



PROFESSIONAL CERTIFICATE IN MEDICAL DEVICE REGULATORY AFFAIRS AND QUALITY ASSURANCE PROGRAMME

**SGS ACADEMY HONG KONG
LEARNING & DEVELOPMENT SOLUTION**

SGS ACADEMY

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SGS

SGS Hong Kong recognizes the future demands of the ever-changing regulatory and quality landscape. SGS Hong Kong launches Professional Certificate in **Medical Device Regulatory Affairs & Quality Assurance Programme** in collaboration with regulatory specialist from **May 2015**. Medical device regulations are coming up in Asia, European and International markets.

The course consists of **9 modules** designed to address the knowledge requirements for **regulatory affairs & quality assurance specialists** described in the multi-countries' medical device regulations, including the E.U., the United States as well as local regulations. The modules provide practical, face-to-face tuition in professional level detail to prepare candidates for the challenging and ever-growing role of acting as a **regulatory affairs & quality assurance specialists** in today's medical device industry. This course uniquely focuses on the practical exercises and professional knowledge necessary to build skills and confidence for the role of **regulatory affairs & quality assurance specialists**. Sufficient time and depth are provided to grow **regulatory affairs & quality assurance specialists** to be the best they can be and to prepare the candidates for the role ahead, not just the assessment process.

PROGRAMME STRUCTURE :

| Code | Module | Duration | Schedule |
|-------|--|----------|-----------------------|
| MD/2 | Medical Device Management | 1 day | 30 October 2015 |
| MD/3 | Medical Device Regulation | 2 days | 13 & 14 November 2015 |
| MD/4 | Medical Device Regulation for specific countries | 2 days | 04 & 05 December 2015 |
| MD/5 | Introduction of Risk Management (ISO 14971) * | 1 day | 18 January 2016 |
| MD/6 | ISO 13485 Internal Auditor * | 2 days | 07 & 08 January 2016 |
| MD/7 | Medical Device Clinical Evaluation and Performance | 1 day | 22 January 2016 |
| MD/8 | Process Validation for Medical Device | 1 day | 19 February 2016 |
| MD/9 | Medical Device Technical File Preparation and its writing skills | 2 days | 26 & 27 February 2016 |
| MD/10 | Post Market Surveillance and Vigilance System | 1 day | 11 March 2016 |

**Candidate who has attended (MD/6) ISO 13485 Internal Auditor Course and (MD/5) Introduction of Risk Management (ISO 14971) offered by SGS within 18 months of the commencing date can apply for course exemption.*

Remarks:

In order to attain the Professional Certificate (MD/11), candidates should complete all the 9 modules within 18 months from the course starts.

WORK WITH A CERTIFICATION PARTNER WHO IS CONSTANTLY UP-TO-DATE AND ABLE TO HELP YOU STAY AHEAD OF CHANGING REQUIREMENTS

PREPARATION FOR FUTURE REGULATIONS

The regulatory frameworks guiding access for medical devices into different markets are frequently evolving. The only way to ensure your products continue to meet the necessary requirements is to work with a certification partner who is constantly up-to-date and who is therefore able to help you stay ahead of the changing requirements. With our support you are aware of future changes, SGS enables you to stay close to the future requirements of CE marking. Through the assessment and certification services that we provide you can be sure to have all the documented evidence to support your market applications in line with.

Original Price: HK\$ 26,940 / person

Early Bird Price: HK\$ 24,246* / person

*Discount will be offered to participant whose enrolment is made one month prior to the course

•“Special offer”

15% discount will be offered to all enrolment made **two** months prior to the course (available for the courses to be commenced between 3 April to 31 Dec of 2015)

TARGET AUDIENCE:

The Professional Certificate would benefit all stakeholders whom have substantial experiences in the medical device industry, in particular,

- Regulatory affairs specialist,
- Management Representative,
- Quality Management,
- Engineering Management,
- Management of Operation,
- And logistics and distribution professional.

GENERAL INFORMATION:

Time: 9:00 am – 5:00 pm / 9:30 am – 5:30 pm

Venue: : T.S.T. / Wan Chai Training Centre / TBC

Medium: Cantonese supplemented with English material

Tutors :

Ir. Albert Poon,

Associate Specialist, Medical Device Program of SGS

More than 30 years experience in Medical Device and Biomedical Engineering Services, for HK Government before he retired in aspects of Medical Device regulation, technology development, commissioning and maintenance engineering of medical equipment for 44 public hospitals in Hong Kong.

Mr. Kelvin SZE

Certification Officer of SGS Hong Kong

Tutor with more than 6 years of working experiences in medical device and pharmaceutical industry

Experiences across R&D, Registration Regulation, Production Technique, Quality Control & Quality Assurance



(SGS Hong Kong Ltd. reserves the right of final tutor arrangement.)

CERTIFICATION:

Delegates who successfully completed the course will be issued a completion of certificate by SGS Hong Kong Limited.

For Enquiry: Email - hk.academy@sgs.com

Phone: (852) 3543 7900

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|---|--|-----------------|--------------|--------------|--|--|
| MD/11 | ENROLL: PROFESSIONAL CERTIFICATE IN MEDICAL DEVICE RA AND QA PROGRAMME | | | | AVAILABLE | |
| | Payment Method: To confirm your booking, please send the completed registration form together with the course fee by cheque payable to "SGS Hong Kong Ltd." (5/F, Manhattan Centre, 8 Kwai Cheong Road, Kwai Chung, NT, Hong Kong – Attention to SGS Academy) OR deposit the required amount to SGS HSBC account 002-617918-001 "SGS HONG KONG LTD." Then, fax the bank-in slip and course registration form to SGS office at 2333 2257. | | | |  OR  Public Class In-House | |
| Course Date: _____ Company: _____ Address: _____ * How do you know about this course? <input type="checkbox"/> Social Media <input type="checkbox"/> Web <input type="checkbox"/> Friends <input type="checkbox"/> Others _____ | | | | | | |
| Contact Person | | Position | Phone | Email | Would you like to receive SGS information via email in the future? | |
| Mr./Ms. | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Course Participant | | Position | Phone | Email | Would you like to receive SGS information via email in the future? | |
| Mr./Ms. | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| Mr./Ms. | | | | | <input type="checkbox"/> Yes <input type="checkbox"/> No | |
| <small># All cancellations/ postponements of registration must be made to SGS Academy in writing. If postponement is received: One month notice before the course starts, 20% of the training fee will be charged as administration fee. If cancellation is received: One month notice before the course starts, 50% of the training fee will be charged as administration fee. Within two weeks before the course starts, 100 % of the training fee will be charged as administration fee. If you do not want to receive any information from us, please fax to us at (852) 2333 2257.</small> | | | | | | |

Any tax or bank charges, etc induced by settling course fee to SGS Hong Kong Limited must be fully absorbed by the client itself.

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WHEN YOU NEED TO BE SURE

