***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**  |