2023

# Guide to CERTIFICATION PROGRAMS

WMDO

WORLD MEDICAL DEVICE ORGANIZATION

**CERTIFICATION PROGRAM**

**THE WORLD'S FIRST AND ONLY INTERNATIONAL CERTIFICATION PROGRAM DESIGNED SPECIFICALLY FOR MEDICAL DEVICE PROFESSIONALS.**

**WMDO SA**
Route de Denges 28E
1027 Lonay
Switzerland

Tel. +41 21 349 96 36
Fax +41 21 349 96 37

contact@wmdo.org
**www.wmdo.org**

WMDO
WORLD MEDICAL DEVICE ORGANIZATION

## Certified Medical Device Associate (CMDA) - Clinical Evaluation

WMDO has setup the first level certification examination for medical device clinical professionals leading to a diploma of CMDA – Clinical Evaluation. This is the first certification examination for clinical research associates or similar positions within the industry, hospitals or regulatory agencies focusing on the medical device requirements and methodologies.

The next levels will follow with the CMDP – certified medical device professional level for clinical evaluation targeting the next level of knowledge for clinical project managers or similar positions in the industry, hospitals or regulatory agencies. The CMDP examination would be a logical follow up after a CDMA certified person evolves in his or her career.

## Who should register for the CMDA – Clinical Evaluation exam?

Professionals who started in medical device clinical research with a basic knowledge acquired through on-the-job training or pertinent training courses can register for the exam. Participants can take WMDO online courses as part of the preparation for the examination (see conditions explained below). The WMDO online training platform offers a full series of over 35 online courses, printable resources and case studies that put learners into practical situations. At the end of each course a quiz provides the opportunity to test knowledge learned. Upon successful completion of the online post course quiz a certificate of completion is obtained.

In conjunction with leading industry experts and authorities, WMDO has created the Medical Device Body of Knowledge for clinical evaluation, which represents a complete set of global concepts, terms and activities specific to the medical device industry.

This unique and important Guide to Certification Programs indicates the functional knowledge you will need to know in order to successfully obtain CMDA certification.

We strongly encourage you to review the Medical Device Body of Knowledge in preparation for the CMDA examination. The following link leads to the outline of the CMDA – Clinical Evaluation Body of Knowledge

In addition to the online training courses, subscribers to the live examination will also get an online pre-examination which will provide them with a feel for the level of knowledge required to successfully pass the live examination.

The live certification examination will lead to the diploma of

CMDA®
CERTIFIED MEDICAL DEVICE ASSOCIATE
CLINICAL EVALUATION

## Taking the examination

The certification examination is organized yearly in different locations. The examination consists of about 90 multiple choice and true/false questions. Candidates will also be required to analyze and present practical solutions to several case studies based on real-life situations.

All exams will be reviewed and corrected by WMDO's independent certification board and individual examination results will be considered as objectively as possible to insure that candidates receive the best possible chances while demonstrating substantial professional competency.

The pass criteria require a 60% and successful candidates will receive the CMDA-Clinical Evaluation certification which carries a validity of three years before recertification is required.

## The WMDO Certification Program

Today more than ever, regulators as well as employers are on the lookout for certified training qualifications that authenticate individuals of having successfully acquired the necessary skills and professional background to correctly and accurately perform their functional duties.

The WMDO Certification Program acknowledges an individual's effort to achieve a professional level of competence within the different specialty areas of the medical device industry.

Certification is based on level of expertise combined with the number of years of experience in a given area and is aimed to reflect objectively the level of expertise of the individual.

## Why device specific certification?

Until now, there is no readily available certification program established for clinical professionals in the medical device industry. It is WMDO's goal to reinforce recognition of knowledge for clinical professionals in the medical device industry in order to contribute to a higher level of professional standards in this area, which to date still suffers from an overwhelming but inappropriate pharmaceutical influence.

Medical device clinical evaluation and investigation processes are significantly different from pharmaceutical; therefore specific regulations have been developed under the different regulatory systems and worldwide standards have been implemented to meet these needs. It is essential that medical device clinical professionals respond to the highest quality standards possible which can be achieved through a combination of high quality training and professional experience.

## WMDO’s Accreditation

The WMDO Certification Program has been established through an independent certification board and is subject to a stringent quality system.

Through the initiation of the CMDA – clinical evaluation exams and other exams that will follow in the near future, WMDO is following the requirements to obtain the Accreditation by the Institute for Credentialing Excellence. ICE’s accrediting body, the National Commission for Certifying Agencies (NCCA), evaluates certification organizations for compliance with the NCCA Standards for the Accreditation of Certification Programs. This accreditation is in progress while a number of exams must have taken place before WMDO will become eligible to become accredited.

## Certification Renewal

The recertification process is essential in ensuring continued professional development for certified individuals. Once certification is awarded, all CMDAs are required to recertify every three years by providing proof of continued professional activity within the medical device clinical area, as well as a combined 40 hours of continued education.

From time to time, and depending on the frequency of changes in industry regulations and rules, CMDAs may be requested to furnish proof of continued education on specific subjects as applicable to their professional activity.

WMDO will offer a system for recognized programs, institutions, conference organizers and other education providers who can apply for credits for their specific programs to be evaluated by the independent certification board and if approved, taken into account by WMDO for credits for continued education.

## How to subscribe, when and where are the exams?

The subscription to the examination can be done online click here

**Registration Fee** : **€715 (USD 913*)**

The registration fee includes a premium account as well as the online pre-exam. Existing premium account holders shall pay €500 (USD 638*)

A premium account will allow the user to get additional support from the subject matter experts while taking the online courses and the online pre-exam. The premium account also entitles to a variety of pricing (up to 40% discount on future course purchases) and resources offers. The online pre-examination contains approximately 120 questions on medical device regulations related to the conduct of clinical investigations globally, questions on GCP requirements throughout the different phases of a medical device clinical investigations whether conducted in Europe or under US requirements.

**CMDA Training Package:** One Year Unlimited access to the CMDA Training Package (35 online courses) **€990 (USD 1254*).** This is a unique offer only available to participants of the CMDA clinical evaluation. The content of the package is listed in the Annex A.

**Buy separate Online Pre-Examination:** the pre-examination can also be purchased separately at a price of **€90 (USD 113*).**

***currency fluctuations may apply***

**Cancellation or postponing the exam:** The participation to the examination can be cancelled at any moment; however fees will not be refunded. Already subscribed but not ready yet? We allow participants to postpone 1 time only, thereafter the subscription will be cancelled and the fees are not refundable.

**Examination Dates:**

March 6th, 2023

September 4th, 2023

**Examination Locations:**

Lausanne – Switzerland

Horsholm – Denmark (in collaboration with Medicoindustrien)

Singapore

Minneapolis – USA

**Additional locations can be setup upon demand provided a minimum of 8 participants.**

## Joining the Certification Board

WMDO currently opens a call to senior clinical industry and regulator's experts to join the WMDO Independent Certification Board. With our independent certification board we ensure an ethical, non-biased process for our Certification exams.

Following is involved in becoming an independent Certification Board Member:

- An agreement between the certification board member and WMDO will be signed outlining each party's role and responsibility and the fee structure for the board member.
- The Certification Board Member assures WMDO to contribute to the certification program in an objective, unbiased and constructive manner.
- We will share our SOP on our certification process with the board member as a basis for operating together
- Certification board members are asked to provide for each examination a set of questions or to serve as a quality control reviewer before the examination questions are released for printing.
- Certification board members may be called upon for correcting some parts of the exams that are not multiple choice or automatic yes/no – true/false answers. In this case the policy of WMDO is to have a second board member making the same correction so as to ensure optimal objectivity. Current exams are not including such questions but CMDP or MMDP exams may.
- When needed, a certification board member may also be called upon as an ombudsman if objections are raised by candidates.

## Disclaimer

The CMDA exam is designed and meant for Clinical Research Associates (CRA) to Junior Project Managers. WMDO cannot be held liable should anyone without proper professional background take and fail the CMDA exam.

WMDO
WORLD MEDICAL DEVICE ORGANIZATION

## About WMDO

The medical device industry's most trusted source for professional online training.

WMDO is a legal entity based in Lonay, Switzerland with offices in Minneapolis– USA and Kuala Lumpur - Malaysia.

Until 2009, there was no readily available certification program established for regulatory & clinical professionals in the medical device industry. WMDO started to reinforce recognition of knowledge for regulatory & clinical professionals in the medical device industry in order to contribute to a higher level of professional standards in this area.

WMDO created courses based on the device life cycle.


Currently there are over 200 courses online, from entry to senior level courses, for pre-clinical, regulatory, quality assurance, clinical, post market surveillance, reimbursement and health technology.

WMDO developed the e-learning training program in conjunction with leading industry experts and authorities. This WMDO faculty board has created the Medical Device Body of Knowledge for regulatory & clinical evaluation, which represents a complete set of concepts, terms and activities specific to the medical device sector. The e-learning modules are prepared by subject matter experts (SME).

Courses developed by the SME's are peer reviewed by industry experts or members of the regulatory authorities. The biographies of all Subject Matter Experts involved at WMDO can be found on our website http://www.wmdo.org/sme.aspx.

The program is fully web-based (e-learning). Learn at your own pace - from work, at home or on the road. All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, practical case studies, online quizzes and include all necessary course materials.

Since 2009, WMDO continues expanding the course library to offer the world's most meaningful and complete e-learning program for medical device professionals.

Please visit our website www.wmdo.org or contact us for more information contact@wmdo.org.

We're looking forward to meeting you at WMDO!

WMDO
WORLD MEDICAL DEVICE ORGANIZATION

# Annex A: CMDA Clinical Evaluation Pre-examination course program

## CERTIFIED MEDICAL DEVICE ASSOCIATE (CMDA) - CLINICAL EVALUATION

### Course package to prepare for the CMDA Clinical Evaluation Certification Exam:

| ID | Course |
|---|---|
| 41 | **History of Good Clinical Practice (GCP)** |
| | An incredible, eye-opening look into the historic events of criminal misconduct and total disregard for human life that led to the introduction of Good Clinical Practice. |
| 42 | **Introduction to Good Clinical Practice** |
| | This introductory course to GCP will take you directly into the fundamental elements and objectives of Good Clinical Practice to illustrate why and how these are enforced throughout every stage of a clinical investigation.<br><br>You will also be introduced to the major requirements outlined within the Declaration of Helsinki and the applicable regulations concerning medical device clinical investigations as specified under GCP and ISO 14155. |
| 43 | **Introduction to Medical Device and Clinical Investigation Planning** |
| | What exactly is a medical device? How are they classified? What are the stages involved within a medical device clinical investigation? Get straight answers to these sometimes confusing questions by unearthing the real significance behind clinical investigations for medical devices delivered in this richly detailed and comprehensible course. |
| 44 | **The Clinical Investigation Plan** |
| | Provides the basic information on roles and responsibilities within the process of writing a clinical investigation plan as well as tools for the monitor to learn the content of a clinical investigation plan. |
| 45 | **The Informed Consent Process** |
| | Includes instructions on how to develop the informed consent and what are the essential elements of an informed consent. |
| 46 | **Ethics Committee / IRB Requirements** |
| | Provides an overview of ethics committee or IRB requirements throughout the world, to ensure an efficient process. |
| 47 | **Selecting Investigation Sites** |
| | Provides practical instructions on how to go about investigation site selection and the qualifications needed to ensure optimal future collaboration and compliance. |
| 48 | **The Initiation Visit** |
| | Provides practical guidance and instructions on the preparation, conduct and follow up on the initiation visit to ensure optimal compliance of all parties involved. |
| 59 | **Adverse Event Processes** |
| | Review of the basics of safety reporting, applicable rules and regulations on documenting, classifying and reporting of safety information during a clinical investigation prior to market approval including practical examples and case studies.<br><br>Part 1: Understanding safety principles Part 2: Reporting safety data |
| 56 | **The Periodic Monitoring Visit** |
| | In depth review of all activities related to the monitoring of a clinical investigation after initiation including preparation, conduct and follow up of a periodic monitoring visit at the investigation site. |
| 50 | **Device Accountability** |

| | |
|---|---|
| | A review of the logistics of device accountability including shipment, ordering, use, disposition and return of investigational devices. |
| 51 | **Deviations and Non-Compliance Handling** |
| | Reviews the different types of deviations during a clinical investigation and necessary actions and reporting requirements to ensure subject safety and data quality. |
| 52 | **Source Document Verification** |
| | Provide the type of source documents and data that should be identified and review systems of active and effective source document verification including skills necessary to reach the objectives. |
| 53 | **The Case Report Form Process** |
| | Reviews the process of data flow with paper and electronic data capturing systems including query processing. |
| 54 | **Visit Report Writing** |
| | Outline of effective visit report writing, practical tips of report contents, style and language. |
| 55 | **The Close Down Visit** |
| | Provides methods and essential information for effective study close down, including preparing, conducting and follow-up on close down visits. |
| 108 | **Overview of Data Management Plan and Query Process** |
| | This course provides you with an easy to understand and excellent overview of the **data management plan** and the **query process.** Here you will be taken through the data management plan in general, with a complete explanation of the process of edit checks, why we use CRF instructions and the difference between database queries and monitoring queries. Believe us; queries (like size) do matter. |
| 96 | **Good Documentation Practices for Clinical Study Files** |
| | This course provides you with an easy to understand and excellent overview of the **data management plan** and the **query process.** Here you will be taken through the data management plan in general, with a complete explanation of the process of edit checks, why we use CRF instructions and the difference between database queries and monitoring queries. Believe us; queries (like size) do matter. |

| ID | Course |
|---|---|
| N158 | **Scope of the ISO 14155** |
| | This course will take you into the background of ISO 14155 and demonstrate how you can use it in conjunction with other regulatory documents as well as providing you with helpful clarifications to the latest revision of the ISO 14155 that now extends the applicability of its requirements to all types of clinical investigations.<br><br>Your attention will also be drawn to a number of important references adapted by ISO concerning other standards of which are applicable when conducting clinical investigations, including ISO 14971 on risk management. |
| N175 | **Ethics Considerations** |
| | This course offers you a detailed outline of the ethical considerations and special circumstances covered under Section 4 of the ISO 14155 concerning clinical investigations that are to be conducted on vulnerable populations.<br><br>Specific requirements of the informed consent process are explained and procedures for obtaining informed consent in special circumstances such as when subjects cannot read or write, or are not capable of giving informed consent due to a specific clinical status are addressed. |
| N176 | **Clinical Investigation Planning** |
| | This course provides you with a close look into Section 5 of the ISO 14155 latest revision describing all required activities during the investigation planning phase including risk assessment, justification of the investigation design, writing and implementation of the CIP, Investigator brochure and CRF, setup of a monitoring plan, site selection, investigation agreements, labeling |

| | |
|---|---|
| | requirements and setup of a data monitoring committee. |
| N177 | **Clinical Investigation Conduct** |
| | Here you will learn all about the ISO 14155 requirements governing activities that are to be performed from the beginning and throughout the duration of a clinical investigation.<br><br>This includes initiation visit, site monitoring, adverse event and device deficiencies reporting, documents and documentation, what to do with new site personnel, how to guarantee subjects privacy and confidentiality, what to do for document and data control, how to account for all subjects and what are auditing requirements. |
| N178 | **Clinical Investigation Close Out** |
| | As outlined in Section 7 of the revised ISO 14155, this course will explain in detail the clinical investigation close out process as well as elaborate on the requirements for either a premature termination of the clinical investigation or a temporary suspension and resuming a clinical investigation. |
| N184 | **Responsibilities of Sponsor** |
| | This course offers you a review the ISO 14155 requirements with regards to responsibilities of the sponsor, including those of the monitor during set-up, conduct and close down of the clinical investigation.<br><br>You will gain insight on specific sponsor responsibilities pertaining to clinical quality assurance and quality control, preparation and planning of a clinical investigation, responsibilities during the clinical investigation including monitoring and safety handling, as well as outsourcing and communication with regulatory authorities. |
| N185 | **Responsibilities of Principal Investigator** |
| | This course details the investigator's qualification requirements and responsibilities during all stages of the clinical investigation as referred to in Section 9 of the ISO 14155, including the requirements on appropriately trained and qualified team members and the procedure for notification of delegated tasks. |

| ID | Course |
|---|---|
| 82 | **Safety Reporting Requirements Europe** |
| | This course provides a review of the overall regulatory requirements for adverse event reporting during clinical investigations in Europe including an outline of the applicable documents and what the different reporting requirements are for both competent authorities and ethics committees. The course takes into account the requirements of MEDDEV 2.7/3, MDD and AIMD requirements. For additional national requirements learners should go to the courses on national requirements for conducting clinical investigations. |
| 90 | **Safety Reporting Requirements Europe US** |
| | This course covers the requirements on safety reporting and any other related reporting requirements during clinical investigations with significant and non-significant risk devices, to both US FDA as well as Institutional Review Boards in the United States of America. The course applies requirements from the CFR 812.150. |

| ID | Course |
|---|---|
| 117 | **Importance of Clinical Investigator´s Brochure (IB)** |
| | This intuitive course on **Importance of Clinical Investigator´s Brochure** serves up key explications and insight as to why it is important to provide the investigator with crucial information supporting your medical device´s use in a clinical investigation. This document along with the instructional training regarding content that you provide will directly impact the establishment of trust and cooperation with your investigator.<br><br>A large section of this course is dedicated to the content and level of detail that the investigator's brochure must present and includes discussion on the role of instructions for use and product training, balancing the information within this document and protecting a company's intellectual property as well as how risk management pulls investigational device information and preclinical/clinical data together to provide a compelling argument to the investigator as to the safety of the investigational device. |

| ID | Course |
|---|---|
| 76 | **Introduction to the US FDA** |
| | This course explains the definition of the US FDA, US FDA`s responsibilities, and the chronological history of the significant dates related to the US FDA and medical devices. This course lays the foundation for subsequent courses explaining the regulations found in 21 CFR and the pathways to marketing medical devices in the US. |

| ID | Course |
|---|---|
| 121 | **US FDA Investigational Device Exemption (IDE) Overview** |
| | According to the risk factor surrounding any investigational device, an **investigational device exemption (IDE)** is required by the FDA in order to allow the investigational device to be used in a clinical study for the purpose of collecting safety and effectiveness data in support of a PMA application and in some cases, a 510(k) submission.<br><br>Sounds simple enough – let's do it. So where do we start?<br><br>This 4 part course by US regulatory expert Carole Stamp outlines FDA regulations related to US clinical studies for medical devices and will provide you with a comprehensible and clear look at the IDE application process, differentiating significant and non-significant risk studies, addressing typical problems that can arise during studies as well as an overview of FDA inspection procedures and requirements. |

| ID | Course (Optional) |
|---|---|
| 70 | **Powerful Presentation Skills** |
| | Learn to skillfully present your ideas with impact and confidence while conveying information in a compelling and persuasive manner with this dynamic 3 part course by master presenter, Chris Colaço.<br><br>From the basics of presentation scoping and structure to developing presentation techniques, voice and body language, uncover the secrets behind preparing and delivering highly successful and engaging presentations.<br><br>This in-depth 3 part course will help you acquire the skills you need to structure your ideas into professional, focused presentations, how to develop your presentation techniques as well as using voice and body language to communicate more professionally and effectively. |

| ID | Course |
|---|---|
| 226 | **Managing Data Release Consent During Post Market Studies** |
| | This course outlines the major data protection legal backgrounds throughout the world while pointing to how these apply in post market clinical investigations with medical devices. The details of the process involved in the data release consent form to be signed by any subject involved in a clinical investigation are outlined including an overview of special circumstances when subjects cannot read or write or are part of a vulnerable population.<br><br>The course is based on the Declaration of Helsinki and both the EU Directive and HIPPAA requirements. |

| ID | Course |
|---|---|
| 148 | **IRB Review of Medical Devices** |
| | In summary, an Institutional Review Board or IRB refers to a group whose function is to review research to assure the protection of the rights and welfare of human research subjects. This 6 part course offers clinical professionals a highly practical and informational look at IRBs from the historical development, structure and function to ethical standards and review of medical device research protocols and related materials. |