

Clinical Immersion in Medical Device Design Certificate Handbook

1. Introduction

The Clinical Immersion in Medical Device Design (CIMD) graduate certificate is designed to provide professionals with an in-depth understanding of medical device design through a hands-on clinical immersion experience. Participants will learn the principles of medical device innovation, development, and regulatory requirements while working closely with clinicians and engineers in a healthcare environment.

2. Program Overview

The CIMD Certificate is a specialized certificate that combines online learning with clinical observation. The program is ideal for professionals in engineering, healthcare, and related fields who wish to gain experience in medical device development and innovation. The certificate consists of a combination of required and elective courses.

- **Program Duration:** 12-18 months
- **Total Credits Required:** 12 credits
- **Delivery Mode:** Hybrid (combination of online and in-person Clinical Observations)
- **Target Audience:** Engineers, healthcare professionals, designers, and anyone interested in medical device development

3. Learning Objectives

Upon completing this certificate program, students will:

- Gain a deep understanding of the medical device design and development process.
- Acquire knowledge of regulatory requirements and standards for medical devices.
- Apply human factors engineering and usability principles to medical device design.
- Understand the clinical environment and how to conduct needs assessments.
- Develop skills to evaluate and validate medical devices in a clinical setting.
- Communicate effectively with multidisciplinary teams, including engineers, clinicians, and regulatory agencies.

4. Admission Requirements

To be eligible for admission to the CIMD certificate, applicants must meet the following requirements:

- **Educational Background:** Bachelor's degree or higher in engineering, life sciences, healthcare, or a related field.
- **Application Form:** Completed online application through Slate
- **Transcripts:** Official transcripts from all post-high school institutions attended.

5. Certificate Requirements

To earn the CIMD Certificate, participants must:

- **Complete 12 credits** of coursework, including:
 - ❖ **Required Courses:** 6 credits
 - ❖ **Elective Courses:** 6 credits
- **A minimum cumulative GPA of 3.0 or higher.**

6. Course Registration

Course Enrollment Process

- **Pre-Registration:** Review the certificate requirements and then search for courses you wish to enroll in via CheckMarq.
- **Registration:** Register for courses through CheckMarq during the registration period. Ensure you receive a confirmation email of successful registration.

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- **Course Changes:** You can add or drop courses within the first week of the term without penalty. After this period, consult the academic calendar for withdrawal deadlines and any associated fees.

Course Load and Scheduling

- **Recommended Course Load:** 3-6 credits per term.
- **Course Schedule:** Courses are offered in both online and clinical observation visits. Clinical Observation sessions will be scheduled in coordination with healthcare facilities.

Tuition and Fees

- **Tuition per Credit:** [Tuition, Fees and Housing | Marquette University](#)
- **Additional Fees:** Technology fee, clinical immersion fee, and any required course materials.

7. Course Descriptions

Required Courses (6 Credits)

- **BIEN 6301: Clinical Needs Findings (3 Credits) 100% Asynchronous**
Covers the fundamentals of medical device design, including user needs assessment, concept development, system approach, medical terminology and regulations.
- **BIEN 6302: Clinical Observation (3 Credits) 25% Asynchronous and 75% Clinical Site Visits**
Focuses on regulatory requirements, standards, and guidelines for medical devices, including FDA and post market surveillance.

Elective Courses (6 Credits)

- **HCTM 6500: Management of Medical Product Development (100% Asynchronous)**
Emphasizes issues involved in the management of the product development process as applied to the design, development, and commercialization of medical devices.
- **HCTM 6995: Healthcare Technology Management Applied Projects (80% online, and 20% for some site visits that may be necessary)**
A project-based course designed to provide students with the opportunity to gain practical experience with a real-world, relevant issue or problem involving the management of healthcare technology.
- **A complete listing of the approved elective courses for the CIMD certificate can be found at the following link [Clinical Immersion in Medical Device Design, Certificate | Marquette University](#)**

8. Program Policies

- **Attendance:** Attendance is mandatory for all clinical immersion sessions and online course components.
- **Grading Policy:** Participants must maintain a minimum cumulative GPA of 3.0 to remain in good standing.
- **Academic Integrity:** All students are expected to adhere to the university's academic integrity policies, including avoiding plagiarism and cheating.
- **Continuity:** Students should register for at least one course during each semester to maintain their status in the certificate and avoid being dropped from the program. For semesters in which students are unable to enroll in a course, they should either enroll in the free "zero-credit" department seminar (BIEN 6953) or register for continuous enrollment (\$100 fee per semester), BIEN 9970. See link below. <https://mcw.marquette.edu/biomedical-engineering/graduate-studies/course-registration-guidelines.php>
- **Withdrawal and Refunds:** Refer to the academic calendar for deadlines related to course withdrawal and tuition refunds. [Tuition, Fees and Housing | Marquette University](#)

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9. Key Dates and Deadlines

- **Application Deadline:** [Application Instructions and Guidelines // Graduate School // Marquette University](#)
- **Registration Opens:** [Clinical Immersion in Medical Device Design Certificate // Graduate School // Marquette University](#)
- **Term Start Date:** [Clinical Immersion in Medical Device Design Certificate // Graduate School // Marquette University](#)
- **Clinical Immersion Sessions:** will be scheduled after the semester starts

10. Support and Resources

- **Academic Advising:** Available by appointment for course planning, registration assistance, and academic guidance. [ACADEMIC AND PROFESSIONAL DEVELOPMENT RESOURCES // Graduate School // Marquette University](#)
- **Technical Support:** For issues related to online learning platforms or accessing course materials, contact. [TechSquad \(formerly Help Desk\) | IT Services | Marquette University](#)
- **Library Access:** Full access to digital and physical library resources, including journals, textbooks, and databases relevant to medical device design. [Libraries | Marquette University](#)
- Information for Admitted Students:
[Information for Newly Admitted Students // Graduate School // Marquette University](#)
- Academic and Professional Development Resources:
[ACADEMIC AND PROFESSIONAL DEVELOPMENT RESOURCES // Graduate School // Marquette University](#)
- Marquette has the Lemonis Center for Student Success and their Career Center:
[Career Center // Marquette University](#)

11. Contact Information

- **Graduate Program Recruiter:** Tim Carter
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For additional information or questions about the Clinical Immersion in Medical Device Design Certificate, please contact the Program Recruiter.