Statistical Techniques to Support Validation Seminar
Syllabus Rev.1

Module	Topics
Session Kick-Off	• Introduction • Course objectives and expectations • The statistical mindset
Location and Dispersion	• Data Type • Average and Standard Deviation • The knowledge of Variance
Regulations and Requirements	• FDA CFR Part 21 820.250 Statistical Techniques • ISO 13485:2016 - §7.3.6 Design and development verifications • Applicative examples
CPP/CQA	• How to find a CPP? • DOE complete example
Normal Distribution	• Histogram and the Standardized Z-distribution • Transformations • Oriented Examples
Intervals	• Confidence Interval • Tolerance Intervals
Sampling	• OC Curves • Confidence and Significance levels • Type I and Type II errors
Sample size Determination	• Continuous Data • Attribute Data
Process Capability	• *Cp* and *Cpk* • Regulatory Guidelines on Process Capability • Sample size for a minimum *Cpk*
Session Wrap-Up	• Feedback • Reflection for next session