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

Part 4 – Process Performance and Product Quality Monitoring System

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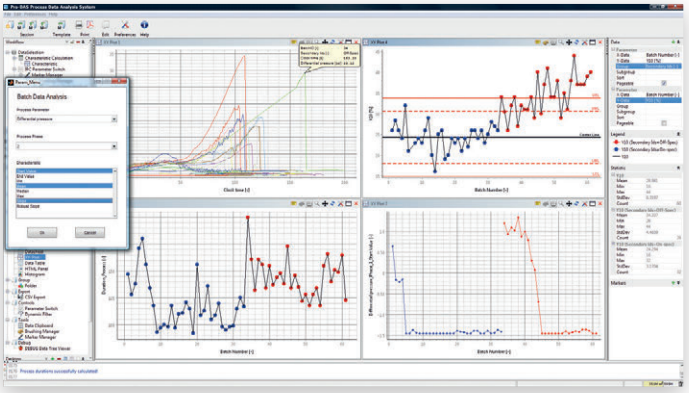

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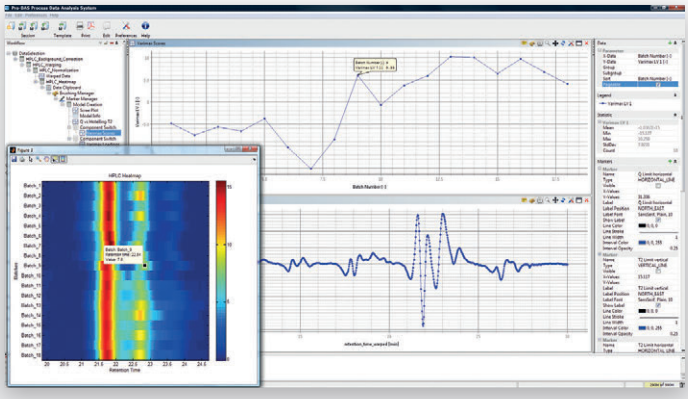

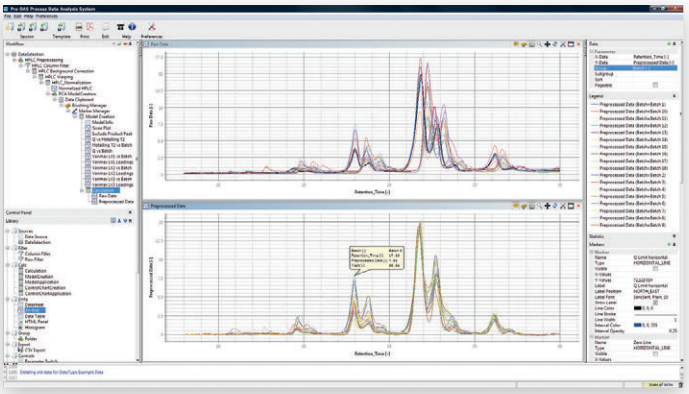

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Guide Series

Product Quality Lifecycle Implementation (PQLI®)
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Part 4 – Process Performance and Product Quality Monitoring System

Disclaimer:
This Guide aims to provide "how to" guidance for establishing and implementing a Process Performance and Product Quality Monitoring System (PP&PQMS) in line with the expectations of the ICH Q10 guideline. 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): Process Performance and Product Quality Monitoring System (PP&PQMS) is Part 4 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: Process Performance and Product Quality Monitoring System considers process performance and product quality monitoring systems established to support products and processes developed using the enhanced, Quality by Design approach. This Guide is intended to be compatible with the process validation guidance issued by the FDA and the draft guideline on process validation issued by the EMA.

This Guide is relevant to the development and manufacture of drug substance and drug product for both small and large molecules. It is also applicable to new and existing products.

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1 Introduction

1.1 Objectives

The ICH Q10 guideline, Pharmaceutical Quality System [1], states that a process performance and product quality monitoring system (PP&PQMS) should be planned and executed to ensure that process performance and product quality are maintained in a state of control. The objective of this Guide is to provide "how to" guidance for establishing and implementing a PP&PQMS in line with the expectations of the ICH Q10 guideline. Examples of technical and scientific methodology and supporting management processes are provided.

Part 4 of the ISPE PQLI Guide Series, PP&PQMS, considers process performance and product quality monitoring systems established to support products and processes developed using the enhanced, Quality by Design (QbD) approach as discussed in ICH guidelines:

- ICH Q8(R2), Pharmaceutical Development [2]
- ICH Q9, Quality Risk Management [3]
- ICH Q11, Development and Manufacture of Drug Substances [4]

These systems are exemplified in other parts of the ISPE PQLI Guides Series including, Part 1, Product Realization using Quality by Design, Concepts, and Principles [5] and Part 2, Product Realization using Quality by Design (QbD), Illustrative Example [6].

This Guide is intended to be compatible with the process validation guidance issued by the FDA [7] and the draft guideline on process validation issued by the EMA [8].

This Guide should be read in conjunction with Part 3 of the ISPE PQLI Guide series, Change Management System [9]. These two Guides are PQS parts of the PQLI Guide series and support implementation of two of the Pharmaceutical Quality System (PQS) elements recognized in ICH Q10 [1] as enhancements of regional Good Manufacturing Practice (GMP) regulations.

1.2 Scope

This Guide (as is the case with ICH Q10 [1]) is relevant to the development and manufacture of drug substance and drug product for both small and large molecules. It is also applicable to new and existing products.

A PP&PQMS should apply to an entire organization or a site or division within an organization. The PP&PQMS should apply to all products within the assigned part of an organization. Each product should have its own control strategy and associated process performance and product quality monitoring program.

This Guide applies across all phases of the product lifecycle from development to product discontinuation. In the pharmaceutical development phase, data and knowledge emerge which support the development of the techniques and methodologies, including appropriate acceptance criteria which are monitored within the PP&PQMS. During the development phase, even in the later stages (e.g., Phase 3 clinical supply manufacture) application of the PP&PQMS is likely to be limited. However, in the technology transfer phase, there is potential to experiment with these techniques and methodologies. Full implementation will usually occur throughout the commercial manufacturing phase and will be gradually discontinued during the product discontinuation phase.[1]

[1] Stability testing may still need to be performed.