

For those who are:

Implementing regulatory requirements across the globe.

Involved in writing Technical Files or Quality Systems for Medical Devices and IVDs around the world.

Quality Engineers or Regulatory Affairs professionals.

Benefits of the Course

Highly skilled tutor with Notified Body (CE) and Competent Authority (SFDA) experience.

Practical, to incite discussion and accelerate learning.

Provides an open forum to air concerns and ask questions.

Offers the opportunity to compare notes and interact with industry peers.

A full set of course notes and guidance documents for post-course referral.

Eight x 2½ hour modules held live in an on-line lecture theatre Global Regulations for Medical Devices



Goals of the Course

1. Introduction & Regulatory Intelligence

2. Global Regulations

Canada.
Australia.
New Zealand.

3. Global Regulations

Japan.
China.

4. Global Regulations

Latin America.

5. Global Regulations

Southeast Asia.
Compilation of an ASEAN STED.

6. Global Regulations

Middle East & Africa.

7. Global Regulations

CIS Jurisdiction.
India.
Korea.

8. Global Regulations

The USA and MDSAP
Medical Device Single Audit
Programme.

Courses

Public course dates available.

All private courses tailored to the client's individual devices.

Hotel and parking at special rates.

The Academy Centre

info@academycenters.com

المؤسسة العامة للتدريب التقني والمهني
Technical and Vocational Training Corporation



Course code
OC0208