

**INFO 7374 - 09 ST: Advanced Medical Devices-
Applied Applications in Medical Device Software Development Process**

Date: 08/20/2024

Fall 2024 Semester (09/04/2024-12/14/2024)

Course Title: Applied Applications in Medical Device Software Development Process

Course Description:

This course offers students an opportunity to achieve an advanced level of practical understating of the Medical Device Software Development Process. The course aims to bridge the gap between theory and practice, it is a comprehensive and hands-on course designed to provide students with practical knowledge and skills in developing software for medical devices according to the FDA and IEC 62304 standards. Through a combination of lectures, case studies, and a capstone project, students will gain the necessary expertise to develop safe and effective medical device software with regulatory compliance.

Grade Scale:

	A Range	B Range	C Range	F Range
+		87% -89.9% B+	77%-79.9% C+	69.9% or below is F
	95% to 100% A	84%-86.9% B	74%-76.9% C	
-	90% to 94.9 is A-	80%-83.9%B-	70%-73.9% C-	

Grade Breakdown :

	Category	Percent
1	Class participation	10%
2	Project	30%
3	Final presentation	20%
4	Mid-term Quiz	10 %
5	Final Exam	30%
TOTAL		100%

Week	Date	Topic	Notes/comments:
1	09/04	Introduction: Course overview Review syllabus Learning Object Grading	
2	09/11	Review for Medical device software regulator Bodies and standards (IEC 62304, FDA..etc) Design control per the US and Europe	
3	09/18	Medical Device software process Risk management fundamental and Quality control	
4	09/25	Hands- on Project to apply the theoretical concept in developing a SW for a medical device application.	

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5	10/02	Medical Device Software Process I 1. Software Development Life cycle 2. Software Planning 3. Software requirements analysis 4. Software Design and Architecture for Medical Devices	
6	10/09	Medical Device Software Process II : 1. Software Detailed Design 2. Software implementation & Unit testing 3. Software Validation and Verification 4. Agile methodologies in MDSD.	
7	10/16	Hands- on Project to apply the theoretical concept in developing a SW for a medical device application.	
8	10/23	Medical Device Software Process III: 1. Software integration testing 2. Software system testing 3. Software release 4. FDA Cyber security and privacy in MDSD	
9	10/30	Hands- on Project to apply the theoretical concept in developing a SW for a medical device application.	
10	11/06	Medical Device Software Process IV: 1. Software Maintenance 2. Software configuration management 3. Software problem resolutions	
11	11/13	Hands- on Project to apply the theoretical concept in developing a SW for a medical device application.	Med Term Quiz
12	11/20	Software Risk management analysis	
13	11/27	Thanksgiving	
14	12/04	Final presentation	
13	12/11	Project Demo	
14	12/18	Final Exam	
15	12/25	Christmas	