

2 day V&V Seminar Syllabus, Rev.1

Day 1 – V&V General	
Module	Topics
Session Kick-Off	<ul style="list-style-type: none"> • Introductions • Course objectives and expectations
Morning before lunch	<ul style="list-style-type: none"> • Definitions\Verification, Validation and Qualification Requirements • Overview of V&V activities • Functionality Testing Overview • What do we need to ask ourselves before we start writing protocols
After lunch	<ul style="list-style-type: none"> • Packaging Validation Overview • Sterilization Validation Overview • Cleaning Validation Overview • Reprocessing Validation Overview • Usability Studies Overview • Software Validation Overview

Day 2 – Standards to protocols	
Module	Topics
Translating Standards into Protocols Morning before lunch	<ul style="list-style-type: none"> • Introductions • Definitions: Guidance, requirement, applicable standard, FDA Guideline • Understanding the difference between guidance and requirements • List of Applicable Standards – how do you know what the applicable standards are
After lunch	<ul style="list-style-type: none"> • Understanding what requirements are relevant to your device • Step by step how to write a protocol from the purpose through to the test methodology