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South 8th Street, Minneapolis
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Clinical Evaluation

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Importance of Clinical Investigator´s Brochure (IB)	117	85 mins	€ 332.00	€ 249.00
IRB Review of Medical Devices	148	153 mins		
ISO 14155:2020 – A Summary Review	144	80 mins	€ 260.00	€ 195.00
Safety Reporting Requirements 2 course Suite				
US Safety Reporting Requirements during Pre-Market Clinical Trials	90	20 mins	€ 65.00	€ 48.00
European Safety Reporting Requirements during Clinical Investigations	82	25 mins	€ 74.00	€ 55.00
Medical Device GCP for Investigators				
GCP for Investigators: Introduction to Medical Devices	193	52 mins	€ 114.00	€ 86.00
GCP for Investigators: How to Qualify for Medical Device Clinical Investigations	200	32 mins	€ 95.00	€ 72.00
GCP for Investigators: Ethics and Legal Processes for Medical Device Clinical Investigations	212	25 mins	€ 84.00	€ 63.00
GCP for Investigators: Initiation of a Medical Device Clinical Investigation	202	30 mins	€ 95.00	€ 72.00
GCP for Investigators: Clinical Investigation Conduct and Reporting	204	51 mins	€ 128.00	€ 96.00
GCP for Investigators: Clinical Investigation Close out or Termination	206	23 mins	€ 66.00	€ 50.00
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	€ 99.00	€ 75.00
Introduction to Medical Device and Clinical Investigation Planning	43	45 mins	€ 146.00	€ 110.00
The Clinical Investigation Plan	44	45 mins	€ 146.00	€ 110.00
The Informed Consent Process	45	45 mins	€ 146.00	€ 110.00
Ethics Committee(EC) / Institutional Review Board Requirements	46	40 mins	€ 130.00	€ 98.00
Selecting Investigation Sites	47	45 mins	€ 146.00	€ 110.00
Initiation Visit	48	45 mins	€ 146.00	€ 110.00
Adverse Event Processes	59	77 mins	€ 218.00	€ 163.00
The Periodic Monitoring Visit	56	120 mins	€ 389.00	€ 293.00
Device Accountability	50	20 mins	€ 65.00	€ 48.00

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Deviations and Non-Compliance Handling	51	15 mins	€ 48.00	€ 36.00
Source Document Verification	52	30 mins	€ 98.00	€ 73.00
The Case Report Form Process	53	45 mins	€ 146.00	€ 110.00
Visit Report Writing	54	15 mins	€ 48.00	€ 36.00
The Close Down Visit	55	30 mins	€ 98.00	€ 73.00
Overview of Data Management Plan and Query Process	108	25 mins		
Good Documentation Practices for Clinical Study Files	96	45 mins		
ISO 14155:2020 - GCP Certificate				
ISO 14155:2020 - Scope	N158	40 mins	€ 130.00	€ 98.00
ISO 14155:2020 - Ethical Considerations	N175	30 mins	€ 98.00	€ 73.00
ISO 14155:2020 - Clinical Investigation Planning	N176	50 mins	€ 163.00	€ 122.00
ISO 14155:2020 - Clinical Investigation Conduct	N177	40 mins	€ 130.00	€ 98.00
ISO 14155:2020 - Clinical Investigation Close Out	N178	25 mins	€ 81.00	€ 61.00
ISO 14155:2020 - Responsibilities of Sponsor	N184	45 mins	€ 146.00	€ 110.00
ISO 14155:2020 - Responsibilities of Principal Investigator	N185	35 mins	€ 113.00	€ 86.00
ISO 14155:2020:				
ISO 14155_1_	N213	40 mins	€ 130.00	€ 98.00
ISO 14155_2_	N214	30 mins	€ 98.00	€ 73.00
ISO 14155_3_	N215	50 mins	€ 163.00	€ 122.00
ISO 14155_4_	N216	40 mins	€ 130.00	€ 98.00
ISO 14155_5_	N217	25 mins	€ 81.00	€ 61.00
ISO 14155_6_	N218	45 mins	€ 146.00	€ 110.00
ISO 14155_7_	N219	35 mins	€ 113.00	€ 86.00
GCP_				
1	N205	52 mins	€ 114.00	€ 86.00
	N206	32 mins	€ 95.00	€ 72.00
	N209	25 mins	€ 84.00	€ 63.00
	N207	30 mins	€ 95.00	€ 72.00
	N210	51 mins	€ 128.00	€ 96.00
	N208	23 mins	€ 66.00	€ 50.00

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Clinical Evaluation

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Clinical Data for Reimbursement	157	57 mins		
Centralized vs. Onsite Monitoring Applying FDA's Risk-Based Approach	N190	50 mins		
Applying GDPR to Medical Devices Clinical Investigations	N246	37 mins	€ 124.00	€ 94.00
EU-MDR 2017/745 Review for Clinical Professionals	N249	80 mins	€ 234.00	€ 176.00
ISO 14155 GCP – Main Differences with ICH 6 clinical professionals should know	N325	45 mins	€ 151.00	€ 113.00
EU Clinical Investigation Agreements				
Understanding EU Clinical Investigation Agreements	111	40 mins		
Negotiating EU Clinical Investigation Agreements	112	40 mins		
Navigating International Medical Device Clinical Investigation Requirements				
Conducting Medical Device Clinical Investigations in Switzerland	N138	35 mins		
Medical Device Clinical Investigation in Germany – Requirements of the Radiation Ordinances	N159	50 mins		
Safety Related Committee Establishment				
Clinical Events Committee (CEC) Establishment	114	90 mins		
Data Safety &Monitoring Board (DSMB) Establishment	127	90 mins		
Clinical Evaluation for Market Approval				
Clinical Evaluation for Market Approval New!!	116	80 mins	€ 352.00	€ 264.00

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Regulatory Affairs

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
Role of RA Specialist in the Design Process	154	40 mins		
Pre-Market Approval for Medical Device in China	N139	53 mins		
The European Medical Device New Regulation 2017/745	N180	330 mins	€ 925.00	€ 694.00
Current and upcoming IVD market access requirements in Europe				
The Draft European IVD Regulation	N181	50 mins		

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Regulatory Affairs

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Understanding Clinical Evaluation for Notified Body and Regulatory Professionals				
Clinical Evaluation Report: Review for Regulatory Professionals	107	70 mins	€ 308.00	€ 231.00

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Quality Assurance

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
ISO 13485:2016 - Medical Devices Quality Management Systems Requirements for Regulatory Purposes	196	183 mins	€ 403.00	€ 303.00
Overview of US FDA Quality System Regulation	118	75 mins		

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Quality Assurance

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Preparing Successfully for a US FDA Medical Device Inspection	215	109 mins		

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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		

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General Interest

Advanced Level : CMDP – Certified Medical Device Professional

Course Title	ID	Duration	Basic	Premium
Effective Time Management	N148	176 mins		

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Certification Exams

Basic Level : CMDA – Certified Medical Device Associate

Course Title	ID	Duration	Basic	Premium
CMDA Clinical Evaluation - Mock Exam	N131	90 mins	€ 90.00	€ 90.00