heig-vd

Centre de Formation Continue

CAS CARAQA: Study plan

The program od the CAS is structured to cover the main requirements of Regulatory Affairs, Clinical Affairs and Quality Assurance applied to Medical devices (MD) and In-Vitro Diagnostic devices (IVD):

Module 1: Introduction to world of devices

1.0.1 Typical products (incl. apps)	Skim over the key families of MD and IVD product and get a grip of what regulations covers
1.0.2 Interaction with bodies	Who are the key stakeholders , competent authorities, notified bodies, legal manufacturers, contractors ?
1.0.3 Markets, startups, acquisitions	What is the structure of the medtech market, big players, startups feeding big players with innovation, typical product lifecycle ?
1.0.4 Implied activities, stakeholders	Get a grip on product lifecycle, innovation, industrialization, atomization of specialties, contractor market outlook, subcontracting design, subcontracting production

Module 2: Regulatory affairs, design and submissions

2.1 CE regulation

2.1.1 CE marking, new MDRs, IVDR	Regulatory pathways, regulations in EC, changes of regulation
2.1.2 Classification, MEDDEVs	What makes an MD & and IVD, borderline classification? claims, Meddevs and NB-med
2.1.3 Assessment procedures	How does the Notified Body review a CE file ? what are the steps ? 1st skim on what is the contents of a technical file, where is the focus depending on product class ?
2.1.4 Vigilance & MDR, MEDDEVs	What are the duties of an LM ? how are incidents managed ? what should be reported, FSCA and FSN ?
2.1.5 Technical Files	In depth review of technical files, visit of an actual technical file for a complex product, what are the modules, usefulness of a STED

heig-vd

2.2	**US regulation, classification, 510k, PMA**	510k vs. PMA, US law, delays, links with QSR, principle of predicate device, product classification codes
2.3	**Foreign registrations**	Procedure of main secondary important markets Canada, Brazil, China, Thailand, Malaysia, Australia, Russia, Korea, classic deployment strategies
2.4	**Regulatory, product & process design**	
2.4.1	Risk management EN ISO 14971	Principles, risk management plan, tools for risk analysis, identification of Harms, HA vs. FMEA, mitigation, residual risk, links with other processes, update
2.4.2	Software lifecycle management EN 62304	Categories of software, firmware, apps, servers, classification of software, lifecycle management, verification and validation
2.4.3	Sterilization EtO, Steam, Radiation	How to select a sterilization process ? principle of validation, how to validate the key cycles, links with packaging validation ?
2.4.4	Usability EN 62366	Principles of usability engineering, user identification, use cases, formative and summative studies
2.4.5	Electrical & safety compliance EN 60601	Principles of safety of ME products, how to organize testing, planning and content of reports, links with risk management and labeling
2.4.6	Biocompatibility EN ISO 10933-1	Scope of application, various scenarios for organizing assessments, impact on suppliers work, links with cleaning validation, organization of tests with test labs, classic tests, chemical characterization
2.4.7	IFUs, labeling	How to structure the work on IFUs, early alignment with product claims, links with risk management, standards for symbols, specific case of ME
2.4.8	Process validation (incl. SW)	Purposes, difference between US and EU, how to plan QC, master validation plan, how to structure a validation plan. Classic processes : cleaning, welding, marking, sterilization
2.4.9	Controlled environments	Cleanrooms and controlled environments setups used for medical device manufacturing and assembly. Contamination control, monitoring, validation.

heig-vd

Module 3: Quality Management

3.0.1 Architecture and deployment QMS	Process approach, how to map processes, sequence of deployment, scope of coverage of QMS, level of details required, layering of documentation, categories of documents.
3.0.2 Change Management	Impact of installing a QMS in a team of engineers, scientists, business people. Key methods for driving the project and the change of behaviors / attitudes
3.0.3 EN ISO 13485:2016	When is it required? what is a certification process? what are the key concepts in the standards? measurability, quality policy and objectives
3.0.4 Quality System Regulation (QSR)	Impact of a regulation, areas of similarities, differences with ISO 13485, QSR audits, common sensible points, FDA audit style
3.0.5 Medical Device Single Audit Program (MDSAP)	New approach for limiting audits, applying countries, expectations for the future, organization, challenges
3.0.6 Management SubSys.	Instances, management review, KPIs, objectives
3.0.7 Resources SubSys.	Human resources, job descriptions, organization charts, training plan, training records, material resources, preventive and corrective maintenance, calibration
3.0.8 Design & development SubSys.	Design planning, staged versus linear model, design input, layering, design methods, design reviews, structure of DHF, planning of verifications, handling of changes, design verification, integration of usability, integration of risk management
3.0.9 Purchasing & supplier SubSys.	Subcontracting of design, sourcing of processes, managing suppliers, suppliers classes, qualification criterion, quality agreements, incoming QC, supplier audits
3.0.10 CAPA + NC handling SubSys.	Device Master Record, Device History Record, production planning, routers, batch records, extents for traceability, work instructions, integration of contractors, product releases
3.0.11 Documentation and records Subsys.	Tools for managing documentation, control process, releases, categories of documentation, list of records, duration of storage, paper vs. electronic
3.0.12 Customer related processes Subsys.	Managing distributors, managing channels, contracts, order processing, good distribution practices, customer complaints handling

heig-vd

Module 4: Clinical

4.0.1	Clinical evaluation of MDDs, MEDDEV	Regulatory requirements, clinical strategy, investigation vs. evaluation, clinical planning, structure of CER, sources of data, appraisal, link IFUs, biocompatibility and risk management, conclusions, maintenance
4.0.2	Performance evaluation of IVDs	Strategy of performance evaluation for IVD, new expectations linked with IVDR, biobanks samples, review of data
4.0.3	Statistical design	Methods for dimensioning an evaluation, power of analysis, statistical models
4.0.4	Investigation strategy & organization, MEDDEV	Planning of a clinical investigation, endpoints, CA and EC authorization, IBrochure, protocol, CRF, Informed Consent, GCP, EN ISO 14155
4.0.5	Post-market surveillance (PMS & PMCF), MEDDEV	Integration of PMS with CER, planning of Post Market Clinical Follow-up, conditional CE marking / market access, protocols and reports

Examination

All 4 modules of the CAS CARAQA will be subjected to a final exam in written form.

CAS thesis

The completion of the program will be accompanied by the writing of an extensive individual thesis. The subject of the thesis is a complete RA, CA & QA study of a medical device or IVD device along the 4 modules of the program. The device can be individually decided by each participant, possibly linked to his/her professional activity.
A personal coach will be assigned to each participant with the responsibility to support and supervise the CAS thesis. The work on the thesis will start at the very beginning of the CAS program, starting with the choice of the studied device, validated by the coach. Then the study will be written as personal assignment along the successive modules of the program, with regular interaction and feedback from the coach.
The thesis is written in English.
The CAS thesis finally belongs to the participant an may be used in the frame of the participant's employment.

Contact HEIG-VD: Didier Maillefer
didier.maillefer@heig-vd.ch
www.cas-caraqa.ch

Contact Medidee: Philippe Etter
www.medidee.com

medídee®

Hes·so
Haute Ecole Spécialisée
de Suisse occidentale