International Alliance for
Biological Standardization

# 9th Annual IABS Statistics Workshop
# Applying Statistics and Data Science to Evolving Technical and Regulatory Paradigms

November 7-9, 2023
University of Maryland - IBBR, Rockville, MD, USA

**Title: Links between Total Analytical Error, Measurement Uncertainty, Analytical Target Profile and Quality Target Product Profile.**

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For decades, the pharmaceutical industry has focused on validating analytical processes to demonstrate the assay or bioassay's effectiveness in terms of accuracy, precision, and linearity. Over time, it has become evident that the primary goal is to ensure that laboratory results meet sufficient quality standards.

Numerous publications have illustrated that achieving acceptable accuracy and precision may not always guarantee appropriate result quality. The recent introduction of ICH Q2(R2), endorsing the concept of "combined accuracy and intermediate precision" or what has long been recognized as "Total Analytical Error," underscores the need to accurately convey the relationship between measurement uncertainty and result quality during method validation.

In this presentation, we will provide an overview of Target Measurement Uncertainty (TMU) as a crucial concept encompassing bias, precision, and their respective uncertainties across various concentration levels within the working range. We'll discuss how TMU can be derived from the product or intermediate acceptance limits (Quality Target Product Profile – QTPP) to establish a well-defined Analytical Target Profile (ATP).

Lastly, we'll explore how TMU and QTPP can aid in identifying zones of uncertainty, especially when a measurement closely approaches a specification. We'll delve into how replication and a comprehensive understanding of the assay (e.g., Target Measurement Uncertainty - MMU) can minimize these zones of uncertainty, ensuring that the measurement's quality consistently aligns with its intended purpose.