

A Step-by-Step Approach to Establishing a Method Validation Program



Cindy Green

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The information in this article is intended to provide a systematic approach for establishing a method validation program. There are a variety of product types that require some level of evaluation and testing either at the raw material, intermediate, or final product level. There is no question that critical decisions may be made based on these test results and therefore, it is logical that one must strive to ensure the accuracy and reproducibility of these results. Recognizing that all of us desire to achieve a high level of confidence in the reported results, we must also be mindful that there...

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