

## Extended V&V course V&V Syllabus, Rev.2

### Day 1

Module	Topics
<b>Session Kick-Off</b>	<ul style="list-style-type: none"><li>• Introductions</li><li>• Course objectives and expectations</li></ul>
<b>Morning before lunch</b>	<ul style="list-style-type: none"><li>• Definitions\Verification, Validation and Qualification Requirements</li><li>• Overview of V&amp;V activities</li><li>• Functionality Testing Overview</li><li>• What do we need to ask ourselves before we start writing protocols</li></ul>
<b>After lunch</b>	<ul style="list-style-type: none"><li>• Packaging Validation Overview</li><li>• Sterilization Validation Overview</li><li>• Cleaning Validation Overview</li><li>• Reprocessing Validation Overview</li><li>• Usability Studies Overview</li></ul>

### Day 2

Module	Topics
<b>Planning your Sterilization Process</b>	<ul style="list-style-type: none"><li>• Introductions</li><li>• How to choose the sterilization method</li><li>• What is suitable and when</li><li>• What do you need to know BEFORE you approach the laboratory</li><li>• How does packaging affect the process</li><li>• Everything that MUST be finalized before starting</li></ul>

## Day 3

### Module

### Topics

#### Cleaning and Reprocessing Validation

- Introductions
- Disinfection, Cleaning – what is the difference
- How do you define Clean for your device
- How do you validate Cleaning in manufacturing
- How do you validate cleaning, disinfection, and sterilization for reprocessed devices?
- When do you have to revalidate

## Day 4

### Module

### Topics

#### Packaging Validation

- Introductions
- Why do we validate packaging
- What are the stages
- What are the tests
- What do you have to do
- What you may want to consider doing
- When do you have to revalidate

## Day 5

### Module

### Topics

#### Translating Standards into Protocols

- Introductions
- Understanding the difference between guidance and requirements
- Understanding what requirements are relevant to you
- Writing a protocol that explains this simple and to the point

#### Session Wrap-Up

- Feedback
- Answering any other questions

