Technical Report No. 60-2

Process Validation: A Lifecycle Approach

Annex 1: Oral Solid Dosage/ Semisolid Dosage Forms

Process Validation: A Lifecycle Approach — Annex 1: Oral Solid Dosage/Semisolid Dosage Forms Technical Report Task Force

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1.0 Introduction

This document is an annex to *PDA Technical Report No. 60: Process Validation: A Lifecycle Approach* (TR 60). It applies the process validation lifecycle to oral solid dosage and semisolid dosage products.

TR 60-2 is organized in a manner that illustrates how the entire process validation lifecycle presented in TR 60 relates to oral solid and semisolid dosage forms, with their unique technologies and well-characterized processes. This includes a brief explanation of the technologies associated with oral solid and semisolid products, as well as a discussion of the lifecycle stages—Stage 1: *Process Design*; Stage 2: *Process Qualification*; and Stage 3: *Continued Process Verification*. Legacy product validation and validation lifecycle enablers, such as risk and knowledge management, are also presented. Finally, but more importantly, TR 60-2 outlines some specific case studies that illustrate how these concepts are specifically addressed for each dosage form.

1.1 Purpose

The purpose of this annex is to illustrate how concepts from TR 60 can be applied to oral solid and semisolid dosage drug products so the reader can gain a clear understanding of the application of the process validation lifecycle to these technologies ***(1).***

1.2 Scope

The scope of this document is limited to the application of the concepts outlined in TR 60 to oral solid dosage forms, such as tablets and capsules (excluding liquid-filled capsules), and semisolid dosage forms, which includes creams, ointments, and suppositories.

2.0 Glossary of Terms

Terminology may differ by company and some terms may be subject to change over time. Those terms used in a validation program should be clearly defined, documented, and well understood. When establishing internal definitions, terminology definitions that are widely recognized by the industry should be considered. These can be found in regulatory guidance documents. Definitions of company-specific terminology should also be included in the validation documents to provide clarity and context. This technical report uses the terms below, which are accompanied by their definitions, synonyms, and references where applicable:

Attributes

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 ***(2).***

Process Performance Attribute (or Process Performance Parameter)

An output variable or outcome that cannot be directly controlled but is an indicator that the process performed as expected ***(3).***

Quality Attribute

A molecular or product characteristic that is selected for its ability to indicate the quality of the product. Collectively, the quality attributes define identity, purity, potency, and stability of the product, and safety with respect to adventitious agents. Specifications measure a selected subset of the quality attributes ***(4).***

Continued Process Verification (CPV)

US FDA

Assuring that during routine production the process remains in a state of control ***(5).***

Continuous Process Verification

ICH

An alternative approach to process validation in which manufacturing process performance is continuously monitored and evaluated ***(2).***

Critical Process Parameter (CPP) (or Critical Operational Parameter)

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 ***(2).***