

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 |

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 |

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 |

Online Training Catalogue for Medical Device Professionals

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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 |

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 |

Online Training Catalogue for Medical Device Professionals

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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 |

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 Pre-market 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 |

Online Training Catalogue for Medical Device Professionals

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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 |

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 |
| 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 |

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 |

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 |

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 |

Online Training Catalogue for Medical Device Professionals

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 |

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 |

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 |

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 |

Online Training Catalogue for Medical Device Professionals

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 |

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 |

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 |