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trilogy of “back to basics” books that focus on analytical quality management. The other two books are Basic QC Practices and Basic Planning for Quality. When I teach these materials, I start with method validation because it introduces the basic concepts of analytical performance and the experimental and statistical techniques needed to describe performance

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IV. ANALYTICAL METHOD VALIDATION

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Guidelines from the USP, ICH, FDA etc., can provide a framework for validations of pharmaceutical

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methods. Results from the method validation can be

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