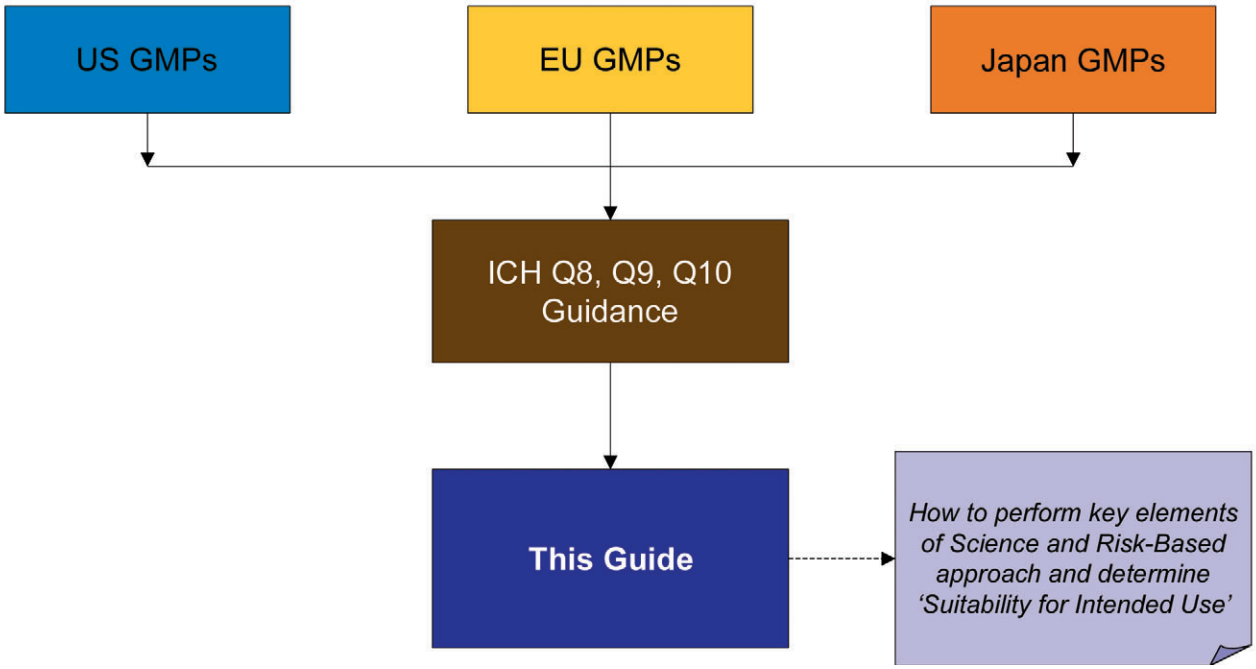
These publications emphasize the importance of science-based process understanding and the use of risk management principles to focus the quality management system on these aspects critical to product quality and patient safety.

This Guide has been published in support of the principles provided in these publications and to provide specific implementation guidance on meeting the expectations of global regulators as embodied in the ICH documents, as applied to the design and delivery of regulated facilities.

Figure 1.1 illustrates the relationships.

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Figure 1.1: Relationship of this Guide to International GMP Regulations and ICH Guidance Documents



More information about the history, development, and regulatory basis of the approach is given in Appendix 5: Regulatory Basis and Background.

1.2 Purpose and Objectives

The objective of this Guide is to facilitate the translation of the scientific knowledge about the product and process into documented specification, design, and verification of equipment, systems, and facilities which are fit for intended use, and minimize risk to patient safety and product quality.

The approach is built on science-based quality risk management and concepts of Quality by Design.

1.3 Scope

This Guide addresses those aspects of planning, specification, design, and delivery of facilities, utilities, equipment, and associated automation necessary to verify that they are fit for intended use.

It is intended to cover all pharmaceutical manufacturing (including drug substance, drug product, and biotechnology). It also may be applied to medical device or blood product manufacturing systems and equipment.

This Guide is applicable to automation elements associated with equipment and system control, and is harmonized with and should be read in conjunction with GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems (Reference 18, Appendix 6) and the associated GAMP Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems (Reference 19, Appendix 6).

The activities described in this approach address the verification (or qualification) portion of the validation life cycle upon which process validation is built by establishing operating ranges and performance capabilities. Well conceived and executed requirements, specification, design, and verification activities greatly facilitate a successful process validation effort. However, the Guide is not intended to directly address the provisions of process or product validation portion of the validation life cycle. Furthermore, this Guide does not cover product development activities.

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The principles contained within this Guide are applicable to the delivery of new commercial manufacturing capability. Its principles also may be used during modifications to existing regulated manufacturing facilities. The use of this Guide for new or existing systems is at the discretion of the regulated company.

Where non-engineering issues are covered (e.g., documentation, decision processes), the guidance is provided to show the importance of such topics and the impact they have on the process. Consequently, non-engineering topics are not covered in detail. Specialist advice from an appropriate SME or group should be sought where additional information is required.

1.4 Benefits

Application of the principles outlined in this Guide encourages the industry and individual organizations to reassess the terminology, practices, and roles and responsibilities involved in delivering new manufacturing capacity to focus on the criteria required to establish suitability for intended use.

Examples of specific benefits associated with individual key concepts are given in the Key Concepts section below.

1.5 Key Concepts

The approach focuses on establishing that which is critical for the process, product, and patient, and recommends verification strategies for confirming these critical aspects.

The following key concepts are applied throughout this Guide:

- science-based quality risk management
- product and process understanding
- flexible approach to specification and verification
- focus on achieving fitness for intended use
- clarification of roles and responsibilities
- leveraging supplier activities

1.5.1 Science-Based Quality Risk Management (QRM)

This Guide describes the importance of a QRM program which uses documented risk assessments that focus on identifying, assessing, and controlling the risks to the patient that may be present in the specific manufacturing process, equipment, or facility environment.

Those aspects of the design which serve to control risk to the patient are termed critical aspects. Critical aspects may include physical or functional design features. Other critical aspects include those physical or functional design features which serve either to control a Critical Process Parameter (CPP) or to meet a Critical Quality Attribute (CQA). Together, these sources of critical aspects serve to define equipment which is fit for intended use. Equipment, systems, facilities, and the associated automation are fit for intended use if they can achieve the CPP or CQA requirements and eliminate or control risks to the patient.

An important aspect of a robust QRM system is the process of ongoing or periodic review.

For more information on Quality Risk Management, see Section 7.

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1.5.2 *Product and Process Understanding*

Process understanding, resulting from scientific investigation, provides the basis for designs which are fit for intended use. Science-based product and process understanding are key inputs to assessing risks to the patient that may be present in the process, equipment, and system design. In the next stage, during commercial manufacturing, process understanding further provides the basis for evaluating deviations and changes and their potential impact on product(s).

Therefore, science and process understanding will be enhanced continually during ongoing operations through improvement projects based on relevant performance monitoring and careful design of experiments. It is important that this enhanced knowledge is recorded, used, and understood.

Process understanding begins with knowing the product Critical Quality Attributes (CQAs) and the associated Critical Process Parameters (CPPs). ICH Q8(R2) (Reference 3, Appendix 6) includes the following definitions:

- Critical Quality Attribute (CQA): a physical, chemical, biological or microbiological property or characteristic that should be within an appropriate limit, range, or distribution to ensure the desired product quality.

- Critical Process Parameters (CPP): a process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality.

CQAs, CPPs, and other process requirements necessary to manufacture a quality product, collectively form *process user requirements*, which form the starting point for designing facilities and equipment systems which meet their intended purpose.

1.5.3 *Focus on Achieving Fitness for Intended Use*

Verification activities should be focused on confirming that the critical aspects of equipment or systems, including associated automation, meet acceptance criteria. Inspections and tests specifically associated with the critical aspects are the inspections and tests which support the determination and approval of fitness for intended use. However, it should be noted that verification inspections and tests are not limited to critical aspects.

1.5.4 *Flexible Approaches to Specification and Verification*

There may be several approaches to structure the documents, inspection, and testing activities to install and verify a given facility, and to demonstrate that associated equipment systems are fit for their intended use.

This Guide provides examples of approaches to verification that provide flexibility and sufficient verification and documentation practices necessary to meet regulatory expectations.

1.5.5 *Clarification of Roles and Responsibilities*

The roles of Quality Unit and SME are described in the context of the scope of activities covered by this Guide.

The Quality Unit has a key role within the quality management system governing facilities, systems, and equipment. In addition to acting as a Subject Matter Expert (SME), the Quality Unit is responsible for overseeing quality and compliance.

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A key focus of the Quality Unit is identifying and approving those aspects that are required to manufacture a quality product, and to ensure that appropriate procedures are followed to ensure that risks to the patient in the manufacturing systems are adequately controlled. The approach presented recognizes that the GxP regulations provide the Quality Unit with the responsibility for ensuring controls to assure drug product quality. The approach recommends that actual performance of activities that contribute to that assurance, e.g., determine of appropriate procedures and specifications, may be performed by other most qualified departments or units, so long as this is agreed by the Quality Unit and the final Quality Unit review is preserved in the design of the verification/ validation program. The Quality Unit is expected to identify, approve, and verify those aspects that are necessary to manufacture a quality product, and to ensure that appropriate procedures are followed to ensure that risks to the patient in the manufacturing systems are adequately controlled.

In this Guide, the term Quality Unit is used as an encompassing term that includes many quality-related roles, including those responsibilities covered by the role of Qualified Person (as defined in Article 51 of EU Directive 2001/83/EC (Reference 13, Appendix 6).

GxP regulations require that persons of appropriate education, training, and experience are used to perform a given task.

Subject Matter Experts (SMEs) are defined as those individuals with specific expertise in a particular area or field (for further information, see Section 2 of this Guide).

1.5.6 Leveraging Supplier Activities

The quality of supplied equipment, systems, and facilities, as well as the associated supplier documentation, has a major impact on the amount and depth of verification activities performed by the regulated company.

Assessment of supplier quality systems should be performed based upon a number of key indicators, including consideration of:

- the intended use of the supplied equipment or system and the associated risks to product quality and patient safety
- the origin of the equipment or system (the supplier capabilities, including the use of a quality systems approach, GEPs)
- the extent the pharmaceutical manufacturer relies upon the work performed by the supplier experience with the supplier for similar equipment

In addition, differences in supplier quality systems should be evaluated and the likelihood of unknown differences should be considered.

On this basis, supplier inspection and test documentation, as described in this Guide, may be leveraged to avoid repeating testing, provided that supplier documentation clearly shows that items of interest have been verified or tested in an appropriate manner.

If inadequacies are found in the supplier's quality management system, technical capability, or application of GEP, the regulated company may choose to mitigate potential risks by applying specific, targeted, additional verification checks, or other controls rather than simply repeating supplier activities and replicating vendor documentation.

Potential effects of shipping, transit, or storage on the functionality or use of supplied equipment, systems, and facilities should be considered during the development of overall system or equipment test plans.

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Equipment and system testing, conducted prior to final installation in the facility, should be evaluated to assure its validity to support the intended use within the facility.

1.5.7 Benefits of These Concepts

Some specific benefits arising from the application of these Key Concepts are given in Table 1.1.

Table 1.1 Benefits Arising from the Application of Key Concepts

Key Concept	Expected Benefit
Science-Based Quality Risk Management	Risk assessment tools based on analyzing risk to the patient will provide better definition of critical aspects, and may save effort in execution (versus system and component impact assessment).
Product and process understanding	Improvements in design to meet science-based process requirements
Flexible approaches to verification	Improved effectiveness and lower cost of inspections and testing.
Focus on achieving fitness for intended use	Efficient and focused use of resources, ensuring that these resources are directed to quality critical aspects and activities.
Clarification of roles and responsibilities	Better application of resources and better conformance to GxP regulations. • SMEs define critical aspects, verification strategies, acceptance criteria, test methods, execute tests, and review results. • SMEs can adjudicate on most departures from specification using change management as required. • Role of QA is focused on ensuring that quality procedures are in place and followed. • QA approves acceptance criteria of critical aspects. Supports the delivery of effective process validation programs
Leveraging supplier activities	Avoiding repeated specification and verification activities

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2 Overview of the Life Cycle

2.1 Science-Based Approach

Specification, design, and verification decisions should be made on the basis of product and process understanding.

Specification, design, and verification are documented activities that utilize the scientific knowledge that is described in ICH Q8(R2) (Reference 3, Appendix 6).

Scientific knowledge should be the basis on which the risk assessments are performed to support design, development, and verification to ensure that pharmaceutical systems are fit for intended use.

Identification of the CPPs and CQAs, along with defined appropriate operating limits or acceptance criteria, should be included in the documented product development data, process flow diagram, and product quality strategy.

Product and process understanding should be utilized to develop a product control strategy. For the purposes of quality by design, the CQAs, CPPs, and process control approach represent the initial process user requirements for systems. Specific regulatory requirements also should be considered.

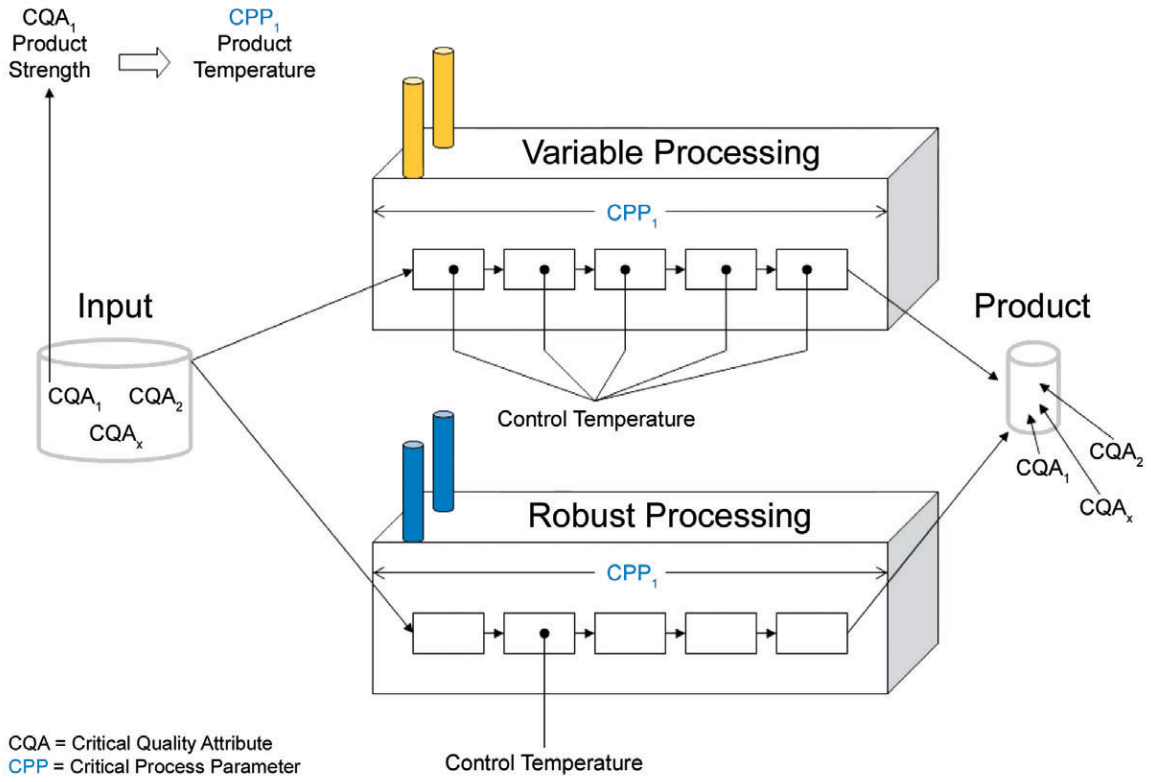
Process user requirements are used to define those critical aspects of the process necessary to ensure product quality specifications. Process user requirements should be used to define appropriate verification activities and acceptance criteria to ensure that manufacturing elements are fit for their intended use.

Risk control functions and functionality to detect process variations exceeding pre-defined limits (ability to detect a failure condition) may be provided by automation and process control system elements.

The process control approach should result in a system design providing measurement and control of the process characteristics in order to meet product specifications during each manufacturing step. The way a process control approach is implemented depends on the robustness of the intended process and its systems. The more variable a process is, the greater the number of hazards to product quality, the more frequent the control of CPPs is needed (see Figure 2.1.)

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Figure 2.1: Critical Quality Attributes versus Critical Process Parameters



The system design may provide a variety of process data in several relevant contexts, e.g.:

- process data in real-time
- Process Analytical Technology (PAT) – based data (multivariate representations of process data)
- historical data (or process data, depicted, trended, and archived over time)

Computer system specification and verification (including risk assessments) should be part of the integrated engineering approach to ensure compliance and fitness for intended use of the complete automated equipment or process.

2.2 Quality Risk Management in the Life Cycle

Quality Risk Management should underpin the specification, design, and verification process, and be applied appropriately at each stage.

Two primary principles of quality risk management are identified in ICH Q9 (Reference 4, Appendix 6):

- the evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient
- the level of effort, formality, and documentation of the quality risk management process should be commensurate with the level of risk

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This Guide provides a basis for understanding whereby these principles are applied to all aspects of the specification, design, and verification of manufacturing elements. The scope and extent of specification, design, and verification activities and documentation should be based on the risk to product quality and patient safety.

See Section 7 for further discussion of Quality Risk Management.

2.3 Quality by Design

Quality should be built into the design throughout the specification, design, and verification process.

Assurance that manufacturing elements are fit for intended use should not rely solely upon verification after installation.

The process control approach is essential to the overall product quality control strategy; a Quality by Design (QbD) approach requires understanding the role of automation:

- to mitigate process risks by design
- to control risks via the process control approach
- to detect failure of the process to meet critical to quality aspects by measurement, alarming, and action as part of an overall product quality control strategy limits

The ISPE Product Quality Lifecycle Implementation (PQLI®) initiative is currently developing guidance on key elements of QbD, including control strategy. (See the ISPE Web site for further details.)

2.4 Specification and Verification

The process of specification, design, and verification of equipment and systems should include the following activities:

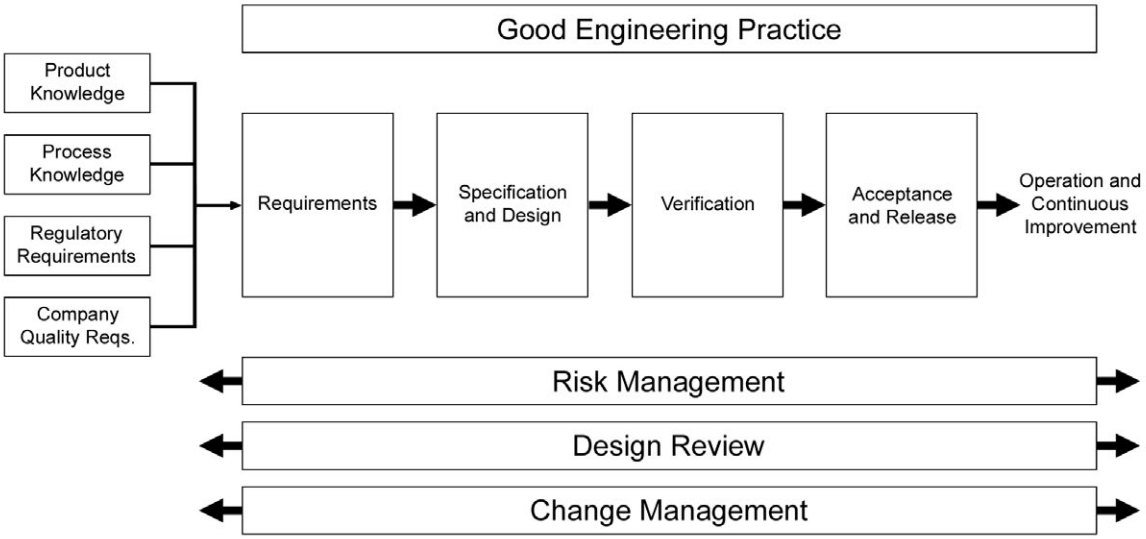
- requirements definition
- specification and design
- verification
- acceptance and release

GEP, QRM, and design reviews should be applied throughout the process and throughout the life cycle.

This process is illustrated in Figure 2.2 (taken from ASTM E2500-07 (Reference 15, Appendix 6).

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Figure 2.2: Requirements, Specification, Design, and Verification



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See Sections 3, 4, and 5 of this Guide for further discussion of these topics.

2.5 Good Engineering Practice

Good Engineering Practice (GEP) is defined as established engineering methods and standards that are applied throughout the project and life cycle and ensure the effective satisfaction of stakeholder requirements (see Section 8 of this Guide).

They deliver appropriate, cost-effective solutions to meet user requirements and compliance with all applicable regulations. GEP is expected to be applied in a pharmaceutical enterprise. GEP methods are not a specific requirement of the GxP regulations, but appropriate application of GEP will support cost-effective verification processes.

GEP should be applied to all stages of the specification, design, and verification process and throughout the life cycle.

GEP ensures that an engineering project meets the requirements of the user while being cost effective, compliant with regulations, and well documented. Established guidance and standards support effective GEP.

For GMP projects, it is critical to the overall project success, that the principles of GEP are applied with the full cooperation of suppliers, engineering and construction companies, and an organization's own cross-functional teams.

See Section 8 for further discussion of Good Engineering Practice.

2.6 Continual Improvement

Once the verification process is completed, the system will be subject to the appropriate quality system(s) for ongoing support and continual improvement.

Where system improvements are recommended, the principles in this Guide may be followed to assist with the appropriate design and implementation of verification activities.

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An evaluation should be performed periodically or upon specific incidents, such as frequent non-conformance of the system or product, to review the performance of the system and its ability to continue functioning as required to meet critical aspects of manufacturing capability. The review should confirm that the system remains fit for intended use or recommend potential improvements.

Where system improvements are recommended, this Guide may assist in their appropriate design and implementation.

2.7 Change Management

Change Management practices should be appropriate to the activities performed and stage within the system life cycle. Change Management practices may, generally, be identified as:

- engineering change management, based upon GEPs
- formal QA change control, using similar GEPs augmented with pre- and post- approvals by the Quality Unit, is required during commercial manufacturing

Implementing formal QA Change Control, with Quality Unit pre and post approvals, prior to starting commercial manufacturing operations is unlikely to provide benefit.

2.8 Roles and Responsibilities

2.8.1 Subject Matter Experts

Subject Matter Experts (SMEs) are defined as those individuals with specific expertise in a particular area or field.

SMEs should take the lead role in the verification of manufacturing elements.

SME responsibilities typically include planning and defining verification strategies, defining acceptance criteria, execution of verification tests, and reviewing results.

SMEs are encouraged to understand, identify, and leverage best practices and processes related to automated equipment systems. Key bodies of knowledge include ISPE initiatives such as GAMP and PQLI, as well as others as listed in the References Section (see Appendix 6).

Table 2.1 shows typical subject matter expertise for various roles.

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Table 2.1: Typical Areas of Subject Matter Expertise

Role	Subject Matter Expertise
Engineering/Technical	Inspecting or testing equipment against engineering specifications, and analyzing and evaluating the results. Evaluating departures from engineering specifications including the potential impact and response to same. The decision and justification to use supplier documentation, to support the verification of critical aspects of the manufacturing element, should be based on the intended use of the manufacturing system, and should be documented and approved by SMEs. Collaboration with automation SMEs.
Quality Unit	In relation to assuring the quality of facilities, equipment, and systems: • the review and approval of product and process user requirements • the review of the project quality plans or similar documents • participation in the risk assessment and approval of the final risk assessment and associated list of critical aspects/acceptance criteria • review and approval of verification summary report and pre- and post-approval of performance testing protocols and any non-conformances that may result • development and approval of the verification plan with other SMEs • checking for compliance with the organization's Quality Management System
Process Scientists	Determining CPPs and CQAs. Leading the resolution of process related issues, e.g., during technical transfer or scale up.
Manufacturing Personnel	Reviewing operability factors of the design. Assisting with and verifying that non-verification type elements (e.g., SOPs pertaining to operations, etc.) needed for commercial manufacturing are developed, documented, and available for use prior to release for service.
Automation SME	Developing, verifying, and optimizing automation and process control elements of manufacturing systems capability, including: • features and functions of systems capability allocated to automation • the process control approach • automation based product quality monitoring and risk control features and functions • security access features and functions to prevent unauthorized access, based upon the intended use of the system Assistance with supplier assessments to ensure reliance on a supplier is appropriate, including: • review of supplier quality system pertaining to automation software • review of supplier engineering practices pertaining to automation software

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2.8.2 The Quality Unit

The Quality Unit promotes quality and ensures compliance with GxP regulations.

This Guide supports the quality assurance role of the Quality Unit in order to provide risk management throughout the system design, development, and implementation.

This Guide also promotes delegation of quality control of installation and operation verification to appropriate SMEs. SMEs should evaluate engineering specifications, test plans, and conformance of results to engineering specifications, and draw appropriate conclusions based upon the results.

In relation to this Guide, the Quality Unit has specific responsibilities for:

- focusing on the important (critical to quality) product and process user requirements, risk assessments, and ensure manufacturing elements are defined
- ensuring that the project team has an adequate quality plan and that good engineering practices are implemented
- verifying, through performance testing, that the product and process user requirements associated with CQAs of manufacturing systems and equipment have been met

The Quality Unit should be involved in:

- the review and approval of product and process user requirements
- review of the project quality plans or similar document
- participates in risk assessments and approves the final risk assessment and associated list of critical aspects/ acceptance criteria
- is involved in the resolution and approval of alternative courses of action when critical aspects of manufacturing cannot conform to acceptance criteria
- verifying the completion of verification tasks and pre- and post-approval of the Performance Testing protocols and any non-conformances that may result
- developing and approving the verification plan with other SMEs
- checking for compliance with the firm's Quality Management System

The Quality Unit also approves changes to any of the above items that had previously been approved by the Quality Unit.

Current industry practice generally divides the responsibilities of the Quality Unit, as defined in the CGMP regulations, between Quality Control (QC) and Quality Assurance (QA) functions. Management within the manufacturing organization should be responsible for determining and documenting specific responsibilities for the Quality Unit, including QC and QA functions, and the role of the Quality Unit within risk management practices.

2.8.3 Head of Production

The Head of Production (or equivalent) should have joint responsibility with the Quality Unit for the effective implementation of the quality management system, and compliance with relevant regulations.

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3 Requirements

3.1 Introduction

The definition of requirements focuses on process user requirements which combine the product and process knowledge, and regulatory and company requirements. The development of the requirements definition should be included in the process of specification, design, and verification of manufacturing systems.

3.2 Requirements Definition

Specific requirements relevant to product quality and patient safety should be identified and used as the basis for further specification, design, and verification of the manufacturing system.

Requirements should describe the intended purpose of the system. Requirements should be stated at a high-level and be non-prescriptive. The intent is to describe the desired output, rather than to develop a specification.

Specific requirements should be based upon:

- product knowledge
- process knowledge
- regulatory requirements
- company quality requirements

Product and process knowledge, including knowledge of sources of variability in the product and process, the identification of CQAs, CPPs, and process control approach information, should be based on scientific data gathered during experimental and development work.

Product and process understanding forms the basis of *design space*. It should, as a minimum, assure product quality, as described in ICH Q8(R2) (Reference 3, Appendix 6).

3.3 Requirements Development

The development of the requirements definition should be a documented and approved process. The development of requirements may be an iterative process. The requirements should typically describe:

- product and process requirements
- operational requirements
- maintenance and technical support
- regulatory requirements
- organization requirements

Product and process requirements should state requirements for what the manufacturing system is intended to achieve for the product and its quality. This may include:

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- critical quality attributes
- product forecasts (and ranges)
- process descriptions
- estimated processing times
- cleaning methods and limits
- materials of construction compatibility
- batch sizes or ranges
- process flow charts
- normal operating ranges and tolerances for critical process parameters
- product safety information
- operating restrictions or problems

Operational requirements typically should include:

- plant operating schedule
- staffing
- impact on existing operations
- supply disruptions

Maintenance and technical support typically should consider:

- past experience with equipment
- past experience with spares
- site specific requirements
- preferred equipment suppliers (and the basis for preferences)

Regulatory requirements should consider relevant regulatory and industry guidance and requirements, as appropriate.

It also may be appropriate to include safety health and environmental considerations; they are not a GMP regulatory requirement.

Organization specific requirements should include local and corporate specific guidance and instructions.

3.3.1 Systems Approach to Engineering Requirements

Requirements (and specifications) management should define needs and acceptance criteria based upon intended use. Automation should be an integrated part of this process.

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A matrix listing requirements, associated specifications (acceptance criteria), and verification results may be used. This matrix may point to more detailed user requirements, technical specifications, and verification protocols.

Requirements should:

- be sufficient, complete, correct, and verifiable
- be specific to the system or element that is to provide the stated capability

Stakeholders may refer to the acronym “SMART,” i.e.:

- Specific
- Measurable
- Achievable
- Realistic
- Traceable

System requirements should be clearly documented and managed to allow them to be allocated, derived, achieved, or verified. System level requirements should be allocated to, or associated with, the sub-system or element that is responsible for providing the stated capability (e.g., pressure vessel, PLC, or Human Machine Interface (HMI)).

The provision of a specific naming convention within the requirements may help to avoid multiple sets of generic “user requirements.”

Systems engineering may be used with a suite of tools to help manage engineering activities, results, and documentation.

The allocation of the system requirements (e.g., process system, utility system, or facility system) to software, hardware, and other system components may be performed by a project team or a systems engineering group. These groups should ensure that relevant system requirements are appropriately documented and controlled.

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4 Specification and Design

4.1 Basis of Design

Manufacturing systems should be appropriately designed based upon relevant knowledge of product, process, and other requirements, as well as actual or potential risks to the patient. The process of specification and design should be based on the requirements defined for that system (see Section 3 of this Guide). During the design phase, defined business needs and system requirements should be analyzed and appropriate engineering solutions should be developed in response to those requirements.

This information and other information including the manufacturing strategy, and process flow documents are the basis of specification and design for the manufacturing systems.

Specification and design processes should be applied to any aspects of system development needed to generate a successful design which meets the requirements defined for the system. For regulated systems, specification and design activities should focus on those aspects that have been identified as being critical to product quality and patient safety. These critical aspects of the manufacturing system should be identified and documented by SMEs. Procedures should be established to communicate requirements, including product quality considerations, to those responsible for the design.

Risk management, design reviews, and change management should be applied throughout the process. (For further information, see Section 2 of this Guide.) GEP should be applied throughout the process to ensure that approved design specifications and conditions are appropriately managed, controlled, and executed.

Organizations may use a formal process description, (sometimes called a process narrative or a process flow diagram or document) to represent an overview of the process, its critical aspects, and the sequence of operations. Such process description may serve as the basis for and complement Piping and Instrumentation Diagrams (P&IDs).

Once the product quality/patient safety requirements, as well as other general requirements have been determined, the appropriate SMEs should draw up a specification for a system that will satisfy both sets of requirements.

4.2 The Design Process

Traditional design programs employ distinct phases commonly identified as:

- Conceptual Design
- Preliminary Design or Basic Engineering
- Detailed Design

Each design phase completes a different layer of design information and level of detail ranging from facility-level architecture to detailed specification of components within a system. Design programs may vary in formality and structure dependent on the requirements of an individual project, system, or organization.

Design reviews and risk assessments should be conducted and documented following the requirements definition phase and each sequential phase of the design process. Design processes may need to be iterative; design processes may generate a range of design solutions in response to a single requirement. Risk assessments should evaluate the potential impact of design solutions on the product and process requirements. Design reviews in conjunction with risk assessments should be used to select the most appropriate design option.

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Risk assessments also should be conducted and documented to evaluate automation aspects of design and potential risks to product quality, patient safety, and overall project delivery.

Automation specification documents may be developed using peer reviews. Peer reviews may be used by suppliers or by an organization to help ensure that quality is built into the process of specification and design.

The basis of design should be based on the best process information available. The design process should include provision to accommodate changes required by new process knowledge transferred from the process development effort.

Life cycle development approaches may be employed during design development engineering, which provide a structured approach that will help ensure quality is built in to the design development process. The selection of the specific methodology may vary according to project needs, project constraints, and the SMEs performing the work.

The use of a specific engineering development life cycle helps identify expectations. For example, when an iterative software development approach is used for automated systems, the project team may decide that iterations of requirements and design documentation are controlled by an engineering documentation process via revision levels, and need only be issued, rather than formally approved. The project team also may decide that an approved revision is needed at three points in the design delivery process:

- prior to a formal design review, as the basis of the review
- prior to commissioning, as the basis for commissioning activities
- prior to the demonstrating systems to be fit for intended use

This approach provides for suitable control of the engineering work and documentation during the iterative development process. It also provides gate-keeping via approved documents at specific points in the project timeline.

Design reviews should:

- evaluate how selected design options meet defined requirements
- confirm that the product and process requirements are addressed appropriately by the design
- include cost and benefit analyses of selected design options
- include trade-off assessments between design options and the incorporation of alternative technological solutions

Design processes should include process hazards assessments and other reviews associated with how a system will be used.

Design processes should generate a final design solution that best meets the defined system requirements.

As part of GEP, a documented design review should be conducted to ensure completeness of each phase of design development, as well as activities supported by other disciplines that ensure readiness to proceed to the next phase of design, and to system fabrication and installation.

4.2.1 Conceptual Design

The purpose of conceptual design is to develop facility and system concepts, including automation strategies, which meet corresponding site, facility, and system-level requirements, as well as legal and code-related requirements.

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The review of requirements and design concepts is an interactive, iterative process to define both design constraints and new requirements.

Strategic planning for verification testing, project delivery processes, and system owner maintenance program concepts should be initiated early in the conceptual design process.

Multiple design concepts may be developed as outputs for further analysis and development.

Outputs of the conceptual design process normally include:

- facility architectural concepts
- additional system requirements and design constraints
- preliminary equipment lists
- process requirements
- associated scope and cost estimates
- milestone schedule

4.2.2 Preliminary Design or Basic Engineering

Basic engineering (also commonly referred to as schematic design or preliminary design) should be focused on the development of system-level designs, including definition of sub-systems and the identification of components required to support system functionality.

Early in basic engineering, strategic planning should be completed for verification testing, project delivery processes, and system owner maintenance program concepts. Execution-level planning for these activities also should be in development.

System and subsystem boundaries should be defined, documented, and approved.

At the conclusion of basic engineering, scope and schedule information should be sufficiently defined to support budget definition and approval for completing the remaining phases of the project.

Primary outputs of basic engineering include:

- “issue–for-design” P&IDs and drawings
- equipment and instrument lists

Following basic engineering, an engineering change management program should be established to manage effectively any significant changes in scope, budget, schedule, or design intent.

4.2.3 Detailed Design

Component-level design specifications and engineering drawings are developed and approved during Detailed Design, providing the basis for equipment purchase and defining requirements for fabrication and installation.

System and subsystem boundary definition approved earlier in the design process should be confirmed.

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Project schedule information should be developed to a level of detail necessary to support construction planning and project delivery activities and identification of need dates for procurement activities.

Project delivery and schedules should consider and evaluate automation development and delivery processes. Design, development, delivery, and installation of automation aspects of a project may differ from those for the physical components of the system.

Long-lead equipment purchases, high cost items, and other items representing risk to the project, or which require special attention, should be identified and addressed prior to the completion of the design phase.

Final design reviews should be conducted to document that critical aspects are identified (those associated with product and process requirements).

Plans for equipment delivery and turn-over of data and documentation from engineering and suppliers should be developed during detail design and finalized at the conclusion of the design program.

Execution-level planning for verification testing, project delivery processes, and system owner maintenance program implementation should be completed and approved by the end of Detail Design.

Outputs of the design process typically include:

- installation drawings
- details and specifications for systems and equipment procurement
- allowable methods and materials for fabrication and installation
- associated requirements for information and document deliverables
- details and specifications for systems and equipment acceptance

4.3 Design and Delivery Processes

4.3.1 Design-Bid-Build

The variations to the design delivery processes described in this Guide most closely represent a “design-bid-build” sequence of activities. However, there are other design delivery approaches that are equally valid and the most suitable choice is a GEP decision.

The primary feature of a design-bid-build process is the development of detailed component-level specifications and acceptance criteria that are approved by the purchaser prior to the purchase.

4.3.2 Design-Build

In a “design-build” delivery program, specifications generally focus on the performance required by the system and do not, typically, include customer-approved component-level specifications.

A construction management organization normally has responsibility for design, procurement, and construction actions necessary to support the requirements of the system performance specification.

Generally, the design-build program offers a faster delivery process in exchange for decreased design control by the purchaser.

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Data and documentation delivery to the purchaser in design-build programs usually occurs later in the process, and may be delivered in a turn-over package following the mechanical completion milestone. This is an important planning consideration for project stakeholders requiring access to data and documentation early in the delivery process.

4.3.3 Modular Construction

Modular construction processes design a facility in several building blocks or modules that can be fabricated and integrated with utility and process equipment off-site, then shipped and stacked at the facility site.

Modular construction processes may offer shortened project timelines and decreased on-site construction activity.

Organization of data and documentation, as well as integrated testing of equipment and/or automated systems may be more challenging on modular construction projects, due to additional information sources and users.

4.3.4 Package Systems

Package systems are either custom-fabricated or commercially available.

The primary distinction between the two is that commercial items have existing design and engineering data and documentation requirements already defined; the purchaser makes selections from available options.

Commercial items may be procured in shorter time than a custom fabricated item, but provide less flexibility to define unique requirements or design features.

Execution of a factory acceptance test program for package systems is considered a GEP that assures correct configuration, functionality, and information prior to shipment of the system from the supplier.

Purchasers of modular and package systems should consider design, specification, and verification requirements associated with the integration of those systems into the facility. Particular attention should be given to physical and functional interfaces, and the level of integration support provided by the supplier.

Quality expectations to be supported by designers, fabricators, and suppliers should be clearly communicated and documented in specifications, plans, and contractual commitment documents.

4.4 Procurement

Project procurement activities may commence at any appropriate stage during the design development, although final design will need review and approval.

Approved design specifications provide the technical basis for issuing purchase orders for equipment and instrument components.

Purchase orders may include:

- technical specifications
- product information requirements (data and documentation)
- requirements for Factory Acceptance Testing (FAT)
- pre-delivery inspections
- Site Acceptance Testing (SAT) and other required supplier support

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- delivery schedule requirements

Suppliers and fabricators supporting process-critical systems or other systems that represent a risk to the project should be audited or evaluated prior to purchase agreements being finalized.

Verification planning and test expectations should be developed, documented, and communicated to project stakeholders. A verification process should be used on receipt to confirm that the correct item has been received (critical components as a minimum), required data and documents are available, and to ensure that the component is undamaged.

A process should be established to gather component physical and functional data to populate engineering and maintenance management program applications for critical items and all maintenance-significant items.

4.5 Fabrication and Installation

Fabrication and installation activities represent the implementation of approved design specifications and drawings.

Fabrication activities may be executed off-site at a supplier or equipment integrator's facility. For critical process systems, or other systems that represent a risk to the project, a factory acceptance test should be conducted prior to the purchaser authorizing shipment of the fabricated assembly.

Additional data and documentation are generated during most fabrication activities. For custom fabricated equipment, the purchaser should define data and document requirements, and delivery timing that should be supported by the fabricator.

Installation activities are normally conducted on-site with the exception of modular construction programs in which equipment can be installed and integrated into building modules off-site.

A construction quality assurance program should be used to ensure that installation activities comply with approved specifications and methods.

A discrepancy management program should be used to track and disposition punch list items associated with fabrication and installation activities.

Installation verification should be conducted to confirm that systems and equipment are properly installed and that engineering drawings correctly reflect the "as-built" configuration of the system.

4.6 Engineering Information Management

Engineering Information Management includes the identification, gathering, and distribution of asset design data and documentation required to build the facilities and systems, and to support life cycle operation, maintenance, and verification. Design data typically includes information such as:

- manufacturer
- manufacturer model number
- equipment range-low
- equipment range-high

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The design information should record the design of the system, including automation elements. Design documentation is usually modular, relating to equipment elements or automation elements. The primary use of both specifications and design information is to support verification that the system works as intended. In addition, this documentation may be used to help support future maintenance and modification of the system.

Design documentation includes information, such as installation, operation and maintenance manuals, bills of material, and material of construction certificate.

Design data and documentation support key events throughout the system life cycle, including:

- procurement
- design reviews
- verification activities
- maintenance program development
- change control actions
- ongoing quality evaluations
- record retention requirements

Activities associated with Engineering Information Management may include:

- identification of all information providers and users during the design phase and mapping information flows from provider to user
- defining a specific format for information organization and delivery
- use of data and document management systems that facilitate information organization, accountability, security, and access for use
- use of data and document version control and change management programs
- periodic review and evaluation of information
- identification of record retention requirements

The extent of engineering information that may be delivered and needs to be managed with a new asset should be considered.

A risk-based data and documentation requirements definition process should be conducted to streamline information deliverables, while supporting minimum information needs.

An effective information management program should include:

- processes for defining information requirements and delivery mechanisms
- information providers and users
- review and determination of status

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- acceptance and release
- access and control
- change management
- information technology management tools

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