Northeastern
College of Engineering

# INFO 7374 Advanced Medical Device Software Engineering

**Course Information**
Course Title: Advanced Medical Device Software Engineering
Course Number: INFO 7374
Term and Year: Spring 2024
Credit Hour: 4
CRN: 41054
Course Format: On-ground

**Instructor Information**
Full Name: Bemin Ghobreal
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**Instructor Biography**
Dr. Bemin Ghobreal is a seasoned professional with a robust background in Biomedical and Electrical Engineering, specializing in Neural Engineering and Surgical Robotics. With a Doctorate in Biomedical Engineering from Rutgers University & New Jersey Institute of Technology, Dr. Ghobreal has led pioneering research projects, exemplified by a significant body of publications and conference papers.

Dr. Ghobreal's career spans across various high-profile roles in prestigious organizations such as Medtronic and DePuy Synthes, where he exhibited exceptional leadership in managing teams, driving innovation, and overseeing the design and development of cutting-edge Surgical Robotics. His contributions have been integral to the successful launch and regulatory approval of groundbreaking medical devices, showcasing expertise in Software and firmware development, embedded systems, and regulatory compliance.

His extensive repertoire includes spearheading projects like the Hugo Surgical Robotics and VELYS TKA Surgical Robotics team, leading the development of control interfaces for robotic arms, and creating innovative medical devices to aid Gulf War Illness veterans. Dr. Ghobreal's proficiency in software development, firmware design, and system integration has been instrumental in revolutionizing medical technology and improving patient care.

Outside his professional endeavors, Dr. Ghobreal actively engages in volunteering activities, demonstrating a commitment to community service and humanitarian causes. His multifaceted expertise, coupled with a passion for advancing healthcare technology, continues to drive innovation and shape the future of Biomedical Engineering.

**Course Prerequisites:** Basic familiarity with software coding

## Course Description

This course offers students an opportunity to achieve an advanced level of practical understanding 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.

## Standard Learning Outcomes

*Learning outcomes common to all College of Engineering Graduate programs:*

1. *An ability to identify, formulate, and solve complex engineering problems.*
2. *An ability to explain and apply engineering design principles, as appropriate to the program's educational objectives.*
3. *An ability to produce solutions that meet specified end-user needs with consideration of public health, safety, and welfare, as well as global, cultural, social, environmental, and economic factors.*

*The Information Systems Program accepts students of different engineering backgrounds with minimum programming skills and produces first class Information Systems engineers that operate at the intersection of real-world complexity, software development, and IT management. Graduating students will be able to construct end-to-end advanced software applications that meet business needs.*

*Specific Learning Outcomes for the Information Systems program:*

1. *Create a strong technical foundation through diverse, high-level courses*
2. *Built crucial interpersonal skills needed to succeed in any industry*
3. *Foster a deep level of applied learning through project-based case studies*

**Required Tools and Course Textbooks:** TBD

**Course Schedule:**

| Week | Date | Topic | Notes/comments: |
|---|---|---|---|
| 1 | TBD | Introduction:<br>Course overview<br>Review syllabus<br>Learning Object<br>Grading | |
| 2 | TBD | Review for Medical device software regulator<br>Bodies and standards (IEC 62304, FDA, etc.)<br>Design control per the US and Europe | |
| 3 | TBD | Medical Device software process Risk management<br>fundamental and Quality control | |
| 4 | TBD | Medical Device Software Process I | |

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|---|---|---|---|
| | | 1. Software Development Life cycle<br>2. Software Planning<br>3. Software requirements analysis<br>4. Software Design and Architecture for Medical Devices | |
| 5 | | Applied methods: Project definition<br>Project : to apply the theoretical concept in developing a SW for a medical device application | Define the project for each group, write SW requirements , Sys Requirements, Start thinking about the project, work with student to define project |
| 6 | TBD | Medical Device Software Process II :<br>1. Software Detailed Design<br>2. Software implementation & Unit testing<br>3. Software Validation and Verification<br>4. Agile methodologies in MDSD. | |
| 7 | | Applied Methods: Project Implementation I<br>Project : to apply the theoretical concept in developing a SW for a medical device application | Start writing code and building the Medical Device application |
| 8 | TBD | Medical Device Software Process III:<br>1. Software integration testing<br>2. Software system testing<br>3. Software release<br>4. FDA Cyber security and privacy in MDSD | |
| 9 | | Applied Methods: Project Implementation II<br>Project : to apply the theoretical concept in developing a SW for a medical device application | Continue building the Medical Device Software. |
| 10 | TBD | Medical Device Software Process IV:<br>1. Software Maintenance<br>2. Software configuration management<br>3. Software problem resolutions | |
| 11 | TBD | Project : to apply the theoretical concept in developing a SW for a medical device application. | Med Term Exam |
| 12 | TBD | Project : to apply the theoretical concept in developing a SW for a medical device application. | Generate unit test and integration test protocol, |
| 13 | TBD | Project I : to apply the theoretical concept in developing a SW for a medical device application. | Validation and verification phase |

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|---|---|---|---|
| 14 | TBD | Project I : to apply the theoretical concept in developing a SW for a medical device application. | Documents completion (DD, SFMEA, etc.) |
| 15 | TBD | Project presentation | |

**Grading 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 | 30% |
| 4 | Mid-term Exam | 30 % |
| TOTAL | | 100% |

**Attendance/Late Work Policy:**

Attendance Policy

Students are expected to complete course readings, participate in class discussions or other learning activities during the unit, and complete written assignments for each unit during the time of that unit. It is understood that there might be one week when active participation in ongoing class conversations and learning activities might be delayed. Beyond one week's time, if there is an absence or lateness in participation (1) faculty must be notified in advance; (2) grades will be adjusted accordingly.

Late Work Policy

Students must submit assignments by the deadline in the time zone noted in the syllabus. Students must communicate with the faculty prior to the deadline if they anticipate work will be submitted late. Work submitted late without prior communication with faculty will not be graded.

## End-of-Course Evaluation Surveys

Your feedback regarding your educational experience in this class is particularly important to the College of Professional Studies. Your comments will make a difference in the future planning and presentation of our curriculum.

At the end of this course, please take the time to complete the evaluation survey at **https://neu.evaluationkit.com**. Your survey responses are **completely anonymous and confidential**. For courses 6 weeks in length or shorter, surveys will be open one week prior to the end of the courses; for courses greater than 6 weeks in length, surveys will be open for two weeks. An email will be sent to your Husky Mail account notifying you when surveys are available.

## Academic Integrity

A commitment to the principles of academic integrity is essential to the mission of Northeastern University. The promotion of independent and original scholarship ensures that students derive the most from their educational experience and their pursuit of knowledge. Academic dishonesty violates the most fundamental values of an intellectual community and undermines the achievements of the entire University.

As members of the academic community, students must become familiar with their rights and responsibilities. In each course, they are responsible for knowing the requirements and restrictions regarding research and writing, examinations of whatever kind, collaborative work, the use of study aids, the appropriateness of assistance, and other issues. Students are responsible for learning the conventions of documentation and acknowledgment of sources in their fields. Northeastern University expects students to complete all examinations, tests, papers, creative projects, and assignments of any kind according to the highest ethical standards, as set forth either explicitly or implicitly in this Code or by the direction of instructors.

Go to http://www.northeastern.edu/osccr/academic-integrity-policy/ to access the full academic integrity policy.

## University Health and Counseling Services

As a student enrolled in this course, you are fully responsible for assignments, work, and course materials as outlined in this syllabus and in the classroom. Over the course of the semester if you experience any health issues, please contact UHCS.

For more information, visit https://www.northeastern.edu/uhcs.

## Student Accommodations

Northeastern University and the Disability Resource Center (DRC) are committed to providing disability services that enable students who qualify under Section 504 of the Rehabilitation Act and the Americans with Disabilities Act Amendments Act (ADAAA) to participate fully in the activities of the university. To receive accommodations through the DRC, students must provide appropriate documentation that demonstrates a current substantially limiting disability.

For more information, visit https://drc.sites.northeastern.edu.

## Library Services

The Northeastern University Library is at the hub of campus intellectual life. Resources include over 900,000 print volumes, 206,500 e-books, and 70,225 electronic journals.

For more information and for education specific resources, visit https://library.northeastern.edu.

## 24/7 Canvas Technical Help

For immediate technical support for Canvas, call 617-373-4357 or email help@northeastern.edu

Canvas Faculty Resources: https://canvas.northeastern.edu/faculty-resources/

Canvas Student Resources: https://canvas.northeastern.edu/student-resources/

For assistance with my Northeastern e-mail, and basic technical support:
Visit ITS at https://its.northeastern.edu
Email: help@northeastern.edu
ITS Customer Service Desk: 617-373-4357

## Diversity and Inclusion

Northeastern University is committed to equal opportunity, affirmative action, diversity, and social justice while building a climate of inclusion on and beyond campus. In the classroom, members of the University community work to cultivate an inclusive environment that denounces discrimination through innovation, collaboration, and an awareness of global perspectives on social justice.

Please visit http://www.northeastern.edu/oidi/ for complete information on Diversity and Inclusion

## Title IX

*Title IX of the Education Amendments of 1972 protects individuals from sex or gender-based discrimination, including discrimination based on gender-identity, in educational programs and activities that receive federal financial assistance.*

Northeastern's Title IX Policy prohibits Prohibited Offenses, which are defined as sexual harassment, sexual assault, relationship or domestic violence, and stalking. The Title IX Policy applies to the entire community, including male, female, transgender students, faculty, and staff.

In case of an emergency, please call 911.

*Please visit **https://www.northeastern.edu/ouec** for a complete list of reporting options and resources both on- and off-campus.*