quality austria
central asia
Succeed with Quality

REGULATORY COMPLIANCE FOR MEDICAL DEVICES

CDSCO CERTIFICATION SERVICES

- Manufacturing License Approval Audits
- Sales & Distribution Compliance
- Storage & Exhibition Authorization
- MD-5 Audits for New Applications & Endorsements
- Regulatory Documentation Support
- ISO 13485 Certification

WHY CHOOSE QACA

- CDSCO-Approved Notified Body
- Expert and Competent Auditors & Compliance Specialists
- Comprehensive Regulatory Compliance
- Audit & Certification Process

CDSCO AUDIT PROCESS

- Client Application on CDSCO Portal
- State Drug Authority assigns to Notified Body
- QACA reviews and accepts the file
- Supporting Documents receiving including filled application form
- Proposal approval & scheduling
- Audit planning & auditor selection
- Audit execution & NC (Non-Conformity) reporting
- Client submits corrective actions evidence
- Final review & file submission on CDSCO Portal
- State Drug Authority reviews the file for granting or rejecting the application

ABOUT US

Quality Austria Central Asia (QACA) is a Notified Body recognized by the Central Drugs Standard Control Organization (CDSCO) under MD-2. We provide regulatory approvals for Manufacturing, Sales, Storage and Distribution of Class A & Class B Medical Devices as per IMDR 2017 (Schedule IV & V).

For non-measurable and non-sterile devices, audits are not required—clients can directly register on the CDSCO portal for license.

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