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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 Device	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	€ 216.00	€ 162.00
Standalone Software Under the Medical Devices Directives	N137	40 mins	€ 160.00	€ 120.00
Imaging Modalities Used in Preclinical 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	€ 300.00	€ 105.00
Managing Data Release Consent During Post Market Studies	226	31 mins	€ 58.00	€ 44.00
The European Medical Device New Regulation	N180	38 mins	FREE	FREE
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
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
Navigating International Regulatory Systems				
Introduction to the US FDA	76	25 mins	FREE	FREE
Hong Kong´s 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	€ 280.00	€ 210.00
The Singapore Regulatory System for Medical Devices	191	51 mins	€ 139.00	€ 104.00
Medical Device Pre-Market Approval Process in Korea	N155	60 mins	€ 177.00	€ 133.00
Registration Process for Medical Devices in Brazil	N174	53 mins	€ 156.00	€ 117.00
Strategic Approach to Bring a Medical Device 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 for 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 Premarket Model	N170	30 mins	€ 89.00	€ 66.00
GHTF/IMDRF – The Post-Market Model	N171	30 mins	€ 89.00	€ 66.00
GHTF/IMDRF – Supporting Documents	N172	30 mins	€ 89.00	€ 66.00
GHTF/IMDRF – International Implementation	N173	35 mins	€ 103.00	€ 78.00

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GHTF/IMDRF – Essential Principles of Safety and Performance for Medical Devices	N182	83 mins	€ 245.00	€ 184.00
GHTF/IMDRF – The 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	50 mins	€ 200.00	€ 150.00
Data from prospective clinical investigation for CE-mark: review for regulatory professionals	122	95 mins	€ 380.00	€ 285.00
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 application 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 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: Foundation and Basic Principles	196	152 mins	€ 304.00	€ 228.00
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

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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	€ 118.00	€ 89.00
German Healthcare System	135	35 mins	€ 103.00	€ 78.00
French Healthcare System	136	22 mins	€ 88.00	€ 49.00
UK Healthcare System	137	35 mins	€ 103.00	€ 78.00
Italian Healthcare System	138	20 mins	€ 59.00	€ 44.00
Developing an EU Reimbursement Strategy for a Medical Device	139	40 mins	€ 118.00	€ 89.00

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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 USA	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 - Test Exam online	N131	90 mins	€ 80.00	€ 80.00