

Duration	Lecture	Workshop
Week 01	Curriculum overview and perspective Domain introduction Product funnel and teams 21 CFR part 800-898 index New product development, P0 and P1 phase Standards adherence IEC 60601-1 approval process Case studies of non-complying global products Group discussion	Understanding Customer / Marketing Requirements Writing requirements for Project work System Level Architecture Discussion on selecting suitable architecture Block Diagram and Interconnects Preparing a Block diagram and Interconnect diagram Flow Diagrams - Power and Signal Drawing a Signal and Power Flow diagram Choosing the right Components Choosing parts for project
Week 02	Management controls Purchasing controls Design controls 510K process Accessories classification New product development, P2 and P3 phase QMS Non-conforming products EHS Six sigma tools Case studies of non-complying global products Group discussion	Quick Prototyping techniques - using breadboards, evaluation boards, simulation software Choosing a suitable solution for prototyping Packaging a prototype Discussion and choosing a suitable Enclosure Packaging the product Design Reviews Reviews within team on project design Labview overview for rapid concept prototyping development
Week 03	Examples of electronic products to global market Process validation New product development, P4 and P5 phase CAPA basics Complaint files Human factors Home use devices Promoting safety in home use devices PLM tool Finance Case studies of non-complying global products Group discussion	PCB Tools - Component library, schematic entry, PCB layout and gerber generation Designing the Schematic and PCB layout in Diptrace Working with Vendors - typical queries - PCB, component ordering Ordering parts from distributor, communicating to vendors Generating design outputs - Gerber's, Bills of materials, assembly Instructions Actual design outputs Firmware - typical firmware design flow Testing - Strategy, test plan, test procedures and test reports Developing a test plan, procedure and documenting reports
Week 04	Key tips for medical device start-ups Art of design inputs & design outputs Verification and validation tips New product development, PE and PS phase Regulatory requirements overview Bio-compatibility guide Value engineering Install base management SME's from industry, sharing experience & learnings IP basics Case studies of non-complying global products Group discussion	Stages of Testing - Prototype, pilot, qualification, manufacturing and service Reliability - What is MTBF, MTBSE. Burn in, temperature cycling, environmental effect Type Testing - What are IEC standards Designing for safety, standards overview, test methods Designing for EMI/EMC - standards overview, test methods How to bring up a prototype board - precautions, techniques Actual board bring up Testing - How to use instruments Actual Testing Integration - how to integrate hardware, firmware and mechanical module or system level testing Automated manufacturing tests