***סילבוס קורס למהנדסי איכות ורגולציה במכשור רפואי***

***V&V What, when, how and most importantly why***

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|  **Morning**  |
| 1. **V&V terminology**
	* The definition, then in plain language followed by a real-world example

 1. **Verification, Validation and Qualification Requirements**
* What do you have to do in each process
1. **Overview of most V&V activities**
* What is done in house, what is done by laboratories and when both can be used.
* Functionality verification – what is this and how do we do it
1. **Functionality Testing Overview**
2. **What do we need to ask ourselves before we start writing protocols?**
3. **What do we need to include in a report**
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|  **Afternoon**  |
| 1. **Packaging Validation Overview (transportation and shelf life testing)**
2. **Sterilization Validation Overview**
3. **Cleaning Validation Overview**
4. **Reprocessing Validation/s Overview**
5. **Usability Studies Overview**
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