NeuLearn
by Neujin Solutions

REGULATORY ACCELERATOR PROGRAM

Medical Device Regulatory Affairs

Certificate Program

A complete two-level pathway — from foundational principles to advanced technical competency — for professionals seeking regulatory mastery in the global medical device industry.

LEVEL 1
Foundational Certificate
12 Modules • Beginner Friendly

LEVEL 2
Advanced Certificate
16 Modules • Technical Mastery

neujinacademy.com

PROGRAM OVERVIEW

Why This Program?

Medical device regulation is one of the most complex and consequential disciplines in healthcare. Every requirement exists to protect patients — and every regulatory professional must understand not just what the rules are, but why they exist.

The NeuLearn Regulatory Accelerator Program offers a structured, two-level pathway that takes you from foundational regulatory principles through to the advanced technical and scientific competencies demanded by today's global medical device industry.

28	2	No Prior
Total Modules	Certificate Levels	Experience Required

Who Should Enrol?

This program is designed for a broad range of professionals and learners:

Beginners & Career Changers
Professionals entering regulatory affairs with no prior background, seeking structured, comprehensive training.

Industry Professionals
Engineers, QA specialists, and R&D professionals who need to understand the regulatory landscape for their work.

Regulatory Coordinators
Those already working in regulatory roles looking to formalise and deepen their knowledge with a recognised certificate.

Global Market Teams
Teams navigating FDA, EU MDR, Health Canada, TGA, PMDA, and NMPA simultaneously who need a global regulatory perspective.

Learning Approach

NeuLearn's regulatory curriculum is built around a single guiding principle: **understand why requirements exist, not just what they are.** This regulatory mindset — thinking like a regulator — is what distinguishes competent professionals from truly effective ones.

Content is delivered through structured narrated modules, accompanied by a comprehensive learner handbook for Level 2. Each module concludes with key takeaways designed to cement understanding and support application in the workplace.

COURSE CURRICULUM

L1

Foundational Certificate in Medical Device Regulatory Affairs

12 Modules • No prior experience required • Regulatory mindset driven training

Level 1 builds your regulatory foundation from the ground up. You will learn how regulators think, how device risk drives decision-making, and how requirements apply across the entire product lifecycle — from concept through post-market surveillance.

1. Foundations of Medical Device Regulation
2. Risk-Based Regulation & Device Classification
3. Quality Management Systems (QMS) Fundamentals
4. Product Lifecycle, Regulatory Pathways & MDSAP
5. Design Controls Fundamentals
6. Risk Management Fundamentals (ISO 14971)
7. Verification & Validation Basics
8. Clinical Evaluation Fundamentals
9. Regulatory Documentation & Technical Files
10. Change Management & Regulatory Impact
11. Post-Market Surveillance & Vigilance
12. Working with Regulators & Inspections

Level 1 Outcomes

Understand regulatory systems
across FDA, EU MDR, and other major jurisdictions

Apply risk management
using ISO 14971 and risk-based classification principles

Navigate key processes
including QMS, design controls, V&V, and clinical evaluation

L2

Advanced Certificate in Medical Device Regulatory Affairs

16 Modules • Builds on Level 1 • Technical & scientific depth

Level 2 moves decisively beyond regulatory fundamentals into the technical and scientific competencies that regulatory professionals must command to be genuinely effective. The sixteen modules form an integrated view of the device lifecycle — from materials science and manufacturing through to post-market surveillance and chemical safety.

1. Biomaterials & Biocompatibility Testing
2. Manufacturing Processes for Medical Devices
3. Clean Rooms & Environmental Controls
4. Sterilisation Methods & Validation
5. Common Test Methods for Medical Devices
6. Testing of Electromedical Devices
7. Software Medical Devices (SaMD)
8. Basics of Clinical Trials
9. Design, Process & Packaging Validation
10. Test Method Validation & Analytical Methods
11. Quality Approaches: QbD, QbT & Hybrid
12. Stability & Shelf Life Fundamentals
13. Statistical Methods for Medical Device Testing
14. Human Factors Engineering & Usability
15. Post-Market Surveillance & Vigilance
16. Extractables & Leachables (Chemical Safety)

Level 2 Outcomes

Evaluate biomaterials
using ISO 10993 biocompatibility frameworks and testing strategies

Oversee validation programs
for manufacturing, sterilisation, packaging, and test methods

Apply cross-module thinking
integrating SaMD, human factors, clinical evidence, and PMS

ENROL TODAY

Begin Your Regulatory Journey

The Regulatory Accelerator Program is available as a complete two-level bundle

Price: Rs.12,000

Complete Bundle

Enrol in both levels together for the full Regulatory Accelerator pathway.

Visit us at **neujinacademy.com** to learn more and register.

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