Medical Device Consultant Certification Scheme

Competence Standard for Medical Device Consultants

Scheme Owner

Life Sciences Sector Skill Development Council

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Version 0.2

Document Type: Competence Standard

Document Name: Competence Standard for Medical Device Consultants
Standard Reference: Job Analysis reports submitted by the Technical Committee and Medical Device Regulations
Status: Final Draft

Document Control

Item	Details
Scheme Name	Medical Device Consultants Certification Scheme (MDCCS)
Scheme Version	1.0
Document No.	LSSSDC/MDCCS/CS/D/V0.3
Drafted on	27 March 2026
Effective Date	To be decided
Reviewed By	Technical Committee for Medical Devices Consultant Certification Scheme
Approved By	Chief Executive Officer, Life Sciences Sector Skill Development Council
Review Cycle	Every 3 years or as required

Table of Contents

1. Purpose

This standard defines the **competence requirements** for Medical Device Consultants. The framework supports a structured, transparent, and impartial assessment criteria and framework aligned with **ISO/IEC 17024 – Conformity Assessment — General requirements for bodies operating Certification of Persons**.

2. Scope

This document applies to all candidates seeking certification under the Medical Device Consultant Certification Scheme, covering:

- Consultant
- Senior Consultant
- Principal Consultant

The framework addresses **common (generic) competence** applicable across medical device domains. Device-specific or clinical-domain competence shall be addressed separately.

3. Eligibility Requirements

3.1. Recommended Educational Background (Non-Mandatory)

Typical but non-restrictive educational backgrounds may include:

3.1.1. Engineering (Biomedical, Mechanical, Electrical, Electronics, Chemical, etc.)

3.1.2. Life Sciences, Pharmacy, Biotechnology

3.1.3. Medical, Dental, or Allied Health Sciences

3.1.4. Quality, Regulatory, or Management disciplines with relevant experience

3.2. Professional Experience Requirements

Consultant Level	Eligibility Criteria for Application
Consultant	Minimum 3 years of experience in the Medical Device Domain (For example, Industry, Auditing, Consulting, Academia, or Research, etc.) with exposure to medical device regulatory/QMS activities and consultative exposure under supervision
Senior Consultant	Minimum 5 years' experience in Medical Device Domain (For example, Industry, Auditing, Consulting, Academia, or Research, etc.) with exposure to medical device regulatory/QMS activities and consultative and ~10 consulting projects

Consultant Level	Eligibility Criteria for Application
Principal Consultant	Minimum 10 years in Medical Device Domain (For example, Industry, Auditing, Consulting, Academia, or Research, etc.) with exposure to medical device regulatory/QMS activities and consultative and ~25 consulting projects

Note: *Final eligibility shall be based on evaluation outcomes rather than experience alone.*

4. Competence Framework Structure

4.1. Mandatory Competence Domain

All candidates seeking certification at any level are expected to have competence across seven (7) domains as given below:

Domain Code	Competence Domain
A	Regulatory Knowledge
B	Technical Documentation & Quality Management System (QMS) Skills
C	Clinical & performance evidence awareness
D	Risk Management & Post-Market Surveillance (PMS), Vigilance & field safety corrective actions (FSCA)
E	Consulting & Methodology Competence
F	Communication, Analytical & Behavioural Competence
G	Experience, Evidence & Professional Practice

Maximum Total Score: 70 points

4.2. Additional Competence Domain

Apart from the 7 competence domains listed in clause 4.1, all candidates seeking certification for **Senior Consultant** and **Principal Consultant** are expected to have additional competence in the **two (2) domains** as given below:

Domain Code	Competence Domain
H	Startup & New Product Launch Competence
I	Mentoring and Coaching Competence

Maximum Total Score: 20 points

5. Competence Domain Descriptions

5.1. Mandatory Competence Domain Descriptors

5.1.1. **Domain A –** Regulatory Knowledge (Indian MDR 2017, CDSCO process and International Regulations (EU MDR, US FDA, UKMHRA, TGA, etc.))

Assessment of ability to:

Sl. No.	Assessment Criteria
A.1.	Understand and interpret the Indian MDR 2017 & CDSCO framework (MD & IVD) and the International Regulation (EU MDR, US FDA, UK MHRA, TGA, etc.)
A.2.	Understand and interpret device classification & regulatory pathway (MD & IVD)
A.3.	Understand and interpret QMS & standards (Schedule V, ISO 13485, ISO 14971, applicable Indian standards, ISO/ IEC standards, IVD standards) and Knowledge to locate/ select NABL-accredited labs for testing
A.4.	Review Technical documentation (MD & IVD)
A.5.	Understand and interpret processes and required documents for regulatory dossier submission and related IT tools, like regulatory information management systems and global regulatory intelligence
A.6.	Perform Licensing, submissions & lifecycle management

5.1.2. **Domain B – Technical Documentation & Quality Management System (QMS) Skills**

Assessment of ability to:

Sl. No.	Assessment Criteria
B.1.	Document and implement Quality Management System, for example, Schedule V MDR2017 or ISO13485
B.2.	Document and implement technical documentation related to products, for example, schedule IV MDR2017, including but not limited to, Design & Development, Clinical Evaluation Plans (CEP) and Clinical Evaluation Reports (CER), Post-Market Clinical Follow-up (PMCF), Usability Engineering, Periodic Safety Update Report (PSUR), and Summary of Safety and Clinical Performance (SSCP)
B.3.	Support audit readiness and documentation compliance

5.1.3. Domain C – Clinical & performance evidence awareness

Assessment of ability to:

Sl. No.	Assessment Criteria
C.1.	Identify applicable clinical or performance evidence requirements
C.2.	Justify waivers or equivalence with documented rationale
C.3.	Define evidence strategy and interfaces effectively with clinical experts

5.1.4. Domain D – Risk Management & Post-Market Surveillance (PMS), Vigilance & field safety corrective actions (FSCA)

Assessment of ability to:

Sl. No.	Assessment Criteria
D.1.	Understand and interpret ISO 14971 risk management principles
D.2.	Understand and interpret Risk analysis, evaluation, and control concepts
D.3.	Understand and interpret Post-Market Surveillance (PMS) and vigilance requirements
D.4.	Understand and interpret the consultant role across the device lifecycle
D.5.	Identify reportable adverse events correctly
D.6.	Derive correct timelines and reporting pathways
D.7.	Manage field safety corrective action (FSCA), recalls, and regulator communication independently

5.1.5. Domain E – Consulting & Methodology Competence

Assessment of ability to:

Sl. No.	Assessment Criteria
E.1.	Define scope, deliverables, and assumptions clearly with reference to regulatory and business objectives
E.2.	Structure multi-site or multi-product engagements coherently and develop executable consulting plans with defined milestones
E.3.	Adapt methodology based on regulatory complexity, client maturity and integrate regulatory, quality, and market considerations to demonstrate planning effectiveness through outcomes
E.4.	Apply structured and risk-based decision tools to identify root causes beyond symptoms

5.1.6. Domain F – Communication, Analytical & Behavioural Competence

Assessment of ability to:

Sl. No.	Assessment Criteria
F.1.	Actively listen and understand the problem statement and communicate concepts
F.2.	Provide clarity to technical and non-technical stakeholders in the context of the meaning, purpose, and impact of non-conformity
F.3.	Handle difficult regulatory conversations amicably to resolve/negotiate objections/inferences/misinterpretation
F.4.	Use structured analysis techniques
F.5.	Draw defensible conclusions from incomplete data
F.6.	Synthesize complex inputs into actionable decisions
F.7.	Identify ethical risks in regulatory decision-making
F.8.	Demonstrate consistent professional judgment with integrity
F.9.	Resolve ethical dilemmas without escalation

5.1.7. **Domain G – Experience, Evidence & Professional Practice**

Assessment of:

Sl. No.	Assessment Criteria
G.1.	Number, scope, and complexity of consulting projects
G.2.	Role performed (supporting / leading / strategic)
G.3.	Quality and relevance of documented evidence
G.4.	Continuous professional development and contribution to the global intelligence ecosystem

5.2. Additional Competence Domain Descriptors (applicable to Senior and Principal Consultant)

5.2.1. **Domain H – Startup & New Product Launch Competence**

Assessment of ability to:

Sl. No.	Assessment Criteria
H.1.	Act as a single-point regulatory integrator for startup teams
H.2.	Assess startup readiness against the MDR and QMS baseline and financial viability
H.3.	Design and budgeting for regulatory roadmap
H.4.	Design minimal yet compliant regulatory and QMS frameworks
H.5.	Align the compliance approach to startup maturity and funding stage
H.6.	Draw defensible conclusions from incomplete data
H.7.	Support first-time submissions with controlled deficiencies
H.8.	Evaluate scalability risks in regulatory and QMS systems
H.9.	Develop scalable regulatory and quality compliance roadmaps

5.2.2. **Domain I – Mentoring and Coaching Competence**

Assessment of ability to:

Sl. No.	Assessment Criteria
I.1.	Embody a Coach mindset, establish and maintain an agreement
I.2.	Demonstrate Ethical Practices & Cultivate Trust & Safety
I.3.	Evoke Awareness and Facilitate Client Growth by coaching the client teams to achieve independent compliance capability
I.4.	Mentor & demonstrate sustained knowledge transfer to client teams
I.5.	Evaluate the process, outcome, and effectiveness of the coaching

Abbreviation and Glossary

Abbreviation	Definition
CDSCO	Central Drugs Standard Control Organisation
CEP	Clinical Evaluation Plans
CER	Clinical Evaluation Reports
EU MDR	EU Medical Device Regulation
FSCA	Field Safety Corrective Action
IEC	International Electrotechnical Commission, which defines a globally recognized series of technical standards
ISO	International Organization for Standardization, which creates international standards to ensure quality, safety, and efficiency across various industries, covering areas like management, technology, and manufacturing
IT	Information Technology
IVD	In-Vitro Diagnostics
MD	Medical Devices
MDR	Medical Device Regulation
NABL	National Accreditation Board for Testing and Calibration Laboratories, a Constituent Board of the Quality Council of India
PMCF	Post-Market Clinical Follow-up
PMS	Post Market Surveillance
PSUR	Periodic Safety Update Report
QMS	Quality Management System
SSCP	Summary of Safety and Clinical Performance
TGA	The Therapeutic Goods Administration (TGA) regulates therapeutic goods in Australia, enforcing stringent standards for safety, quality, and efficacy on medicines, medical devices, and chemicals.
UKMHRA	The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices, and blood components for transfusion in the United Kingdom
US FDA	The U.S. Food and Drug Administration (FDA) is a federal agency within the Department of Health and Human Services responsible for protecting public health

- **End of Competence Standard -**