

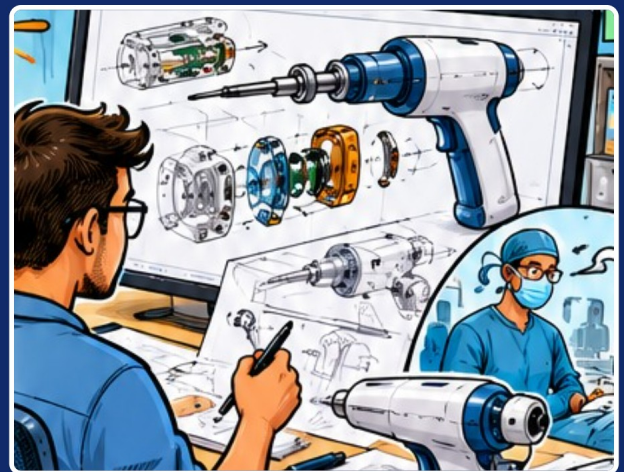
PROFESSIONAL PROGRAMME

Medical Device Design & Development

From concept to patient impact.

The engineering, quality, regulatory and manufacturing disciplines behind a medical device, learned through a guided development case.

IDEA DESIGN TEST VALIDATE MARKET



DURATION

3 Months

12-13 weeks

LEARNING HOURS

120 Hours

live & interactive

MODE

Live

online workshops

COHORT

Max 30

participants

BATCH #1 STARTS

6 December 2026

Inaugural fee • regular ₹39,900

₹9,900

01 / PROGRAMME OVERVIEW

Every safe device follows a traceable path

“ *An application-oriented programme in the engineering, quality, regulatory and manufacturing disciplines of medical device development.* ”

You work through a guided development case, connecting user needs with design requirements, risk controls, verification, validation and design transfer.

Who should attend?



Students & early-career engineers

UG/PG and graduates in mechanical, biomedical, electronics, electrical and related disciplines.



Working professionals

R&D, product design, quality, manufacturing, testing, supplier quality and regulatory affairs.



MedTech founders

Innovators seeking a structured understanding of how devices get developed.

Eligibility: basic engineering or science literacy is recommended. Prior medical-device experience is not required.

Programme objectives

01 Translate intended use and user needs into **traceable design inputs and outputs**.

02 Understand **design controls, quality, risk management** and regulatory considerations.

03 Plan practical prototyping, engineering evaluation, **verification and validation**.

04 Connect design decisions to **manufacturing readiness**, documentation and post-market quality.

02 / DETAILED CURRICULUM

Six modules across the device lifecycle

MODULE 01

01

Medical Device Development Process

- Device types, intended use, user needs and clinical context
- Product lifecycle, feasibility, design planning and requirements
- Stakeholder mapping and development milestones

You produce: product concept brief and user-needs map.

MODULE 02

02

Design Controls & Quality Management

- Design inputs/outputs, reviews, traceability and design changes
- FDA QMSR, ISO 13485 and documentation fundamentals
- Design and development files; introduction to ISO 14971 risk management

You produce: sample requirements and traceability matrix.

MODULE 03

03

Engineering Design & Analysis

- Mechanical/electromechanical architecture, materials and CAD
- DFM/DFA, tolerance analysis and design trade-offs
- Risk-based design decisions, FMEA and preliminary design reviews

You produce: concept architecture and preliminary risk analysis.

MODULE 04

04

Prototyping, Verification & Validation

- Prototype builds and iterative design evaluation
- Test methods, acceptance criteria, verification protocols and reports
- Validation, usability/human factors and reliability basics

You produce: draft verification plan and test matrix.

MODULE 05

05

Regulatory Pathways & Global Standards

- FDA device classification and premarket pathways
- EU MDR and CE-marking fundamentals
- ISO 13485, ISO 14971, applicable IEC/ISO standards; technical documentation

You produce: indicative regulatory and standards checklist.

MODULE 06

06

Quality, Manufacturing & Launch Readiness

- Design transfer, supplier quality and process validation basics
- Manufacturing readiness, complaint handling and CAPA
- Post-market surveillance, change control and lifecycle management

You produce: design-transfer readiness checklist and final pitch.

03 / PEDAGOGY & WORKSHOP EXPERIENCE

Half the hours are hands-on practice

Expert-led instruction combined with guided practice, collaborative development and evidence-based presentation.



How the 120 learning hours are shared

Learn 12 hrs Expert sessions, fundamentals, standards overview and guided case discussions.	Practice 60 hrs Requirements exercises, risk analysis, design reviews, documentation and test-planning workshops.
Build 24 hrs Team-based device concept development, prototype planning and project documentation.	Present 24 hrs Peer review, mentor feedback, project demonstration and final design review.

How the live workshops run

-  Live sessions with instructor demonstrations, questions and structured group activities.
-  Small teams tackle a realistic device challenge with templates and sample documentation.
-  Case studies illustrate industry practice. Examples are educational, not confidential product records.
-  Milestone reviews keep each team on track at every stage below.

MILESTONE REVIEWS

Requirements

Design

Risk

Verification

Launch readiness

04 / CAPSTONE PROJECT

From concept to design-review package

Your team picks an illustrative low-risk device or accessory concept and builds a concise portfolio containing:



An educational exercise: no clinical use or regulatory approval is implied.

Assessment & certification



An ENGGECT Innovation certificate is issued on meeting the attendance, assessment and completion requirements.

Key takeaways

- ✓ A working understanding of the end-to-end medical device development lifecycle.
- ✓ Practical templates for requirements, traceability, risk analysis and verification planning.
- ✓ A portfolio-ready capstone case study and stronger cross-functional communication.
- ✓ A clear view of how engineering, quality, regulatory and manufacturing connect.

Better devices. Better care.

Batch #1 is limited to 30 participants. Reserve your seat at the inaugural fee.

BATCH #1 STARTS 6 Dec 2026	FORMAT 3 months • 120 hours Live online • Max 30	INAUGURAL FEE ₹9,900 Regular fee ₹39,900
---	---	--

ENQUIRIES & ENROLMENT



WhatsApp

+91 80089 50333



Email

info@enggect.com



Website

www.enggect.com



THE ACADEMY OF INNOVATION AND DESIGN, HYDERABAD



Please note: programme content, timings and assessment weights are subject to final faculty confirmation. This course is professional education, not an accredited regulatory qualification or a guarantee of employment.