



Test Method Validation TMV Seminar- in Medical Device Industry

Module	Topics
Session Kick-Off	<ul style="list-style-type: none">• Reflections from last session
MSA Motivation	<ul style="list-style-type: none">• Daily Life• Built-in manufacturing Variance• Types of study for MSA and TMV
Regulations	<ul style="list-style-type: none">• FDA CFR Part 21 820.72 Inspection, measuring and test equipment• ISO 13485:2016 - §7.6 Control of Monitoring and Measuring Equipment
Metrology	<ul style="list-style-type: none">• Introduction• Application fields• Traceability and Main components
Correction approach for Measuring error	<ul style="list-style-type: none">• Static errors• Dynamic Errors• Accuracy X Precision
Type I study	<ul style="list-style-type: none">• Definitions• Cg and Cgk• Examples
TMV Example	<ul style="list-style-type: none">• How to Plan a TMV study• Cross X Nested approach definitions and NDC Concept• Formulae and Calculations
TMV Class exercise	<ul style="list-style-type: none">• Measuring with active participation using templates• Analysis of data (Consistency and Bias) obtained from the exercise• Improvement recommendations• ANOVA approach for TMV
Attribute TMV	<ul style="list-style-type: none">• Real life example• Accuracy, False Acceptance, False Rejection• Repeatability and Reproducibility Analysis• Kappa Statistics
Final Remarks	<ul style="list-style-type: none">• Trouble-shooting for TMV• Common mistakes, when not to do TMV• How to improve Test Method Validation
Session Wrap-Up	<ul style="list-style-type: none">• Open Questions• Feedback