Analytical Quality by Design Approach to the Development Stage in the Lifecycle of an Analytical Procedure

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1 Introduction

The lifecycle approach to analytical procedures is based on processes, terms, and techniques that ensure adequate risk analysis is performed, thus reducing the chance of failure. In addition the lifecycle approach, through the use of decision rules, target measurement uncertainty (MU) and the analytical target profile (ATP), provides a mechanism for effective, timely, complete communication within a company. An example of dfinieveloping an analytical procedure using the approaches and statistical tools of analytical quality by design (aQbD) in the lifecycle of an analytical procedure is presented.

In this article we use the terminology from the USP stimuli articles i, ii, iii, iv, v, vi on the lifecycle approach to analytical procedures. Analytical procedure is used instead of method or test method. The term method is reserved to describe the analytical technique or technology. Analytical procedure qualification is used instead of method validation, lifecycle stage 2. Continued verification is used to describe the lifecycle stage 3, routine use of an analytical procedure.

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