***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** |
| **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** |