***סילבוס קורס רגולציה, ואיכות במכשור רפואי / נובמבר+דצמבר***

***2022***

***A practical approach to medical device regulatory and quality aspects***

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| **Day 1** - **Medical Devices Quality System Requirements** |
| 1. **Culture for Quality & Quality System According to ISO 13485:2016**  * General requirements, Scope & Definitions * Document and Record controls (DHF, DMR, DHR, QMS records) * Management responsibility, Resource management, Quality reviews      1. **Purchasing controls**  * Purchasing process, Purchasing information, Evaluation and selection of suppliers * Acceptance sampling inspection principles  1. **Production controls**  * Production & service control, Process Verification and Validation, Measuring equipment * Process capability and process control concepts   **Practical exercises** |
| **Day 2 - Design Controls & Monitoring and Feedback** |
| 1. **Design controls**  * Design planning and development, Customer related processes * Design verification and Product validation  1. **Monitoring and Feedback**  * Nonconforming product, Complaint handling, Corrective and Preventive Action (CAPA) * Internal audit & MDSAP concepts   **Practical exercises** |
| **Day 3 - Medical Device Regulations - Europe** |
| 1. Medical device classification according to Europe regulations 2. Principles of MDR and communication with Notified Bodies 3. PMS (Post marketing surveillance and on-going clinical evaluation in PMCF)   **Practical exercises** |
| **Day 4** - **Medical Device Regulations** – USA |
| 1. Regulatory strategy 2. Medical device classification according to US regulations 3. Principles of US medical device regulations and communication with FDA   **Practical exercises** |
| **Day 5** - **Risk management – Making it work for you !** |
| * ISO 14971: 2019 Overview, Terms and definitions, requirements * Risk management practices & tools (including dFMEA and pFMEA) * Product verification and validation tests   **Practical exercises** |