

Medical Devices and Digital Transformation

Translating Engineering into Healthcare Impact

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Course Description

This course bridges the gap between electrical and computer engineering and the healthcare industry practice, focusing on how connected devices, software, and data create clinical and operational impact. Students learn how engineering design, regulatory pathways, and commercialization strategies intersect in developing safe, effective, and scalable digital health and medical technologies. Through real-world case studies from medical devices, software as a medical device (SaMD), AI/ML, and population health analytics, students will gain the tools to translate innovation into regulated healthcare products.

Learning Outcomes

This course is designed as a guided journey where each student begins by identifying a potential healthcare technology concept (whether a connected device, digital health platform, or AI-driven solution) and progressively refines it through the course timeline. Weekly assignments mirror the real-world lifecycle of product development in regulated healthcare: from problem discovery and stakeholder analysis to regulatory strategy, validation planning, and go-to-market execution. By the end of the quarter, each student will have developed a concise Product Concept Dossier representing a near-complete strategy and design plan that connects engineering, compliance, and clinical value.

By the end of the course, students will be able to:

1. **Explain how ECE principles apply** to the healthcare ecosystem (devices, data, and compliance).
2. **Develop a strategic roadmap** from concept to commercialization for a regulated device or SaMD.
3. **Navigate key regulatory** and standards frameworks (21CFR820, ISO13485/14971/62304, IEC60601).
4. **Apply verification, validation,** and usability testing principles to connected device or SaMD.
5. **Evaluate the impact** of AI/ML, LLMs, and agentic AI in clinical workflows.
6. **Analyze case studies** of success and failure in digital health adoption, including change management and stakeholder alignment.

Topics (Tentative)

Module 1 - Engineering in the Healthcare Context

- Healthcare vs. traditional engineering ecosystems.
- High-level system-of-systems view: devices, data, protocols, compliance.
- Stakeholders and market dynamics. The 7 P's in Healthcare: *Provider, Payor, Patient, Policymaker, ProductMaker, Purchaser, Pharma.*
- Engineering tradeoffs in healthcare: balancing innovation, safety, regulatory compliance, clinical workflow, and reimbursement constraints from the outset.

Module 2 - From Concept to Clinical Value

- From Strategy to ideation, and commercialization in regulated industries.
- Understanding the problem and defining value propositions for providers, payors, and patients.
- Voice of customer (VOC) and requirements engineering.
- Start at the end and walk backwards, think of usability from the beginning.

Module 3 - Devices, Software, and Data

- Medical devices vs. Software as a Medical Device (SaMD).
- IoHT and interoperability standards (FHIR, HL7, DICOM).
- Understanding targets and designing for workflow integration.

Module 4 - Regulated Innovation

- Product Design controls and documentation (DHF, DMR, DHR).
- FDA, EU MDR/IVDR regulatory strategies and pathways.
- Risk management and quality systems (ISO 14971, 13485,).

Module 5 - Verification, Validation, and Meaningful Use

- Human factors and usability (IEC 62366).
- Software lifecycle (IEC 62304).
- Difference between Verification and Validation. Validation of AI/ML models and data pipelines.

Module 6 - AI and Digital Transformation in Healthcare

- From LLMs to agentic AI and autonomous systems.
- Clinical decision support, predictive analytics, and population health.
- Geographic and site-specific bias within ethical clinical data usage and AI frameworks, including responsible AI, governance, and explainability.

Module 7 - From Devices to Digital Health

- Cloud platforms (SaaS/PaaS/DaaS) and system architecture.
- Connected ecosystems: interoperability and cybersecurity.
- Examples: Digital pathology, connected diagnostics, remote monitoring.

Module 8 - Adoption and Behavior Change Management

- Barriers to adoption in healthcare IT.
- Pilot-to-scale strategy and measuring outcomes.
- Leadership, team, and stakeholder management.

Module 9 - Failures, Pivots, and Lessons Learned

- Real-world case studies: when products fail and why. Sharing industry learnings.
- Post-market surveillance and evidence generation.
- Sustaining innovation under evolving market expectations (clinical, regulatory, reimbursement, and competitive pressures)

Module 10 - Future of ECE in Healthcare and AI

- The role of engineers in the evolving healthcare landscape.
- Where ECE skills matter most in digital health and AI. Bidirectional feedback/feedforward (students and industry expertise).
- Capstone presentations.

Weekly Rhythm

- **Lecture (2×/week):** 80-100 min each; one on-campus, one via Zoom (recorded).
- **Assignments:** ~1 per week, alternating between short written reflections, design briefs, and applied analyses.
- **Office Hours:** To be announced.

Assessment

Component	Weight	Description
Weekly Assignments	60%	Case studies, design briefs, and short analytical reports.
Class Participation	10%	Discussions, peer reviews, and reflections.
Midterm Project	15%	Group project on concept-to-market strategy for digital health solution.
Final Presentation	15%	Individual/group capstone on translating ECE innovation to healthcare.

Homework Examples

- Week 2:** HC problem where ECE innovation could have measurable clinical or operational impact.
- Week 3:** Develop a stakeholder map and define the customer/s for a proposed medical technology.
- Week 4:** Create a draft regulatory pathway for product concept and what standards might apply.
- Week 5:** Design a basic V&V plan for a SaMD feature or AI module.
- Week 6:** Evaluate a published AI-in-healthcare study for bias, validation, and clinical usability.
- Week 8:** Draft a change-management plan for implementing a solution in a hospital workflow.
- Week 10:** Present final concept-to-clinic commercialization strategy.

Policies

- **Late Work:** One assignment may be ≤1 week late with prior notice; otherwise -25% per day.
- **AI Tools:** Use of AI for writing or coding is permitted only if **disclosed and cited**.
- **Collaboration:** Discussion encouraged; individual submissions must represent your own analysis.
- **Integrity:** Follow UW's academic honesty and ethical conduct guidelines.

Materials & Tooling

- **Recommended:** *FDA SaMD Guidance (2022)*, *ISO 13485:2016 Summary*, *Design for Regulation* (Daoura et al., selected readings).
- **Online resources:** FDA Digital Health Center of Excellence, IEEE EMBS Digital Health Standards, and HIMSS Digital Health Toolkit.