Z L G (Zerimar Lagnar Group)

ISO 13485:2016 – Training & Auditor Certification

Medical-device QMS training with strong focus on documentation, validation, risk-based auditing, and compliance readiness.

Audience

Quality/Regulatory teams, Manufacturing/Engineering, Validation, CAPA owners, Document Control, Supplier Quality.

Typical Duration

Awareness: 1 day | Internal Auditor: 2 days | Lead Auditor: 4–5 days (depending on regulatory complexity and scope).

Learning Objectives

- Interpret ISO 13485 requirements and typical objective evidence.
- Audit document control, CAPA, complaint handling, and traceability effectively.
- Evaluate process validation and validation documentation (IQ/OQ/PQ).
- Assess supplier controls and purchasing requirements.
- Build audit trails and write compliant nonconformities.

Course Agenda (High-Level)

- ISO 13485 clause walk-through with medical-device examples
- Documentation hierarchy and record integrity (controls, retention, changes)
- Risk-based auditing approach and audit trails
- CAPA system auditing (root cause, effectiveness, metrics)
- Validation auditing (IQ/OQ/PQ, revalidation triggers)
- Supplier/purchasing controls and incoming acceptance
- Audit reporting, NCR writing, and follow-up verification

What You Receive

- Course slides and participant workbook (PDF)
- Medical-device focused audit checklists and audit-trail guides
- Exam (for certification) and certificate of completion
- Templates: audit plan, report, NCR, CAPA verification checklist

Delivery Options

Live virtual | On-site | Hybrid. Custom modules available (e.g., validation deep-dive, CAPA effectiveness, supplier controls).

Contact

Use the website contact form to request a quote or schedule training. Include your industry, headcount, sites, and target certification timeline.