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

Day 1 – V&V General	
Module	Topics
Session Kick-Off	• Introductions • Course objectives and expectations
Morning before lunch	• 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	• Packaging Validation Overview • Sterilization Validation Overview • Cleaning Validation Overview • Reprocessing Validation Overview • Usability Studies Overview • Software Validation Overview
Day 2 – Standards to protocols, Cleaning and Reprocessing	
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 simply and to the point
Cleaning and Reprocessing Validation	• 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 3 – Sterilization (GAMMA, EtO, and Steam)	
Module	Topics
Before Luch	• Introductions
	• How to choose the sterilization method
	• What do you need to know BEFORE you approach the laboratory
	• How does packaging affect the process
	• Everything that MUST be finalized before starting
After Lunch	• Validation requirements for Steam, EtO and Gamma
	• IPCDs, EPCDs and other monitoring methods
	• Sterilization Monitoring and Revalidation

Day 4 – Sterile Barrier (Packaging)	
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