Curriculum CARAQA 2022 - 1/2

The team of CARAQA lecturers is composed of experts from the university sector and Swiss MedTech Company Medidee, as well as regional and international industry representatives

On site training in Lübeck as currently planned.
Amendments due on-going developments in the sector may be possible.

Friday, 21.01.22

Module: 1) Intro Topic: 0) 2 Hrs

1) Typical products (inclus e/ apps)
Skimm around the key families of MD and IVD product and get a grip of what regulations covers

Module: 1) Intro Topic: 0) 2 Hrs

2) New Approach, NLF, Interaction with bodies
Background of the EU system of conformity assessment, modular approach, Who are the key stakeholders, competent authorities, notified bodies, legal manufacturers, contractors

Module: 1) Intro Topic: 0) 2 Hrs

3) Implied activities, stakeholders
Get a grip on product lifecycle, innovation, industrialization, atomization of specialties, contractor market outlook, subcontracting design, subcontracting production

Saturday, 22.01.22

Module: 2) Reg Topic: 1) CE Reg 2 Hrs

1) CE marking, new MDR, IVDR
Regulatory pathways, regulations in EU, changes of regulation

Module: 2) Reg Topic: 1) CE Reg 3 Hrs

2) CE marking, new MDR, IVDR
Case study

Module: 2) Reg Topic: 1) CE Reg 2 Hrs

3) Demarcation & Classification Part 1
Intended use What makes an MD & and IVD, demarcation, borderline products, claims, classification rules, Meddevs, NB-med, MDCG

Module: 2) Reg Topic: 1) CE Reg 1 Hrs

4) Demarcation & Classification Part 2
Case study, both MDR & IVDR

Online training as currently planned

Friday, 04.02.22

Module: 2) Reg Topic: 1) CE Reg 3 Hrs

1) Technical documentation according to MDR/IVDR - Overview
Annex II, III of MDR & IVDR, Major overview

Module: 2) Reg Topic: 1) CE Reg 3 Hrs

2) Assessment procedures
How does the Notified Body review a CE file, what are the steps, 1st skimm on what are the contents of a technical file, where is the focus depending on product class, bridging pre and post MDR / IVDR, accent on future

Module: 2) Reg Topic: 1) CE Reg 2 Hrs

3) Vigilance & MDR, MEDDEVs, MDCG
What are the duties of an LM, how are incidents managed, what should be reported, FSCA and FSN

Saturday, 05.02.22

Module: 2) Reg Topic: 2) US Reg 6 Hrs

1) US regulation, classification, 510k, PMA
510k vs PMA, US law, delays, links with QSR, principle of predicate device, product classification codes

Friday, 18.02.22

Module: 2) Reg Topic: 3) Foreign 5 Hrs

1) Foreign registrations
Procedure of main secondary important markets Canada, Brasil, China, Thailand, Malaysia, Australia, Russia, Korea, classic deployement strategies

Module: 2) Reg Topic: 4) Prod 3 Hrs

1) Risk management 14971
Principles, risk management plan, V-model, tools for risk analysis, identification of Harms, RA vs FMEA, mitigation, residual risk, links with other processes, update

Saturday, 19.02.22

Module: 2) Reg Topic: 4) Prod 6 Hrs

2) Risk management 14971
Case study

Friday, 04.03.22

Module: 2) Reg Topic: 4) Prod 8 Hrs

3) Software lifecycle management 62304
Categories of software, firmwares, apps, servers, classification of software, lifecycle management, verification and validation

Saturday, 05.03.22

Module: 2) Reg Topic: 4) Prod 6 Hrs

4) Sterilization Eto, Steam, Radiation
How to select a sterilization process, principle of validation, how to validate the key cycles, links with packaging validation

Friday, 18.03.22

Module: 2) Reg Topic: 4) Prod 4 Hrs

5) Laser technology - technical, clinical and safety aspects

Module: 2) Reg Topic: 4) Prod 4 Hrs

6) Electrical safety & EMC 60601
Principles of safety of ME products, how to organize testing, planning and content of reports, links with risk management and labeling

Saturday, 19.03.22

Module: 2) Reg Topic: 4) Prod 6 Hrs

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

Friday, 01.04.22

Module: 2) Reg Topic: 1) CE Reg 5Hrs

8) Process validation (inclus SW)
Purposes, difference between US and EU, how to plan QC, master validation plan, how to structucre a validation plan. Classic processes : cleaning, welding, marking, sterilization

Module: 2) Reg Topic: 1) CE Reg 3 Hrs

9) Biocompatibility EN ISO 10933-1
Scope of application, various scenarios for organizing assessements, impact on suppliers work, links with cleaning validation, organization of tests with test labs, classic tests, chemical caracterization

Saturday, 02.04.22

Module: 2) QM Topic: 0) 6 Hrs

1) Architecture and deployment QMS
Process approach, how to map processes, sequence of deployement, scope of coverage of QMS, level of details required, layering of documentation, categories of documents.

Curriculum CARAQA 2022 - 2/2

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Friday, 22.04.22

Module: 3) QM Topic: 0) 6 Hrs

2) ISO 13485:2016 & US QSR
When is it required, what is a certification process, what are the key concepts in the standards, measurability, quality policy and objectives; Impact of a regulation, areas of similarities, differences with ISO 13485, QSR audits, common sensible points, FDA audit style

Module: 3) QM Topic: 0) 2 Hrs

3) MDSAP
New approach for limiting audits, applying countries, expectations for the future, organization, challenges

Saturday, 23.04.22

Module: 3) QM Topic: 0) 2 Hrs

4) Management SubSys
Instances, managment review, KPIs, objectives

Module: 3) QM Topic: 0) 2 Hrs

5) Resources SubSys
Human resources, job descriptions, organization charts, training plan, training records, material resources, preventive and corrective maintenance, calibration

Module: 3) QM Topic: 0) 2 Hrs

6) Design & development SubSys
Design planning, staged versus linear model, desing input, layering, design methods, design reviews, structure of DHF, planning of verifications, handling of changes, design verification, integration of usability, integration of risk management

Online training as currently planned

Friday, 06.05.22

Module: 3) QM Topic: 0) 4 Hrs

7) Purchasing & supplier SubSys
Subcontracting of design, sourcing of processes, managing suppliers, suppliers classes, qualification criterion, quality agreements, incoming QC, supplier audits

Module: 3) QM Topic: 0) 4 Hrs

8) CAPA + NC handling SubSys
Context of detection of events, process for handling NC, process for CAPAs, single layer to double layered systems, tools for managing, link with other processes (vigilance, risk management)

Saturday, 07.05.22

Module: 3) QM Topic: 0) 4 Hrs

9) Production & process controls Subsys
Device Master Record, Device History Record, production planning, routers, batch records, extents fo traceability, work instructions, integration of contractors, product releases

Module: 3) QM Topic: 0) 2 Hrs

10) Production & process controls Subsys
Case study, including spectrum from simple to complex

Friday, 20.05.22

Module: 3) QM Topic: 0) 3 Hrs

11) Documentation and records Subsys
Tools for managing documentation, control process, releases, categories of documentation, list of records, duration of storage, paper vs electronic

Module: 3) QM Topic: 0) 3 Hrs

12) Customer related processes Subsys
Managing distributors, managing channels, contracts, order processing, good distribution practices, customer complaints handling

Module: 3) QM Topic: 0) 2 Hrs

13) Concepts for Integration of Management systems
Regulatory requirements for integration, implementation concepts, examples

Saturday, 21.05.22

Module: 3) QM Topic: 0) 6 Hrs

14) 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

Friday, 10.06.22

Module: 4) Clin Topic: 0) 4 Hrs

1) Clinical evaluation of MDDs, MEDDEV
Regulatory requirements, clinical strategy, investigation vs evaluation, clinical planning, structure of CER, sources of data, appraisal, link IFUs, biocomp and risk management, conclusions, maintenance

Module: 4) Clin Topic: 0) 2 Hrs

1) Clinical evaluation of MDDs, MEDDEV
Case study

Module: 4) Clin Topic: 0) 2 Hrs

2) Performance evaluation of IVDs - 1
Strategy of performance evaluation for IVD, new expectations linked with IVDR, biobanks samples, review of data

Saturday, 11.06.22

Module: 4) Clin Topic: 0) 2 Hrs

2) Performance evaluation of IVDs - 2
Strategy of performance evaluation for IVD, new expectations linked with IVDR, biobanks samples, review of data

Module: 4) Clin Topic: 0) 4 Hrs

3) Statistical design
Methods for dimensionning an evaluation, power of analysis, statistical models

Friday, 24.06.22

Module: 4) Clin Topic: 0) 5 Hrs

4) Investigation strategy & organisation, MEDDEV
Planning of a clinical investigation, endpoints, CA and EC authorization, IBrochure, protocol, CRF, Informed Consent, GCP, 14155

Module: 4) Clin Topic: 0) 3 Hrs

4) Investigation strategy & organisation, MEDDEV
Case study

Saturday, 25.06.22

Module: 4) Clin Topic: 0) 5 Hrs

5) PMS & PMCF, MEDDEV
Integration of PMS with CER, planning of Post Market Clinical Follow-up, conditonnal CE marking / market access, protocols and reports

1 Hr

Wrap up + questions

Friday, 09.07.22

Final written exam

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