



NEUROVERSE GLOBAL

# ISO 13485 – Medical Devices Quality Management

## Excellence Program

*A 5-Day Intensive Executive Training Program*

Training Course Code: NV-TR-15-009

Prepared for: [Client Organization]

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## Executive Summary

The ISO 13485 – Medical Devices Quality Management Program is a comprehensive 5-day executive training designed to equip professionals with the knowledge and practical tools to establish, implement, and optimize quality management systems specific to the medical devices industry. The program integrates regulatory requirements, risk-based thinking, and lifecycle management principles aligned with global standards. Participants will gain hands-on experience in audit readiness, documentation control, and compliance with international regulatory frameworks. Through real-world case studies and interactive workshops, attendees will strengthen their ability to ensure product safety, traceability, and continuous improvement. This program is essential for organizations aiming to achieve certification, enhance operational excellence, and meet stringent healthcare quality standards.

| Program Element         | Details  |
|-------------------------|--|
| <b>Duration</b>         | 5 Days (40 Hours)  |
| <b>Target Audience</b>  | C-Suite Executives, Senior Leaders, Strategy Professionals   |
| <b>Delivery Options</b> | 5★ Hotel   Traveling (Global Centers)   Training Institute   Onsite at Your Location   Virtual Live   Hybrid |
| <b>Certification</b>    | yes  |
| <b>Class Size</b>       | Optimum number of participants for highest interaction and engagement  |

We provide flexible and premium delivery formats tailored to your strategic priorities:

- **5★ Hotel Experience:** Executive retreat setting combining strategic learning, executive networking, and high-level team in luxury venues (e.g., Amman, Dead Sea, Aqaba).
- **Traveling (Global Centers):** Delivered at world-class international locations such as London, Istanbul, Dubai, Singapore, Georgia, or select European hubs, offering premium facilities and global networking opportunities.
- **Training Institute:** Hosted at leading accredited institutes equipped with advanced learning technologies and innovation-driven environments.
- **Onsite at Your Location:** Conducted at your corporate headquarters for a fully customized, confidential, and organization-focused experience.
- **Virtual Live:** High-definition, interactive online sessions with digital collaboration tools ideal for distributed leadership teams.
- **Hybrid Model:** A strategic blend of in-person engagement and synchronized virtual participation to maximize flexibility and international reach.

# Curriculum Structure

The ISO 13485 Medical Devices Quality Management Program is structured as an intensive 5-day professional journey, designed to provide a deep understanding of quality management systems within the regulated medical devices sector. Each day progressively builds capabilities in compliance, risk management, and operational excellence aligned with ISO 13485 standards and global regulatory expectations.

## Day 1: Foundations of ISO 13485 & QMS Principles

**Theme:** Building a Compliance-Driven Quality Culture

| Module                                   | Key Activities   |
|--|--|
| <b>Introduction to ISO 13485</b>         | Overview of ISO 13485:2016; Scope and applicability in medical devices |
| <b>Quality Management Principles</b>     | Process approach; Risk-based thinking; Regulatory alignment            |
| <b>QMS Framework &amp; Documentation</b> | Quality manual; SOPs; Document control systems                         |
| <b>Regulatory Landscape</b>              | FDA, EU MDR, and global regulatory requirements overview               |

## Day 2: Risk Management & Product Lifecycle Control

**Theme:** Ensuring Safety Through Risk-Based Thinking

| Module                                   | Key Activities   |
|--|--|
| <b>Risk Management Fundamentals</b>      | ISO 14971 principles; Risk identification and evaluation |
| <b>Design &amp; Development Controls</b> | Design inputs/outputs; Verification & validation         |
| <b>Product Lifecycle Management</b>      | From concept to post-market surveillance                 |
| <b>Hazard Analysis &amp; Mitigation</b>  | FMEA workshops; Risk control strategies                  |

## Day 3: Operational Controls & Supplier Quality Management

**Theme:** Strengthening Operational Excellence

| Module              | Key Activities                             |
|---------------------|--|
| Service Controls    | Process validation; Cleanroom requirements |
| Supplier Quality    | Qualification and monitoring               |
| Purchasing Controls | Approved vendor lists                      |
| Maintenance         | Preventive maintenance systems             |

## Day 4: Performance Evaluation & Audit Excellence

**Theme:** Driving Continuous Improvement & Compliance

| Module                   | Key Activities                                  |
|--------------------------|---|
| Internal Auditing        | Audit planning; Execution; Reporting techniques |
| CAPA System              | Preventive Actions; Root cause analysis tools   |
| Nonconformity Management | Documentation and escalation                    |
| Performance Metrics      | Mock ISO 13485 audit with real-time feedback    |

## Day 5: Regulatory Compliance & Certification Readiness

**Theme:** Achieving Certification & Sustaining Excellence

| Module                   | Key Activities  |
|--------------------------|---|
| Certification Process    | ISO 13485 certification lifecycle; Audit stages           |
| Regulatory Submissions   | Technical files; CE marking; FDA submissions              |
| Digital QMS & Innovation | eQMS platforms; AI in quality management                  |
| Capstone Project         | QMS implementation roadmap + certification readiness plan |

## Delivery Options

NeuroVerse Global offers unparalleled flexibility in program delivery, ensuring that world-class strategic education is accessible regardless of location or logistical constraints. Choose the format that best suits your organizational needs:

| Format   | Description   | Best For  |
|--|---|---|
| <b>Executive Retreat</b><br>*****<br><b>5* Hotel</b> | Multi-day experience at luxury venues in <b>hotels 5*</b> combining learning with strategic planning and team activities.<br>Amman, Dead Sea, Aqaba           | Board offsites, strategic planning, executive bonding                         |
| <b>Premier Training Institute</b>                    | Delivered at internationally accredited, state-of-the-art institutes equipped with advanced learning technologies, executive facilities, and innovation labs. | Executive education, certified programs, high-impact professional development |
| <b>Global Centers With Traveling</b>                 | Conducted at NeuroVerse world-class facilities in London, Istanbul, Egypt, Dubai, Singapore, Georgia, or Europe. Premium amenities and networking.            | International exposure, cross-cultural learning, executive networking         |
| <b>Onsite Premium</b>                                | NeuroVerse facilitator at your corporate headquarters or preferred location. Full materials, and immersive experience.  | Leadership teams, confidential strategy sessions, team building               |
| <b>Virtual Live</b>                                  | Synchronous online sessions with interactive tools, breakout rooms, and digital collaboration platforms. HD streaming.  | Distributed teams, cost optimization, time-constrained executives             |
| <b>Hybrid Model</b>                                  | Blend of in-person and virtual elements. Regional hubs with synchronized virtual participation for global teams.  | Global organizations, flexible participation, maximum reach                   |



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Make you Training in more than 35 Countries Around the World

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