Mapping Document for ISPE Specification and Verification Guides

Introduction

This document explains the relationship between the following ISPE Guides:

ISPE Baseline Guide, Volume 5: Commissioning and Qualification[1] (Baseline Guide Volume 5)
ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment[2] (FSE Guide)
ISPE Good Practice Guide: Applied Risk Management in Commissioning and Qualification[3] (Applied Risk Management Guide)

Overview

Baseline Guide Volume 5 represents established, baseline practice. This approach achieves adequate compliance in an effective way, but doesn't fully leverage the latest Quality by Design (QbD)and risk-based concepts.

The FSE Guide describes a comprehensive and strategic science- and risk-based approach, focused on Quality by Design, and based on *fitness for intended use*. It reflects the latest industry and regulatory thinking, by focusing on the aspects most critical to product quality and patient safety.

The Applied Risk Management Guide describes how organizations can move from established baseline practice to a more efficient science- and risk-based framework. It describes a transition strategy and helps companies to judge the best and most effective path forward for them.

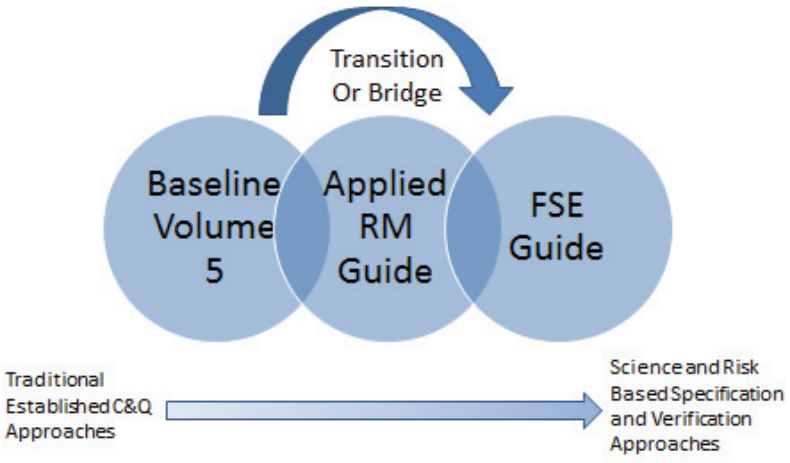

Figure X: Relationship between the Guides

Objectives of the Guides

1. *ISPE Baseline Guide, Volume 5: Commissioning and Qualification*

This Guide (Baseline Guide Volume 5) focuses on the engineering approaches and practices involved in providing cost effective manufacturing facilities in a timely manner that meet their intended purposes. Specifically, the Guide addresses the process of designing, constructing, commissioning, and qualifying the facilities, utilities, and equipment regulated by the US FDA or other health authorities.

It applies a process of impact assessment with subsequent enhanced design review and qualification as appropriate.

2. *ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment*

This Guide (FSE 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*. This Guide is intended to be compatible with International Conference on Harmonisation (ICH) Guides Q8(R2), Q9, and Q10,[4, 5, 6] and the ASTM Standard E2500-07 Standard Guide.[7]

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

3. *ISPE Good Practice Guide: Applied Risk Management in Commissioning and Qualification*

This Guide (Applied Risk Management Guide) describes the application of Quality Risk Management to traditional Commissioning and Qualification (C&Q) practices. It links the traditional terminology and approaches of C&Q (as used in Baseline Guide Volume 5) to the newer science- and risk-based specification and verification terminology and approaches applied in the FSE Guide, and other documents such as ICH Q9[5] and ASTM E2500.[7]

Comparison of the Guides

Topic	**Baseline Guide Volume 5**	**Applied Risk Management Guide**	**FSE Guide**
Terminology	Traditional C&Q	Traditional C&Q	Specification and Verification
Adoption	Traditional/established	Transitional Strategy	Immediate implementation
Organization	Traditional/established	Transition based on maturity	ASTM E 2500 roles / responsibilities in place
Risk Assessment	Impact Assessment	Qualitative Risk Assessment based on product knowledge	Integrated QRM based on ICH Q9
Regulatory	Compliance focus	Product Quality focus	Patient safety focus

Advantages of a Science- and Risk-Based Approach

Application of a Science- and Risk-Based Approach 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.

Risk management approaches based on analyzing risk to patient safety and product quality provides better definition of critical aspects, and may save effort in execution (versus system and component impact assessment). Other benefits include:

Improvements in design to meet science-based process requirements, and improved effectiveness and lower cost of inspections and testing.

Efficient and focused use of resources, ensuring they are directed to quality critical aspects and activities.

Better application of resources and better conformance to GxP regulations, due to the clarification of the roles of Quality Assurance (QA) and Subject Matter Experts (SMEs).

Role of the Applied Risk Management Guide

The ISPE Good Practice Guide: Applied Risk Management in Commissioning and Qualification aims to assist companies to achieve these benefits, by moving from traditional approaches toward a fully science- and risk-based approach. It does this by:

describing the application of Quality Risk Management (QRM) to traditional C&Q practices

linking the traditional terminology of C&Q (as used in Baseline Guide Volume 5) to the Verification terminology of the FSE Guide and ASTM E2500

outlining bridging strategies for organizations with well-established Qualification-based Quality Management Systems

providing a roadmap showing the spectrum of potential approaches for moving from the approach described in Baseline Guide Volume 5 to that suggested in the FSE Guide, ASTM E2500, and ICH Q9

A Transitional Strategy

A Transitional Strategy is described in the Applied Risk Management Guide, reflecting that the full framework of approaches described in the FSE Guide may not be immediately achievable in all organizations.

The full science- and risk-based approach as described in the FSE Guide has prerequisites for effective implementation, and it may take time for an organization to put these in place.

Traditional terminology and concepts are often embedded in Quality Management Systems. Changing the QMS must be done carefully, and with input from appropriate stakeholders, while ensuring continued compliance.

Existing documents and templates must be taken into consideration, and changes may require significant time and cost. As processes, documents, and templates are changing, the organization will still require practical approaches and tools, such as classification systems, for on-going projects.

Adopting the science- and risk-based approach will bring long term benefit, but the short term day-to-day business needs must also be considered.

Strategically, however, the regulatory expectations for adoption of Quality Risk Management approaches are becoming very clear. This requirement will increasingly lead to purely traditional approaches becoming non-compliant as well as non-competitive over time.

Which Approach to Take?

Given the major benefits of adoption of the science- and risk-based approach, should a particular organization immediately adopt the FSE Guide approach? Or should it adopt a transitional strategy for moving from a traditional C&Q approach, by following the Applied Risk Management Guide?

The following table will assist organizations in deciding which approach is suitable for them.

Adopt FSE Guide Immediately	**Follow Applied Risk Management Guide Transitional Approach**
New or flexible Quality Systems	Established Quality Systems
Without significant legacy terminology/mechanisms	Embedded terminology
Organizationally capable	Non-risk based culture
	Organizational maturity curve

References

1. ISPE Baseline Guide, Volume 5: Commissioning and Qualification.
2. ISPE Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment.
3. ISPE Good Practice Guide: Applied Risk Management in Commissioning and Qualification.
4. Pharmaceutical Development – Q8(R2), International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
5. Quality Risk Management – Q9, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).
6. Pharmaceutical Quality System – Q10, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), www.ich.org.
7. ASTM E2500-07 Standard Guide for Specification, Design, and Verification of Pharmaceutical and Biopharmaceutical Manufacturing Systems and Equipment.