



Standard Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture¹

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INTRODUCTION

This document provides guidance on the implementation of risk assessment and risk control for Process Analytical Technology (PAT) processes within the pharmaceutical industry. Wherever possible, other appropriate standards on risk assessment/management have been referenced and acknowledged. Where practical, further details of methods and additional references have been provided for information within the appendices.

The application of risk assessment and risk control is pivotal to the creation of PAT systems, which are described as “science-based” and “risk-based.” Such application starts at an early stage in the development of the process and continues throughout development and production. In the production phase, it is a crucial component of applying continuous improvement to the process.

RELATIONSHIP TO ICH Q9

The ICH Q9 Guideline for Quality Risk Management is intended for general application within the pharmaceutical industry. ICH Q9 describes the requirements for pharmaceutical quality risk management and considers the risk as “risk to the patient.”

This document provides specific guidance on the risk assessment and risk control phases identified in ICH Q9 in a limited set of conditions. It is applicable where the manufacturing method is compliant with Process Analytical Technology (PAT) principles, and where the primary considerations are product quality and reduction of process and product variability. The only component of risk to patient considered here is risk to product quality. Other components fall outside the scope of the document. In addition, other areas identified in ICH Q9, such as general risk management and risk communication, are not considered here.

This document provides guidance which applies to the design, development, and operation of PAT systems. It should be considered as a specific extension, supporting the ICH Q9 guidance for these processes.

1. Scope

1.1 This document provides guidance on the assessment of risks to product quality within and related to PAT processes in

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the pharmaceutical industry. It addresses those risks to product quality arising from, associated with, identified by, or modified by the implementation of PAT in pharmaceutical development and manufacturing for primary, secondary, and biotech sectors of the industry. It does not replace those assessments of risk currently undertaken by pharmaceutical companies, but is, rather, an additional component focused specifically upon the evaluation and design of PAT processes. See Practice E2474, Guide E2500, and ICH Q8.