APAX
ASSESSMENT PRIVATE LIMITED

COMPLY YOURS'S BUSINESS WITH

MEDICAL DEVICES
QUALITY MANAGEMENT SYSTEM
ISO 13485:2016

AS PER NORMS OF CDSCO
FOR
A,B,C &D CLASS OF MEDICAL DEVICES

APAX ASSESSMENT PRIVATE LIMITED

CDSCO

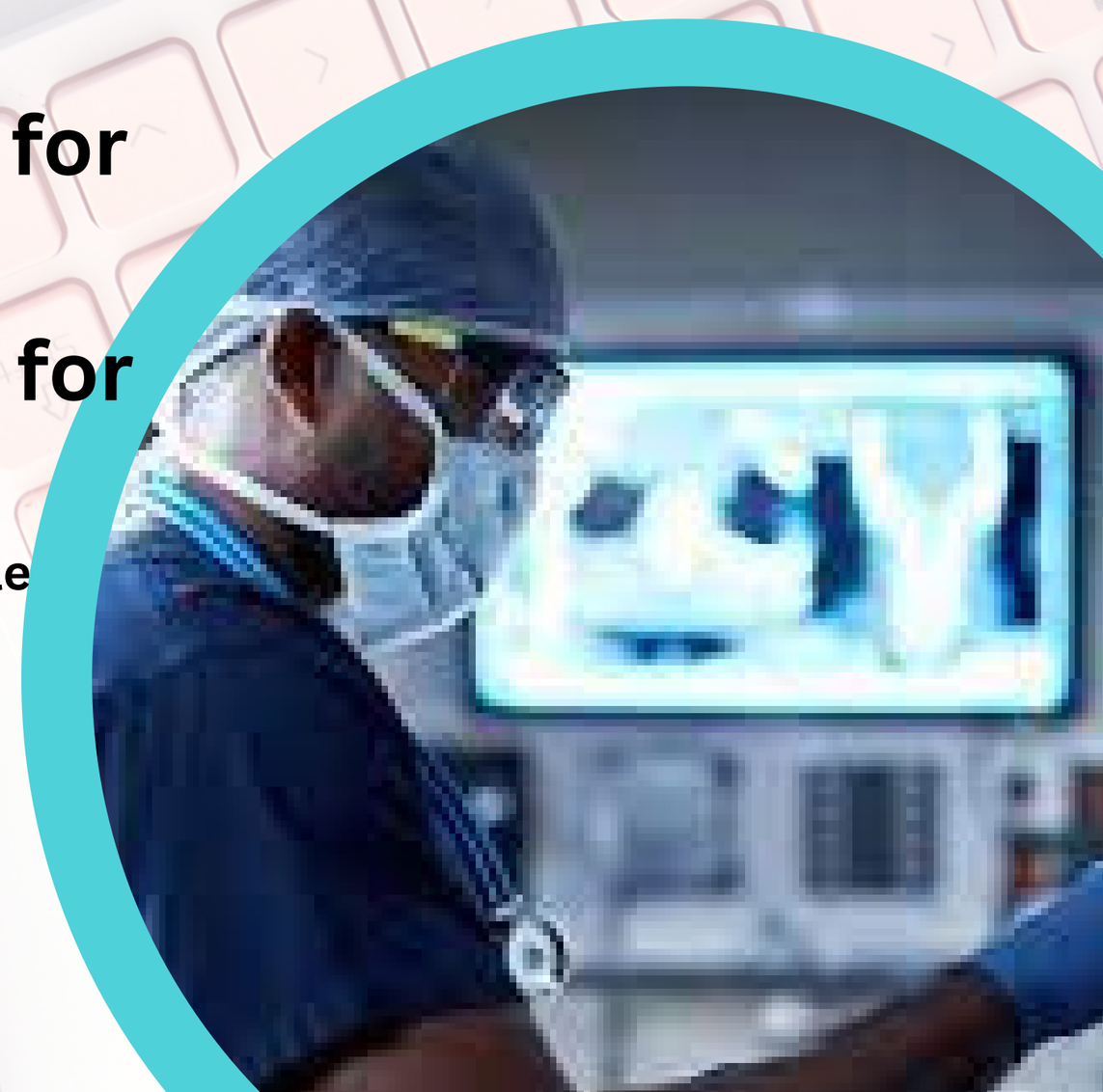
CENTRAL DRUGS STANDARD CONTROL ORGANISATION
DIRECTORATE GENERAL OF HEALTH SERVICES

The Central Drugs Standard Control Organisation (CDSCO) under Directorate General of Health Services, Ministry of Health & Family Welfare,Government of India is the National Regulatory Authority (NRA) of India. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of New Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations as well as Under the Medical Device Rules, the CDSCO is responsible for approval of Medical Devices, which comes under Class A, B, C & D according to the level of their respective risk.

SCHEME FOR MANUFACTURING LICENSE (MD-5) FOR MEDICAL DEVICES -

- **For Class-A & Class-B, Deadline for Application MD-3 - 30.Sept.22**
- **For Class-C & Class-D, Deadline for Application MD-3- 30.Sept.23**

Note- As per Latest GO, Non Measurable and/or Non Sterile Medical Devices only need to apply for registration.



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MEDICAL DEVICES
QUALITY MANAGEMENT SYSTEM
ISO 13485:2016

ISO 13485:2016 is an Latest international standard developed by the International Organization for Standardization which provides management tools for organizations that deals in Manufacturing & services of Medical Devices. It intends to help organizations to meet regulatory requirements and respective needs.

BENEFITS OF ISO 13485:2016 (MD-QMS)

- Better alignment of mission, vision, objectives and action plans.
- Inclusive and quality production of Medical Devices.
- Promotion of lifelong learning opportunities.
- More focus on Legal compliance, customer specific requirements and effective response of needs.

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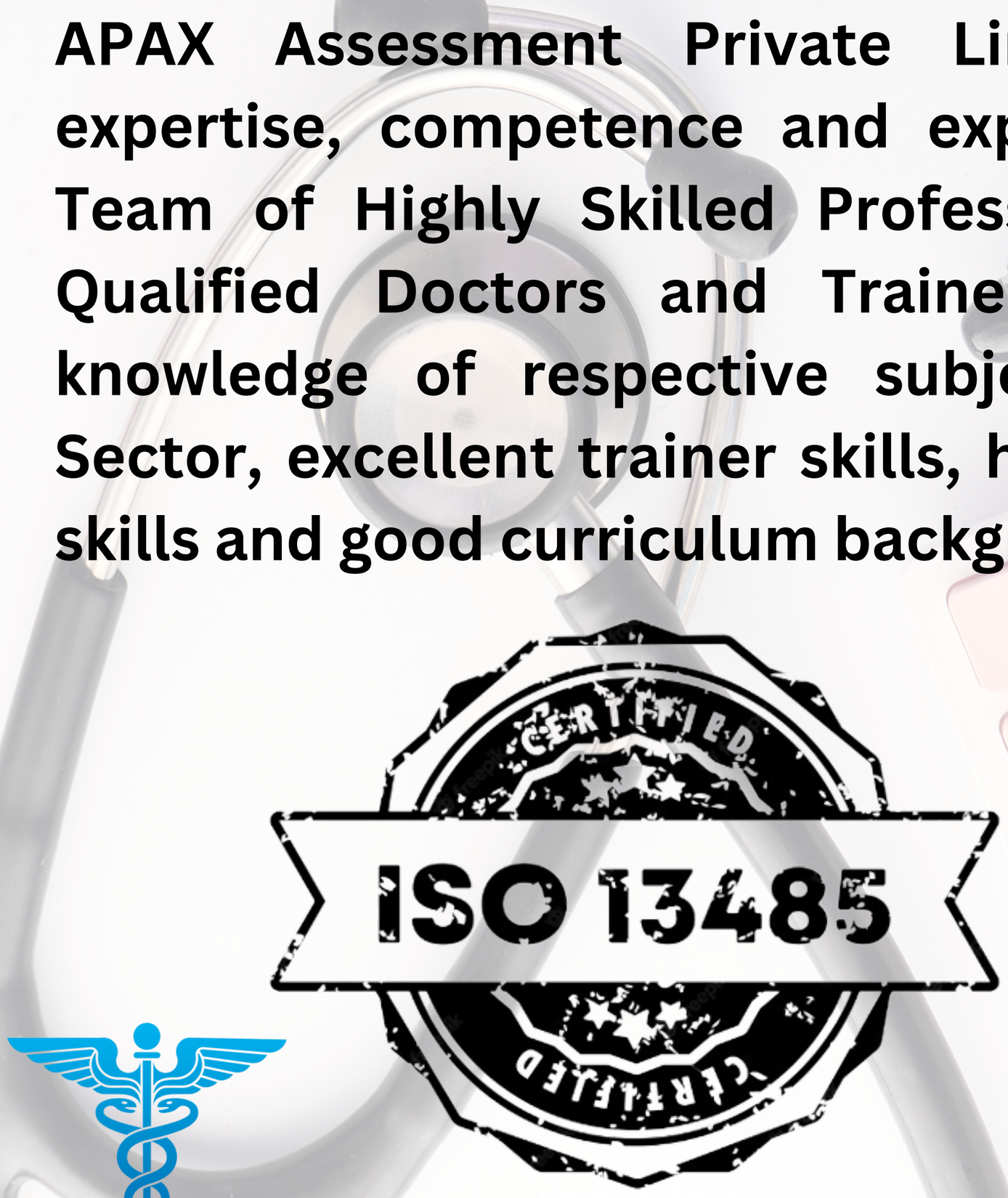
OBJECTIVES OF
ISO 13485:2016
MEDICAL DEVICES QUALITY MANAGEMENT SYSTEM

To facilitate harmonized medical device regulatory requirements for Quality Management Systems and Implement best practice in Manufacturing of Medical Devices.

HOW DOES APAX ASSESSMENT PRIVATE LIMITED HELPS

To Contribute the trustful efforts in Growth of Client organizations involved in manufacturing of medical devices, APAX Assessment Private Limited maintain it's own expertise, competence and experience through having a Team of Highly Skilled Professionals viz. Engineers and Qualified Doctors and Trainers, who have the depth knowledge of respective subjects/standards of Medical Sector, excellent trainer skills, high quality communication skills and good curriculum backgrounds.



APAX
ASSESSMENT PRIVATE LIMITED

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MEET TO US ON META

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