***סילבוס קורס Process Validationבמכשור רפואי 2022***

***A practical approach to Medical Device Process Validation***

The aim of this course is to learn Process Validation for Medical Devices. The emphasis of this content-rich course is to provide the participants those methods which will enable them to cope with the Validation challenges at the Medical Device industry under the regulatory requirements from the 21CFR 820 FDA and ISO 13485. Special processes, Validation principles and hands-on techniques will be discussed including Risk Assessment, Master Validation Plans, Installation, Operational and Performance qualifications.  Examples of worst-case conditions and case studies will be extensively explored including Sample size selection, Process Capability and how to maintain the state of validation.

**Intended for:** Validation engineers, QA, Process engineers, R&D, NPI

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| **Day 1 Introduction and requirements** |
| 1. Regulatory Requirements
2. When is Process Validation required?
3. How to start Process Validation
	* Process flow diagram, Risk Management
	* dFMEA X pFMEA
4. Process Validation Master Plan – PVMP
5. Installation Qualifications – IQ (Requisites and Engineering support)
6. Computer Software Validation

**Practical examples**  |
| **Day 2 – OQ/PQ**  |
| 1. Operational Qualification – OQ
	* DOE and Worst-Case determination
2. Performance Qualification – PQ
	* Manual Assembly and Complex manufacturing processes
3. Maintaining the State of Validation and Guidelines for Re-Validation
4. Protocols & Reports

**Practical examples**

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| **Day 3 – Statistical aspects for a Successful Validation** |
| 1. Regulation and Requirements
2. Critical Process Parameters
3. Normal Distribution and Transformations (When to use it?)
4. Confidence and Tolerance Intervals
5. Operational Characteristics Curve
6. Sample Size Determination for Continuous and Discrete variables
7. Cp and Cpk

**Practical exercises**  |

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| **Day 4 – Test Method Validation (TMV)** |
| 1. Regulatory aspects of measuring and test equipment
2. Measurement Systems – an Introduction to Metrology
3. Test Method Validation – TMV (Variable and Attribute).
4. Gage R&R – (Average Range X ANOVA methods)

**Practical exercises** |
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