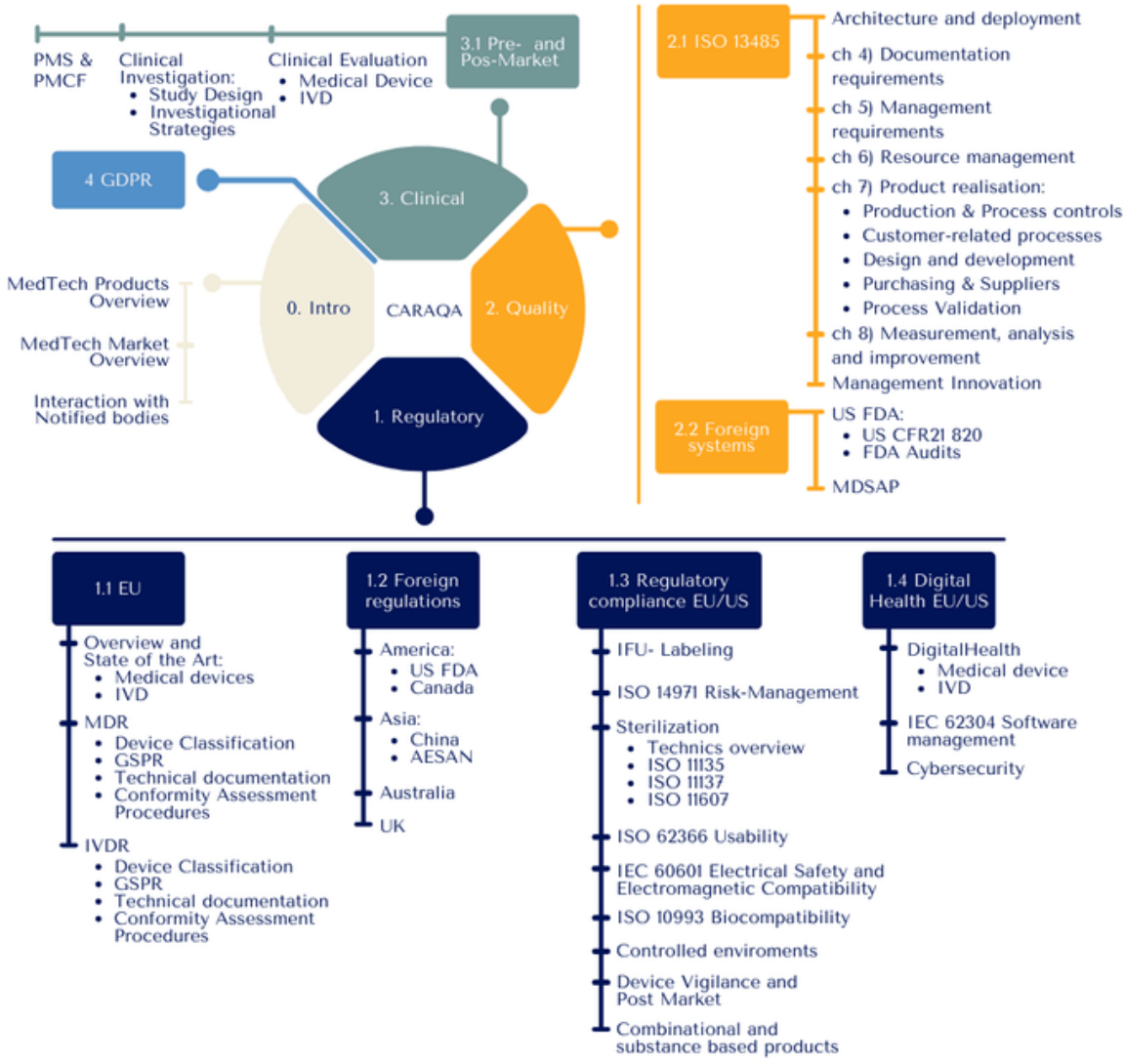
Book your 15' call with Dr Elena Lucano, Training Manager of CARAQA programs.

# CARAQA Study Plan
## 2023-2024 Lübeck

Gain a high-level preparation to match the competencies required by the MedTech Industry. The CARAQA training consists of three main pillars: Clinical Affairs, Regulatory Affairs and Quality Assurance – CA/RA/QA.

## Structure of the program




TECHNISCHE HOCHSCHULE LÜBECK
medídee® Now a Part of Veranex
oncampus

Book your 15' call with Dr Elena Lucano, Training Manager of CARAQA programs.

# CARAQA Study Plan

## 2023-2024 Lübeck

### October

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| 22 | 23 | 24 | 25 | 26 | 27 | 28 |
| 29 | 30 | 31 | | | | |

### November

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 |
| 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 | 20 | 21 | 22 | 23 | 24 | 25 |
| 26 | 27 | 28 | | | | |

### December

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | 1 | 2 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | |
| 31 | | | | | | |

### January

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | 29 | 30 | 31 | | | |

### February

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | 1 | 2 | 3 |
| 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | 29 | | |

### March

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | 1 | 2 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |
| 31 | | | | | | |

### April

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | | | | | | |

### May

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 |
| 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 | 20 | 21 | 22 | 23 | 24 | 25 |
| 26 | 27 | 28 | 29 | 30 | 31 | |

### June

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | 1 | 2 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |

Lesson day

Online Lesson day

Holiday

TECHNISCHE HOCHSCHULE LÜBECK

medídee® Now a Part of Veranex

oncampus

# CARAQA Study Plan
## 2023-2024 Lübeck

## Schedule

| PROJECT PHASE | STARTING | ENDING |
|---|---|---|
| 0 - INTRO | 06.10.2023 | 06.10.2023 |
| 1 - REGULATORY | 07.10.2023 | 12.01.2024 |
| 2 - QUALITY | 13.01.2024 | 16.02.2024 |
| 3 - CLINICAL | 23.02.2024 | 08.03.2024 |

| EVALUATION | DATES |
|---|---|
| EXAM | End of March 2024* |
| THESIS DEADLINE | May 2024* |
| THESIS PRESENTATIONS | June 2024* |

**Tentative dates, may still be subject to change. More information will be provided closer to the beginning of the program.*

TECHNISCHE HOCHSCHULE LÜBECK
medídee® Now a Part of Veranex
on campus

Book your 15' call with Dr Elena Lucano, Training Manager of CARAQA programs.

# CARAQA Study Plan
# 2023-2024 Lübeck

## Dates & Topics

### INTRO

06.10.2023 COURSE INTRODUCTION, MEDTECH PRODUCTS OVERVIEW, NEW APPROACH, NLF, INTERACTION WITH NOTIFIED BODIES, MEDTECH MARKET AND OPERATIONS

### 1 - REGULATORY AFFAIRS, DESIGN AND SUBMISSIONS

07.10.2023 EUROPEAN REGULATION: CASE STUDY

13.10.2023 EUROPEAN REGULATION: OVERVIEW AND STATE OF THE ART, MDR: TECHNICAL DOCUMENTATION

03.11.2023 MDR: DEVICE CLASSIFICATION AND CONFORMITY ASSESSMENT, MDR: TECHNICAL DOCUMENTATION

04.11.2023 FOREIGN REGULATIONS: EURASIA,  ASEA, UK, AUSTRALIA AND CANADA

10.11.2023 IVDR: DEVICE CLASSIFICATION + CASE STUDY + TECHNICAL DOCUMENTATION AND CONFORMITY ASSESSMENT

17.11.2023 US REGULATION: OVERVIEW

18.11.2023 COMBINATION AND SUBSTANCE BASED PRODUCTS

24.11.2023 DEVICE LABELING AND INSTRUCTIONS FOR USE + CONTROLLED ENVIROMENTS

01.12.2023 RISK MANAGEMENT (ISO 14971) + EXPECTATIONS ON THESIS AND EXAMS

02.12.2023 RISK MANAGEMENT (ISO 14971)

08.12.2023 BIOCOMPATIBILITY (ISO 10993-1) + LASER TECHNOLOGY: TECHNICAL, CLINICAL AND SAFETY ASPECTS

15.12.2023 ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY: IEC 60601 + USABILTY

16.12.2023 STERILIZATION + DEVICE VIGILANCE AND POST MARKET SURVEILLANCE

12.01.2024 DIGITAL HEALTH: MD AND IVD + SOFTWARE MANAGEMENT 62304 + REGULATORY CONCEPTS FOR ARTIFICAL INTELLIGENCE

TECHNISCHE HOCHSCHULE LÜBECK  medídee® Now a Part of Veranex  on campus

# CARAQA Study Plan
## 2023-2024 Lübeck

## Dates & Topics

### 2 - QUALITY MANAGEMENT

13.01.2024 QUALITY MANAGEMENT SYSTEM: ARCHITECTURE AND DEPLOYMENT

19.01.2024 QUALITY MANAGEMENT SYSTEM: ARCHITECTURE AND DEPLOYMENT + ISO 13485 CHAP. 4: DOCUMENTATION AND RECORDS + ISO 13485 CHAP. 6: RESOURCE MANAGEMENT

26.01.2024 ISO 13485 CHAP. 7: PRODUCT REALIZATION: PRODUCTION AND PROCESS CONTROLS, ISO 13485 CHAP. 7: PRODUCT REALIZATION: PROCESS VALIDATION

27.01.2024 ISO 13485 CHAP. 7: PRODUCT REALIZATION: DESIGN & DEVELOPMENT

02.02.2024 ISO 13485 CHAP. 8: MEASUREMENT, ANALYSIS AND IMPROVEMENT: CAPA AND NC, ISO 13485 CHAP. 7: PRODUCT REALIZATION: PURCHASING & SUPPLIER, ISO 13485 CHAP. 7: CUSTOMER RELATED PROCESSES

09.02.2024 ISO 13485 CHAP. 5: MANAGEMENT RESPONSIBILITIES + MANAGEMENT INNOVATION

10.02.2024 JOLLY

16.02.2024 MDSAP PROGRAMME + FDA AUDITS

# CARAQA Study Plan
## 2023-2024 Lübeck

## Dates & Topics

### 3 - CLINICAL AFFAIRS

23.02.2024 MDS CLINICAL EVALUATION + CASE STUDY + THESIS KICK-OFF (SUBMISSION OF THESIS PLAN)

24.02.2024 POST MARKET ACTIVITIES (MDR)

01.03.2024 IVDS CLINICAL EVALUATION

08.03.2024 CLINICAL INVESTIGATION: STUDY DESIGN + INVESTIGATIONAL STRATEGIES & ORGANIZATION + Q&A

Class material will be provided through the school Teams platform.

Information provided is subject to changes due to lecturer availability.
Students will be informed of any change as soon as possible.

It will be possible to follow the classes remotely in case the current sanitary situation would impose it or due to personal impediments.