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Delphi Analytical Services, Inc. has spent the past several years helping companies in the pharmaceutical industry improve their level of compliance with current good manufacturing practices (CGMPs). This involvement has included large and small companies who have already been subject to regulatory action from the Food and Drug Administration (FDA) as well as companies who are taking preventative measures to avoid regulatory action. As part of this effort, a significant amount of time has been spent reviewing analytical and bioanalytical methods and methods validation documentation.

Unfortunately, our experience leads us to conclude that despite improved guidance from the FDA, leadership by the International Conference on Harmonization (ICH), and the plethora of validation experts and courses, a substantial need still exists for education, training, and periodic retraining in the field of methods validation.

Make no mistake, analytical methods validation is not a trivial undertaking. And like snowflakes, no two are exactly alike. However, our experience has brought us in contact with what we consider to be the best practices in the industry. In addition, we have seen some of the mistakes that often degrade the overall quality of the finished product: A validated, transferable, analytical method that will serve its end users for an extended period of time with minimal complications.

In our experience, very few labs have it “all together” and execute *all* the components of a methods validation well. This guide was written with the intent to bring order to the potentially chaotic process of methods validation.

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If you are new to methods validation, we hope to provide you with enough practical information and tools to keep you from having to reinvent the wheel by having to develop your own systems and to attack methods validation from scratch. If you are experienced with methods validation, we hope you will use this guide to upgrade and improve your existing systems.

This guide focuses on chromatographic methods validation, specifically high performance liquid chromatographic (HPLC) methods validation. This approach was chosen in that HPLC is by far the most common analytical technique used in modern pharmaceutical analytical R&D/QC laboratories. However, the concepts are in many cases directly applicable to validation of other analytical techniques as well.

In that CGMPs are always changing (hence the “C” meaning “current”) and the industry is always improving and upgrading its best practices, we encourage your feedback and comments so that we can keep this guide in line with the best practices of the industry. We look forward to your input and hope this guide assists you in your continuing quest for quality.

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