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Pre-Clinical

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Biological Evaluation of Medical Devices: A Risk-Based Approach	N134	63 mins	€ 186.00	€ 144.00
Introduction to Process Validation	N135	75 mins	€ 221.00	€ 166.00
Validation of Ethylene Oxide Sterilization of Medical Devices	N186	53 mins	€ 156.00	€ 117.00

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Pre-Clinical

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Good Laboratory Practices &Biological Evaluation for Medical Devices	110	70 mins	€ 213.00	€ 160.00
Understanding Software Validation	227	54 mins		
Standalone Software Under the Medical Devices Directives	N137	40 mins		
Imaging Modalities Used in Pre-Clinical Research	N161	62 mins	€ 248.00	€ 186.00
Validating Software used in Company Processes	N162	65 mins	€ 260.00	€ 195.00
Biocompatibility of Medical Devices	N188	50 mins	€ 151.00	€ 113.00
IEC 60601-1 Ed 3.1 Compliance Program				
IEC 60601-1 Ed 3.1 - Background and Introduction	N114	45 mins	€ 176.00	€ 132.00
IEC 60601-1 Ed 3.1 - Risk Management and General Requirements	N196	59 mins	€ 236.00	€ 177.00
IEC 60601-1 Ed 3.1 - Protection Against Electrical Shock, and verifying Electrical Insulation	N197	94 mins	€ 376.00	€ 282.00
IEC 60601-1 Ed 3.1 - Medical Electrical Systems and Protection Against Mechanical Hazards	N198	69 mins	€ 276.00	€ 207.00
IEC 60601-1 Ed 3.1 - Protection Against Thermal and Other Hazards and Components	N199	54 mins	€ 216.00	€ 162.00

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Clinical Evaluation

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Accelerating Successful Patient Recruitment	119	70 mins	€ 207.00	€ 155.00
Directive 93/42/EEC and update 2007/47/EC: A review for clinical professionals (rev 1.2)	60	60 mins	€ 183.00	€ 137.00
Importance of Clinical Investigator´s Brochure (IB)	117	85 mins	€ 332.00	€ 249.00
IRB Review of Medical Devices	148	153 mins	€ 452.00	€ 339.00
ISO 14155 Version 2003 vs. 2011: Gap Analysis	176	0 mins		
Managing Data Release Consent During Post Market Studies	226	31 mins	€ 58.00	€ 44.00
The European Medical Device New Regulation	N180	38 mins		
Medical Device GCP: A Practical Summary	N191	75 mins	€ 221.00	€ 166.00
Safety Reporting Requirements 2 course Suite				
US Safety Reporting Requirements during Pre-Market Clinical Trials	90	20 mins	€ 59.00	€ 44.00
European Safety Reporting Requirements during Pre-Market clinical Investigations	82	25 mins	€ 74.00	€ 55.00
ISO 14155: In Depth Review				
ISO 14155:2011- Scope	61	20 mins	€ 61.00	€ 46.00
ISO 14155:2011 - Ethical Considerations	62	20 mins	€ 61.00	€ 46.00
ISO 14155:2011 - Clinical Investigation Planning	63	30 mins	€ 61.00	€ 46.00
ISO 14155:2011 - Clinical Investigation Conduct	64	40 mins	€ 122.00	€ 91.00
ISO 14155:2011 - Clinical Investigation Close Out	65	20 mins	€ 61.00	€ 46.00
ISO 14155:2011 - Responsibilities of Sponsor	66	45 mins	€ 137.00	€ 103.00
ISO 14155:2011 - Responsibilities of Principal Investigator	67	30 mins	€ 91.00	€ 69.00
Medical Device GCP for Investigators				
GCP for Investigators: Introduction to Medical Devices	193	52 mins	€ 104.00	€ 78.00
GCP for Investigators: How to Qualify for Medical Device Clinical Investigations	200	32 mins	€ 86.00	€ 65.00
GCP for Investigators: Ethics and Legal Processes for Medical Device Clinical Investigations	212	25 mins	€ 76.00	€ 57.00

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GCP for Investigators: Initiation of a Medical Device Clinical Investigation	202	30 mins	€ 86.00	€ 65.00
GCP for Investigators: Clinical Investigation Conduct and Reporting	204	51 mins	€ 116.00	€ 87.00
GCP for Investigators: Clinical Investigation Close out or Termination	206	23 mins	€ 60.00	€ 45.00
Effective Monitoring of Medical Device Clinical Investigations				
History of Good Clinical Practice (GCP)	41	15 mins	FREE	FREE
Introduction to Good Clinical Practice	42	45 mins	€ 90.00	€ 68.00
Introduction to Medical Device and Clinical Investigation Planning	43	45 mins	€ 133.00	€ 100.00
The Clinical Investigation Plan	44	45 mins	€ 133.00	€ 100.00
The Informed Consent Process	45	45 mins	€ 133.00	€ 100.00
Ethics Committee(EC) / Institutional Review Board Requirements	46	40 mins	€ 118.00	€ 89.00
Selecting Investigation Sites	47	45 mins	€ 133.00	€ 100.00
Initiation Visit	48	45 mins	€ 133.00	€ 100.00
Adverse Event Processes	59	77 mins	€ 198.00	€ 148.00
The Periodic Monitoring Visit	56	120 mins	€ 354.00	€ 266.00
Device Accountability	50	20 mins	€ 59.00	€ 44.00
Deviations and Non-Compliance Handling	51	15 mins	€ 44.00	€ 33.00
Source Document Verification	52	30 mins	€ 89.00	€ 66.00
The Case Report Form Process	53	45 mins	€ 133.00	€ 100.00
Visit Report Writing	54	15 mins	€ 44.00	€ 33.00
The Close Down Visit	55	30 mins	€ 89.00	€ 66.00
Overview of Data Management Plan and Query Process	108	25 mins	€ 74.00	€ 55.00
Good Documentation Practices for Clinical Study Files	96	45 mins	€ 133.00	€ 100.00

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Clinical Evaluation

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Conducting studies using Electronic Data Capture	109	30 mins	€ 91.00	€ 69.00
ISO 14155: 2011 – A Summary Review	144	44 mins	€ 134.00	€ 100.00
Centralized vs. Onsite Monitoring Applying FDA's Risk-Based Approach	N190	50 mins	€ 152.00	€ 114.00
Auditing Medical Device Clinical Investigations				
Clinical Audits: Fundamentals of Auditing Medical Device Clinical Investigations	217	36 mins	€ 110.00	€ 82.00
Clinical Audits: Sponsor/Third Party Audits of Clinical Investigation sites	218	66 mins	€ 201.00	€ 151.00
Clinical Audits: Auditing the Clinical Research Organisation and the Sponsor	219	82 mins	€ 250.00	€ 187.00
US Bioresearch Monitoring 3 Course Suite				
BIMO: US FDA BIMO Compliance Program	143	54 mins	€ 165.00	€ 123.00
BIMO: IDE Sponsor Obligations	150	180 mins	€ 549.00	€ 411.00
BIMO: IDE Investigator Obligations	155	190 mins	€ 594.00	€ 446.00
EU Clinical Investigation Agreements				
Understanding EU Clinical Investigation Agreements	111	40 mins	€ 122.00	€ 91.00
Negotiating EU Clinical Investigation Agreements	112	40 mins	€ 122.00	€ 91.00
Navigating International Medical Device Clinical Investigation Requirements				
Conducting Medical Device Clinical Investigations in Switzerland	N138	34 mins	€ 104.00	€ 78.00
Conducting Medical Device Clinical Investigations in Germany	N157	85 mins	€ 340.00	€ 255.00
Medical Device Clinical Investigation in Germany – Requirements of the Radiation Ordinances	N159	50 mins	€ 200.00	€ 150.00
Conducting Medical Device Clinical Investigations in Romania	N165	20 mins	€ 61.00	€ 46.00
Conducting Medical Device Clinical Investigations in Singapore	N164	25 mins	€ 76.00	€ 57.00
Safety Related Committee Establishment				
Clinical Events Committee (CEC) Establishment	114	90 mins	€ 360.00	€ 270.00
Data Safety &Monitoring Board (DSMB) Establishment	127	90 mins	€ 360.00	€ 270.00

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Clinical Data for Reimbursement	157	57 mins	€ 233.00	€ 175.00
Clinical Project Management Complete 10 course Suite				
CPM: Objectives and Setup of a Medical Device Clinical Trial	97	35 mins	€ 160.00	€ 120.00
CPM: The Clinical Trial master plan for Medical Devices	98	50 mins	€ 200.00	€ 150.00
CPM: Medical Device Clinical Trials - Budget and Timelines Planning	99	100 mins	€ 400.00	€ 300.00
CPM: Medical Device Clinical Trial Team Resources	100	50 mins	€ 200.00	€ 150.00
CPM: Tracking and Reporting Rules for Medical Device Clinical Trials	101	25 mins	€ 100.00	€ 75.00
CPM: Project Guidelines for Medical Device Clinical Trials	102	30 mins	€ 120.00	€ 90.00
CPM: Managing Ongoing Medical Device Clinical Trials	103	20 mins	€ 80.00	€ 60.00
CPM: Compliance Management during Medical Device Clinical Trials	104	40 mins	€ 160.00	€ 120.00
CPM: Effective Communication Methods during Medical Device Clinical Trials	105	50 mins	€ 200.00	€ 150.00
CPM: Close Out and Clinical Report of a Medical Device Clinical Trial	106	30 mins	€ 120.00	€ 90.00
Clinical Evaluation for Market Approval				
Clinical Evaluation for EU Market Approval: Process and Regulatory background	116	80 mins	€ 328.00	€ 246.00
Clinical Evaluation for EU Market Approval: Literature Review	120	50 mins	€ 205.00	€ 154.00
Performing a Clinical Evaluation for EU Market Approval: Step by Step Primer	124	58 mins	€ 238.00	€ 178.00
Designing a Strategic Clinical Investigation Plan				
Format and Structure of a Medical Device Clinical Investigation Plan/Protocol	N140	42 mins	€ 132.00	€ 99.00
Designing a Strategic Medical Device Clinical Investigation Plan/Protocol	N141	90 mins	€ 454.00	€ 341.00
Clinical Protocol Writing Process and Ensuring Compliance	N142	35 mins	€ 110.00	€ 83.00

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Regulatory Affairs

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Complaint Handling and Reporting Process for Medical Devices	141	65 mins	€ 192.00	€ 144.00
Demarcation of Medical Devices to Other Products	75	60 mins	€ 177.00	€ 133.00
Role of RA Specialist in the Design Process	154	40 mins	€ 118.00	€ 89.00
The Australian Regulatory System for In-Vitro Diagnostic (IVD) Devices	132	80 mins	€ 390.00	€ 293.00
Regulatory Framework for In-Vitro Medical Devices in the US	N149	60 mins	€ 177.00	€ 133.00
The ASEAN Common Submission Dossier Template (CSDT) and Its Contents	N203	70 mins	€ 200.00	€ 150.00
Navigating International Regulatory Systems				
Introduction to the US FDA	76	25 mins	FREE	FREE
The Hong Kong Regulatory System for Medical Devices	186	72 mins	€ 213.00	€ 159.00
The Australian Regulatory System for Medical Devices	113	110 mins	€ 325.00	€ 244.00
The European Union Regulatory System for Medical Devices	145	175 mins	€ 517.00	€ 388.00
The Japanese Regulatory System for Medical Devices	146	95 mins		
Singapore’s Regulatory System for Medical Devices	191	68 mins	€ 139.00	€ 104.00
Pre-Market Approval for Medical Device in China	N139	53 mins		
Medical Device Pre-Market Approval Process in Korea	N155	60 mins		
Registration Process for Medical Devices in Brazil	N174	53 mins	€ 156.00	€ 117.00
Strategic Approach to Bringing Medical Devices to the Indonesian Market	N146	50 mins	€ 148.00	€ 111.00
Labeling Requirements for Medical Devices				
Labeling Requirements for Medical Devices in Europe	N133	87 mins	€ 257.00	€ 193.00
Electronic Instructions for Use of Medical Devices in the European Union	N143	50 mins	€ 152.00	€ 114.00
Labeling Requirements for Medical Devices in the US	N144	70 mins	€ 207.00	€ 155.00
GHTF/IMDRF Regulatory Model for Medical Devices				
Introduction to the GHTF or IMDRF	N169	25 mins	€ 74.00	€ 55.00
GHTF/IMDRF: The Pre-Market Model	N170	30 mins	€ 89.00	€ 66.00
GHTF/IMDRF – The Post-Market Model	N171	30 mins	€ 89.00	€ 66.00

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GHTF/IMDRF – Supporting Documents	N172	30 mins	€ 89.00	€ 66.00
GHTF/IMDRF – International Implementation	N173	35 mins	€ 103.00	€ 78.00
GHTF/IMDRF – Essential Principles of Safety and Performance for Medical Devices	N182	83 mins	€ 245.00	€ 184.00
GHTF/IMDRF: Summary Technical Documentation (STED) and Its Contents	N187	50 mins	€ 148.00	€ 111.00
Current and upcoming IVD market access requirements in Europe				
Pathways to CE Marking under the In Vitro Diagnostics Directive	N168	50 mins	€ 148.00	€ 111.00
The Draft European IVD Regulation	N181	50 mins	€ 152.00	€ 114.00

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Regulatory Affairs

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Good Documentation &Writing Practices for Regulatory Submissions	129	60 mins	€ 234.00	€ 176.00
US FDA 510(k) Notification Process	92	50 mins	€ 152.00	€ 114.00
US FDA Investigational Device Exemption (IDE) Overview	121	125 mins	€ 381.00	€ 286.00
Active Medical Devices in Europe: Particular Requirements	N183	58 mins	€ 177.00	€ 133.00
RoHS Directive 2011/65/EU &WEEE Directive 2012/19/EU	N200	33 mins	€ 101.00	€ 75.00
Risk Management for Medical Devices in the EU and US				
ISO 14971: 2007 Review	78	35 mins	€ 107.00	€ 80.00
Preparing Risk Management File &Which Techniques Apply	83	24 mins	€ 73.00	€ 55.00
Integrating Risk Management into Your Quality Management System	94	35 mins	€ 107.00	€ 80.00
Implications of EN ISO 14971:2012	N189	28 mins	€ 85.00	€ 64.00
Understanding Clinical Evaluation for Notified Body and Regulatory Professionals				
Clinical Evaluation report of Existing data for CE-mark: review for regulatory professionals	107	70 mins	€ 280.00	€ 210.00
Data from Prospective Clinical Investigation for CE-Mark: Review for Regulatory Professionals	122	95 mins	€ 380.00	€ 285.00
What's changing in Rev 4 of MEDDEV 2.7.1 New!!	N194	50 mins	€ 200.00	€ 150.00
Including an IVD on the Australian Register of Therapeutic Goods				
IVD Australia: Basics for including an IVD on the ARTG	N150	44 mins	€ 176.00	€ 132.00
IVD Australia: The Use of GMDN Codes for IVDs in Australia	N151	45 mins	€ 180.00	€ 135.00
IVD Australia: Making Applications for Inclusion on the ARTG	N152	33 mins	€ 132.00	€ 99.00
IVD Australia: Obtaining a TGA Conformity Assessment Certificate for IVD devices	N153	40 mins	€ 160.00	€ 120.00
IVD Australia: Fees for Including an IVD Device on the TGA or ARTG	N154	43 mins	€ 172.00	€ 129.00

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Quality Assurance

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
ISO 13485 - Medical Devices Quality Management Systems Requirements for Regulatory Purposes	196	183 mins	€ 366.00	€ 275.00
Importance of Technical Standards in the Medical Device Sector	185	72 mins	€ 213.00	€ 159.00
Overview of US FDA Quality System Regulation	118	75 mins	€ 300.00	€ 225.00
ISO 13485: Foundation and Basic Principles	N179	183 mins		

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Quality Assurance

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
How to Navigate Through the ISO 13485 Certification Process	195	44 mins	€ 176.00	€ 132.00
Preparing Successfully for a US FDA Medical Device Inspection	215	109 mins	€ 332.00	€ 249.00
Internal Auditor Training for Medical Device Manufacturers	209	214 mins	€ 652.00	€ 489.00
Project Management of Medical Device Development	N136	85 mins	€ 340.00	€ 255.00

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Health Economics &Reimbursement

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
The Basics of US Private Payer Reimbursement for Medical Devices	140	32 mins	€ 64.00	€ 48.00
Reimbursement Strategy for Medical Devices in the US	156	45 mins	€ 86.00	€ 64.00
Introduction to EU Funding and Reimbursement of Medical Devices				
Introduction to European Funding and Reimbursement Systems	134	40 mins		
German Healthcare System	135	35 mins		
French Healthcare System	136	22 mins		
UK Healthcare System	137	35 mins		
Italian Healthcare System	138	20 mins		
Developing an EU Reimbursement Strategy for a Medical Device	139	40 mins		

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Health Economics &Reimbursement

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Health Economic Evaluation of Medical Technologies	115	65 mins	€ 322.00	€ 241.00

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Combination Products

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Introduction to Combination Products in the US	213	62 mins	€ 242.00	€ 182.00
Introduction to Drug-Device Combination Regulations in Europe	N160	55 mins	€ 162.00	€ 122.00

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Start-ups &Business Ethics

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Introduction to Digital Governance: A Four-Step Approach	184	57 mins	€ 168.00	€ 126.00
Introduction to Medical Devices from Idea to Market				
The Lifecycle of Medical Devices from Idea to Market	159	42 mins	€ 124.00	€ 93.00
Creating Value in Healthcare	175	44 mins	€ 172.00	€ 129.00
Introduction to the EU Regulatory System	160	36 mins	€ 106.00	€ 80.00
What is considered a Medical Device?	161	40 mins	€ 118.00	€ 89.00
Steps to CE Mark	162	52 mins	€ 154.00	€ 115.00
The Main Concepts for Safe and Performing Devices	163	39 mins	€ 115.00	€ 86.00
Clinical Evaluation of Medical Devices: an Introduction	165	43 mins	€ 127.00	€ 95.00
Post Market Surveillance: an Introduction	166	34 mins	€ 100.00	€ 75.00

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Start-ups &Business Ethics

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Developing Markets for Medical Technologies: How to Drive Adoption	220	42 mins	€ 168.00	€ 126.00
Introduction to Medical Devices from Idea to Market				
Intellectual Property Concepts for Medical Devices	N132	38 mins	€ 112.00	€ 84.00
Business Plan Essentials for Medical Products	177	60 mins	€ 246.00	€ 184.00

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General Interest

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Powerful Presentation Skills	70	140 mins	€ 267.00	€ 200.00

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General Interest

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Team Building	93	100 mins	€ 390.00	€ 293.00
Effective Time Management	N148	176 mins	€ 604.00	€ 483.00
Applied Project Management				
Applied Project Management: Project!	72	23 mins	€ 68.00	€ 51.00
Applied Project Management: Project Stakeholders	73	20 mins	€ 59.00	€ 44.00
Applied Project Management: Objectives and Arena	74	30 mins	€ 89.00	€ 66.00
Applied Project Management: Visualizing	84	10 mins	€ 30.00	€ 22.00
Applied Project Management: Project Planning	85	40 mins	€ 118.00	€ 89.00
Applied Project Management: Project Organization	86	35 mins	€ 103.00	€ 78.00
Applied Project Management: Project Environment	87	30 mins	€ 89.00	€ 66.00
Applied Project Management: Risks and Opportunities	88	30 mins	€ 89.00	€ 66.00
Applied Project Management: Project Realization	89	60 mins	€ 177.00	€ 133.00
Applied Project Management: Project Leadership	91	50 mins	€ 148.00	€ 111.00

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Certification Exams

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
CMDA Clinical Evaluation - Online Exam	N131	90 mins	€ 80.00	€ 80.00