

Quality-by-Design for Analytical Procedures: The Analytical Target Profile

By **Jane Weitzel** Mar 12, 2014 1:39 pm PDT

Clarity, confidence, probability, prospective, and fit-for-intended-use are all characteristics and outcomes of the analytical target profile (ATP). As discussed in the previous column, the ATP is analogous to the quality target product profile (QTPP), which is a prospective summary of the quality characteristics of a drug product. For an analytical procedure, the ATP is a prospective summary of the objectives of the procedure. It defines the quality requirements, including the expected level of confidence, for the reportable result that will ensure the analytical result is fit-for- its- intended-use. Criteria defined in the ATP refer to the quality data attributes of the reportable result (i.e., bias [accuracy] and target measurement uncertainty), which includes all sources of variability, including precision.

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