Method Development and Validation

As companies are focusing on achieving ever shorter times of drug to market, it is vital that a tailored, pragmatic approach is adopted when engaging in both method development and validation activities for an Active Pharmaceutical Ingredient (API), Drug Product (DP) or Medical Device.

Successfully developed and validated analytical methods can reduce overall turnaround times spanning from pre-clinical right through to commercial release, with a well-developed method underpinning a robust product. Starting with the end point in mind, methods would have the desired flexibility built in during the early stages to allow easy translation from API to DP, thus potentially reducing costs throughout the product life cycle.

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Method Development

Many years of experience working with a diverse client base and a multitude of different dosage forms means we can support you on developing robust, fit-for purpose methods appropriate for potency, purity, physical characteristics and stability.

Our specialists offer a wealth of knowledge and advice on areas ranging from sample preparation and extraction techniques to regulatory requirements and specialised methodology.

Method Validation

Following successful method development, we can perform Phase appropriate method validation (see table below) according to the ICH Q2 (R1) recommendation for the analytical procedure. We can also validate methods developed by other laboratories, and perform a gap analysis of previously validated methods to ensure they meet the current guidelines and maximise the success for a regulatory filing.

Typical Drug Life-Cycle Validation Requirements:

Preclinical	Tox. Studies	Phase I & II	Phase III

Method Development
• Create robust method
	Limited Validation
	• Accuracy
	• Precision
	• Repeatability
	• Specificity
	• Detection Limit*
	• Quantitation Limit*
	• Linearity
	• Range
		Limited Validation
		• Accuracy
		• Precision
		• Repeatability
		• Specificity
		• Detection Limit*
		• Quantitation Limit*
		• Linearity
		• Range
			Full ICH Validation
			• Accuracy
			• Precision
			  • Repeatability
			  • Intermediate Precision
			• Specificity
			• Detection Limit
			• Quantitation Limit
			• Linearity
			• Range
			• Robustness

Good documentation and development report	**Good documentation and development report, protocol where applicable**	**Validation protocol with pre-defined acceptance criteria and report**	**Full ICH validation protocol with pre-defined acceptance criteria and report**

* Optional parameter dependent upon method requirements

Contact us to find out more about our expertise and how we can support you:

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