PQLI®
Guide Series

Product Quality Lifecycle Implementation (PQLI®)
from Concept to Continual Improvement

Part 3 – Change Management System as a Key Element of a Pharmaceutical Quality System

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Disclaimer:
This Guide aims to describe potential product lifecycle approaches to a change management system within a Pharmaceutical Quality System. 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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Preface

The ISPE Product Quality Lifecycle Implementation (PQLI) Good Practice Guide (GPG): Change Management System is Part 3 of the ISPE Guide Series: PQLI from Concept to Continual Improvement, which is a product of the ISPE PQLI program.

The modern pharmaceutical quality system described in ICH Q10 is a holistic approach which helps to facilitate the consistent development and production of high quality pharmaceutical products. The ISPE PQLI GPG: Change Management System describes potential product lifecycle approaches to the change management system element of a pharmaceutical quality system. These approaches can help to achieve the opportunities described in ICH Q10.

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This Guide was produced by an individual Task Team led by Rob Hughes of AstraZeneca (Chair). The work was supported by the ISPE PQLI Technical Committee.

Change Management Core Team

Rob Hughes (Chair)	AstraZeneca	United Kingdom
Lilian Hamilton	AstraZeneca	Sweden
Claire Myles	formerly of AstraZeneca	United Kingdom
Susan L. Schebler	Eli Lilly	USA
Mike James	GlaxoSmithKline	United Kingdom
Ron Taticek	Genentech, Inc.	USA

Corresponding Team

Michael Choi	Teva Pharmaceutical	USA
Bernd Boedecker	Trade & Industry Inspection Agency (German Inspectorate)	Germany
Gregory Tewalt	Samsung BioLogics	South Korea
Takeshi Takashima	Powrex Corp. / ISPE Japan	Japan

ISPE PQLI Technical Committee

Gretchen Allison	Pfizer Inc.	USA
Joanne Barrick	Eli Lilly	USA
John Berridge	Consultant	USA
Bruce Davis	Bruce Davis Global Consulting	United Kingdom
Ranjit Deshmukh	MedImmune	USA
Joe Famulare	Genentech, Inc.	USA
Rob Hughes	AstraZeneca	United Kingdom
John Lepore	Merck & Co., Inc.	USA
Line Lundsberg-Nielsen	NNE Pharmaplan	United Kingdom
Roger Nosal	Pfizer Inc.	USA
Chris Potter (Co-Chair)	Consultant and PQLI Technical Project Manager	United Kingdom
Steve Tyler (Chair)	Abbott Laboratories	USA

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Connecting a World of Pharmaceutical Knowledge

ISPE Headquarters
600 N. Westshore Blvd., Suite 900, Tampa, Florida 33609 USA
Tel: +1-813-960-2105, Fax: +1-813-264-2816

ISPE Asia Pacific Office
73 Bukit Timah Road, #04-01 Rex House, Singapore 229832
Tel: +65-6496-5502, Fax: +65-6336-6449

ISPE China Office
Suite 2302, Wise Logic International Center
No. 66 North Shan Xi Road, Shanghai, China 200041
Tel +86-21-5116-0265, Fax +86-21-5116-0260

ISPE European Office
Avenue de Tervueren, 300, B-1150 Brussels, Belgium
Tel: +32-2-743-4422, Fax: +32-2-743-1550

www.ISPE.org

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1 Introduction

1.1 Background

The modern Pharmaceutical Quality System (PQS) described in ICH Q10 [1] is a holistic approach which helps to facilitate the consistent development and production of high quality pharmaceutical products. It also aims to support innovation and continual improvement of products, processes, and methodologies in accordance with the concepts described in ICH Q8 (R2) [2] using knowledge management and quality risk management, (see ICH Q9) [3].

A modern PQS is considered key to enabling the effective implementation of ICH Q8 (R2) and Q9.

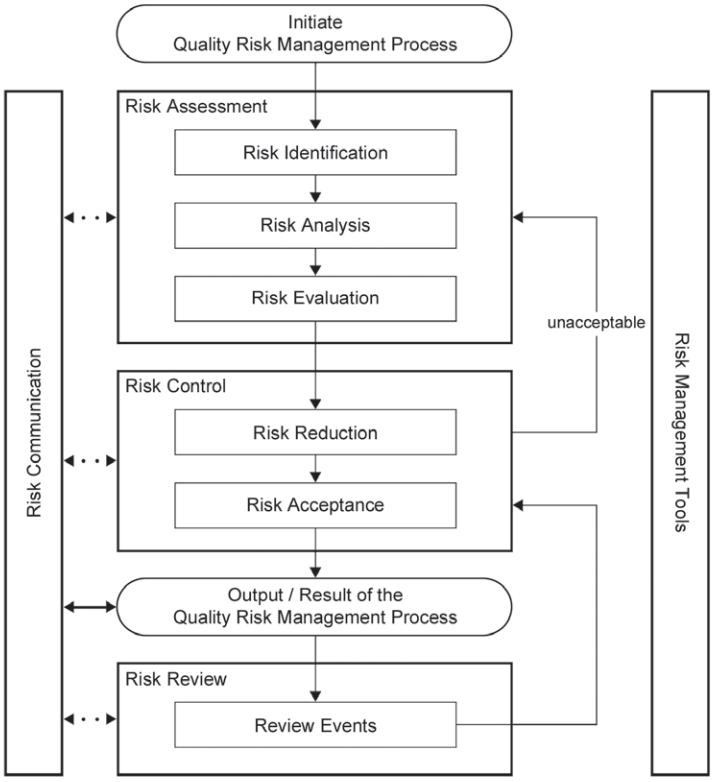
As part of the approach to support the implementation of modern quality thinking and design strategies, ICH Q8 (R2) aims to allow manufacturers to apply more effective control over the management and implementation of changes for drug products which have been developed using the principles of Q8 (R2). It also encourages the assessment of process performance and monitoring of product quality.

ICH Q8 (R2) is one in a suite of complementary ICH guides that define and encourage a modern approach to pharmaceutical quality management. It defines key concepts such as design space and control strategy, and is considered a key enabler in the acquisition, development, and transfer of knowledge for drug products.

ICH Q11 [4] provides further clarification on the principles of ICH Q8 (R2), ICH Q9, and ICH Q10 as they relate to the development and manufacture of drug substance (API).

ICH Q9 provides guidance on the principles of quality risk management and the use of quality risk management tools. These tools can enable more effective and consistent risk-based decisions across the product lifecycle (see Figure 1.1).

Figure 1.1: Overview of a Typical Quality Risk Management Process (from ICH Q9)

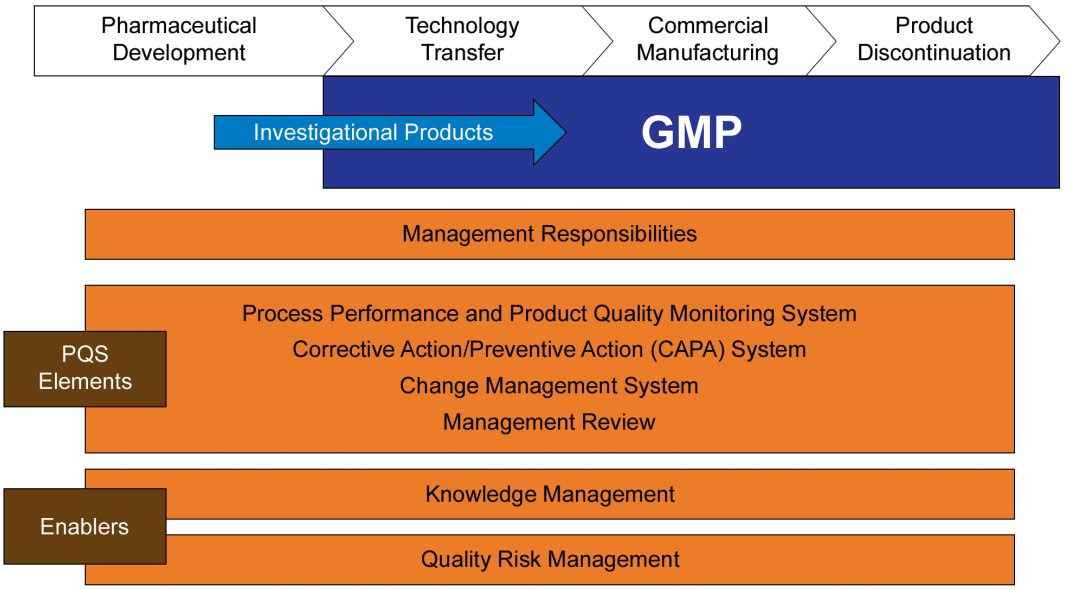


ICH Q10 describes a lifecycle approach to a PQS, from development through product discontinuation. The knowledge about a pharmaceutical product and the processes required to reliably produce that product starts with product and process development. An effective PQS uses the knowledge acquired throughout the lifecycle of the product, builds on that knowledge, and applies it to:

- Other stages of the product lifecycle
- Other product lifecycles

A change management system is an important element of a PQS as seen in Figure 1.2 – reproduced from ICH Q10, [1], which illustrates the major features of the ICH Q10 PQS model over the product lifecycle.

Figure 1.2: Diagram of the ICH Q10 Pharmaceutical Quality System (from ICH Q10)



The ICH Q10 model also describes management responsibilities and specifies the four elements of a PQS (ICH Q10 Section 3.2) as:

1. Process Performance and Product Quality Monitoring System
2. Corrective Action and Preventive Action (CAPA) System
3. Change Management System
4. Management Review of Process Performance and Product Quality

A change control system which is a GMP requirement is described in ICH Q7 [5]; however, a change management system which is discussed in ICH Q10 is considered much broader in scope.

1.2 Purpose

The purpose of this Guide as a key element of a pharmaceutical quality system is to describe potential product lifecycle approaches to the change management system element of a PQS (ICH Q10 Section 3.2). These approaches can help to achieve the opportunities described in ICH Q10.

The principles described in this Guide also can be applied to alternative PQS approaches that organizations may choose to implement.

The Guide aims to:

1. Describe different interpretations of PQSs, based on regional GMPs, ICH Q10 guidance, and ISO standards, to help meet regulatory expectations.

2. Provide clear guidance on achieving compliant change management systems.

3. Describe how to implement compliant change management systems within a PQS with example case studies.

4. Demonstrate the inter-relationship between ICH Q8 (R2), ICH Q9, and ICH Q10.

1.3 Scope

This Guide aims to provide descriptions of good practices for change management.

Good practices can apply to products and processes developed using minimal or enhanced, Quality by Design (QbD) approaches as discussed in Appendix 1 of Q8 (R2) [2]. Changes may occur as a response to a problem-solving activity or due to a corrective action resulting from an investigation, even when using the minimal QbD approach. Some form of change management system is required regardless of the type of quality system used.

Note: good practices described in this Guide also may be applied to drug substance (API) manufacture as given in the change control Section 13 of ICH Q7, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients [5].

1.4 Benefits

The benefits of this Guide as applied to products and processes developed using minimal or enhanced, QbD approaches as discussed in ICH Q8 (R2) and Q11 include:

1. Facilitating a compliant and consistent approach to the implementation of change management.

2. Provision of practical guidance on the use of ICH Q9 in the context of change management within a modern PQS.

3. Description of approaches to change management within a PQS which are consistent with GMP regulations and ISO standards.

1.5 Key Concepts

The key concepts in this Guide include:

1. The lifecycle approach, as promoted in ICH Q10; using a consistent change management model throughout.

2. The role of the change process steward and how that can be applied in national and multi-national settings.

3. ICH Q10 and ISO 9001 quality systems and how they can be applied to assist GMP compliance in a modern PQS setting.