Course Title & Description	Topics	Typical Course Duration
Data Visualization for Problem Solving: Leverage graphical tools along with problem solving methods to increase process understanding and speed root cause analysis	• Become a data sleuth • Benefits and criticality of graphical and exploratory analysis tools to solve problems and in combination with formal statistical analysis • Sources of variability and how graphical tools reveal information about them	1/2 – 1 day
Introduction to Design of Experiments: Concepts, Benefits, Common Designs, Results	• Common DOE terms and fundamental DOE concepts • Benefits of DOE and advantages of multifactor vs. one-factor-at-a-time (OFAT) experiments • Attributes of common designs • Sequential strategy of experimentation • Common DOE output	1/2 – 1 day
Intermediate Design of Experiments: Develop Level 1 skills (create and analyze with mentor)	*All from Introduction to DOE +* • Choosing among common designs and planning for experimentation • Design elements of a DOE (replicates, blocking, power, residual analysis, etc.) • Design and analyze (in class, with guidance): • 2-level full factorial (in class, with guidance) • 2-level fractional factorial • Response surface design • Planning sequential stages of experimentation	2 additional days beyond introduction
Intermediate Design of Experiments: Develop Level 2 skills (create and analyze with confirmation from expert)	*All from Introduction to DOE +* • Design and analyze (*first* in class, with guidance, *then* independently with confirmation from expert a selection from): • 2-level fractional factorial • Response surface design • Identify other advanced design options (optimal designs, definitive screening design, custom designs), describe when they might be appropriate to choose instead of a traditional design, and analyze with guidance	4 additional days beyond introduction
Statistics Across the Process Lifecycle: Overview and benefits of common statistical methods leveraged across the process lifecycle	• Statistics as an integral part of a risk-based approach to PV • Key statistical concepts and analyses that relate to objectives in each stage of the process validation lifecycle • DOE role in a robust control strategy • Statistical intervals and assurance of quality • Increase understanding and reduce risk with control charts • Avoid the dangers of applying “textbook SPC” to CPV	1/2 – 1 day

Introduction to Sampling Plans for PPQ: Key concepts	• Link statistical sampling plans to the goals of PPQ • Key considerations for determining an optimal sampling plan for PPQ • Sampling schemes • Variance components analysis • Assure quality with statistical intervals • Key concepts to develop sample size for both continuous and pass/fail measurements • Avoid the risks of statistically based pass/fail criteria • A risk-based approach to the number of PPQ batches	1/2 day

PPQ Sampling Design and Analysis: Statistical methods for continuous and attribute data	*All from Introduction to Sampling Plans for PPQ +*
	• Statistical assessment of PPQ performance
	  ○ Data visualization
	  ○ Tolerance interval for a continuous measurement
	  ○ Design and analyzing variance components
	  ○ AQL and RQL sampling plans
	• Computing sample size with the end in mind using development data
	• Preparation for Stage 3A
		1 – 1.5 additional days beyond introduction

Introduction to CPV: CPV Plan concepts and general statistical methods to monitor the process	• Goals of CPV, including the differences between Stage 3a and Stage 3b • Increase process understanding and reduce risk with control charts • Monitoring vs trending • "State of control" • Risk-based evaluation of signals on a control chart • Process capability including difference between Cpk and Ppk • Clinically relevant vs performance based specifications	1/2 day
Statistical Methods for CPV: Deeper dive into CPV: Design of a CPV Plan, Stage 3 A enhanced sampling, statistical Methods	*All from Introduction to CPV +* • Risk based approach to the what and when of a CPV plan • Types of control charts • Common violations of assumptions for a control chart and capability analysis • Enhanced sampling in Stage 3a • Historical, logistical, and scientific context to control chart interpretation • Establishing static control limits • Lean thinking in a CPV plan	1.5 days additional days beyond introduction

Common Mistakes in Data Analysis	• Normality - is it required, and how to test for it • Statistical power and common conclusions that rely on adequate power • Underlying assumptions of control charts and how that affects the interpretation • Dangers of aggregation • Model residual analysis • Statistical vs practical interpretation	1/2 day

Analytical Procedure Lifecycle concepts	• USP <1220> revisions
	• Using DOE and Gage R&R to:
	  ○ Develop method robustness
	  ○ Streamline assay validation
	  ○ Identify optimal assay format
	Dive deeper into DOE with any of the general DOE classes we offer!
	• Analytical Procedure Lifecycle Management (monitoring, transfers, bridging)
		1 day