

BIC Academy 2023



BIC Academy can meet every training need of modern organizations, by providing high-level expertise in management systems in a wide range of scopes. Since its foundation, BIC has successfully completed a great number of training courses globally and has achieved important training partnerships with International Organizations like the [United Nations Industrial Development Organization - UNIDO](#), National Authorities and multinational Companies.

All the trainers of BIC's training programs are experienced and qualified Lead Auditors of Management Systems, ISO Technical Committee members etc, with extensive knowledge and experience in the respective field of training.

In BIC we understand the needs of modern companies for Quality and therefore we also design in-house training courses tailored to your business.

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BIC Academy

<u>Duration</u>	<u>Courses</u>
QUALITY	
1 day	ISO 9001:2015 Awareness and Introduction
1 day	ISO 9001:2015 Strategic Approach Risk-Based Thinking
2 days	ISO 9001:2015 Internal Auditor Course
1 day	ISO 9001:2015 Interpretation, Implementation & Documentation
1 day	Effective Documentation Control and Management
1 day	Supplier Audit Training
ENVIRONMENTAL & CHEMICAL	
1 day	ISO 14001:2015 Awareness and Introduction
2 days	ISO 14001:2015 Internal Auditor Course
1 day	ISO 14001:2015 Interpretation, Implementation & Documentation
1 day	Environmental Aspects and Impact Evaluation Techniques
1 day	Environmental Law and Application in EMS
1 day	Chemical Spillage, clean up and Control
1 day	Chemical Awareness
2 days	Hazardous Chemical Waste Management

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OCCUPATIONAL HEALTH & SAFETY	
1 day	ISO 45001:2018 Awareness and Introduction
2 days	ISO 45001:2018 Internal Auditor Course
1 day	Hazard Identification, Risk Assessment & Control (HIRAC)
1 day	OHS Legal Requirements and Implementation
2 days	Emergency Response Plan
1 day	Ergonomics
1 day	Fire Fighting and Drills
1 day	Accident Analysis & Prevention
1 day	Lockout and Tag out (LOTO)
1 day	Forklift Safety
1 day	First Aid and CPR
MEDICAL DEVICES	
1 day	ISO 13485:2016 Awareness and Introduction
2 days	ISO 13485:2016 Internal Auditor Course
1 day	MDSAP Auditor Training
1 day	Risk Management – ISO 14971 / EN ISO 14971
1 day	Usability Engineering – IEC 62366
1 day	Fundamentals of Medical Device Safety

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1 day	Post Market Surveillance, Vigilance and Adverse Event Investigation
US FDA 	
1 day	US FDA Regulations – US Food, Drugs & Cosmetics Act and title 21 of the code of Federal Regulations
1 day	Market Access Requirements – Pre Market Approval (PMA)
1 day	cGMP / 21 CFR 820 Quality System Regulation
1 day	Good Documentation Practice
1 day	Quality System Inspection Technique (QSIT)
European Union  	
1 day	EU Medical Device Regulations / CE Marking
1 day	EU Directives for Medical Devices / CE Marking
1 day	EU Directives: Machinery; Low Voltage; EMC
Canada 	
1 day	Canadian Food & Drugs Act; and Medical Device Regulations
1 day	Canadian Medical Devices Conformity Assessment System (CMDCAS)
Australia 	
1 day	Australian Therapeutic Goods Act; and Therapeutic Goods (Medical Devices) Regulations
other jurisdictions     	
1 day	ASEAN Medical Device Directive (AMDD)
1 day	Common Submission Dossier Template (CSDT)

1 day	Malaysian Medical Device Act & Regulations 2012
1 day	Malaysian Good Distribution Practice for Medical Devices (GDPMD) & Product Registration
1 day	Singaporean Health Products (Medical Devices) Regulations
1 day	Good Distribution Practice for Medical Devices in Singapore (GDPMDS)
1 day	Gulf Cooperation Council (GCC) – Saudi Arabia, Kuwait, UAE, Qatar, Bahrain, Oman
1 day	Taiwanese Pharmaceutical Affairs Law & Good Manufacturing Practice
1 day	Japanese Pharmaceutical & Medical Device Act (PMD Act)
1 day	Japanese Good Manufacturing Practice (J-QMS Ordinance (MO 169 (amd. 2014)))
QUALITY TOOLS & TECHNIQUE	
1 day	Six Sigma Improvement Methodologies
1 day	Lean Manufacturing
1 day	Kaizen – Continuous Improvement
1 day	7 QC Tools
1 day	APQP, Control Plan & PPAP
1 day	Failure Mode and Effects Analysis (FMEA)
1 day	Statistical Process Control (SPC)
1 day	Measurement System Analysis (MSA)

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Term & Condition

1. All courses and services listed can be delivered in-house or online.
2. Training material and certificate of attendance will issue after the training.
3. Please call or email for quoting and more information inquiries.

Further information please contact:

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Business Integrity Certification Sdn. Bhd.

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