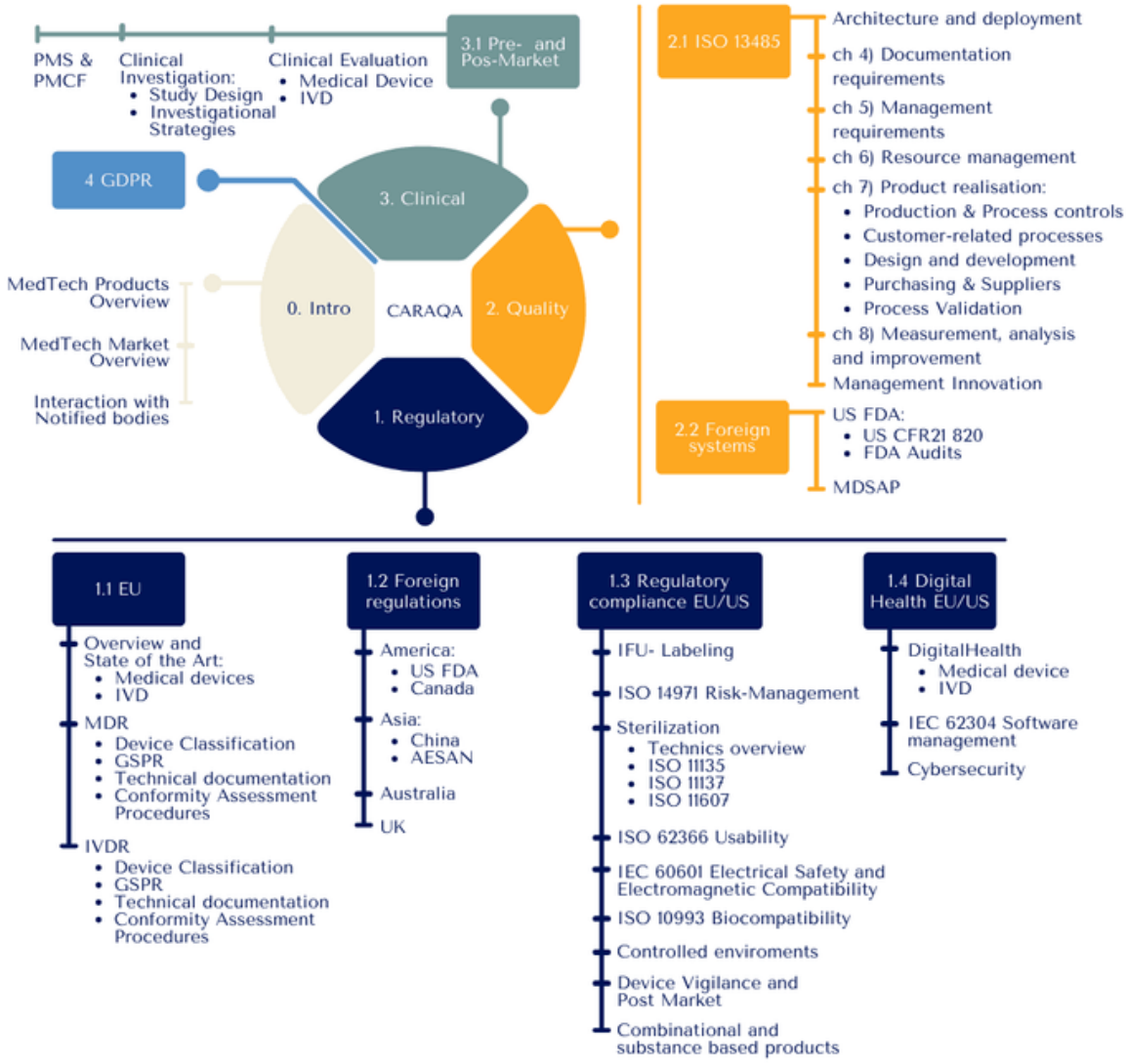
Book your 15' call with Zuzana Tumova, Training Manager of CARAQA programs.

CARAQA Study Plan
2024-2025 UCLouvain

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



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CARAQA Study Plan

2024-2025 UCLouvain

September

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					

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	29	30

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	30	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	

- Lesson day
- Half-day remote lesson
- Full-day remote lesson
- Holiday

Thesis deadline and thesis defense dates To Be Defined, but will likely fall on the month of May for the thesis deadline and June for the defense.

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CARAQA Study Plan
2024-2025 UCLouvain

Schedule

PROJECT PHASE	STARTING	ENDING
0 - INTRO	13.09.2024	13.09.2024
1 - REGULATORY	14.09.2024	29.11.2024
2 - QUALITY	06.12.2024	17.01.2025
3 - CLINICAL	24.01.2025	07.02.2025

EVALUATION	DATES
THESIS DEADLINE	05.2025
THESIS DEFENSE	06.2025

CARAQA Study Plan
2024-2025 UCLouvain

Dates & Topics

INTRO

13.09.2024 COURSE INTRODUCTION, TYPICAL PRODUCTS, INTERACTION WITH BODIES, IMPLIED ACTIVITIES, STAKEHOLDERS

1 - REGULATORY

14.09.2024 EUROPEAN REGULATION: OVERVIEW AND STATE OF THE ART

20.09.2024 IVDR: TECHNICAL DOCUMENTATION, CLASSIFICATION AND CONFORMITY ASSESSMENT PROCEDURES

04.10.2024 MDR: TECHNICAL DOCUMENTATION, CLASSIFICATION AND CONFORMITY ASSESSMENT PROCEDURES

11.10.2024 US REGULATION

12.10.2024 ASIA, CANADA, UK, AUSTRALIA

18.10.2024 COMBINATION PRODUCT, SUBSTANCE BASED PRODUCT

25.10.2024 RISK MANAGEMENT 14971

26.10.2024 RISK MANAGEMENT 14971

08.11.2024 USABILITY 62366, ELECTRICAL SAFETY AND ELECTROMAGNETIC COMPATIBILITY 60601

15.11.2024 STERILIZATION: ETO, STEAM, RADIATION, CONTROLLED ENVIROMENTS

16.11.2024 BIOCOMPATIBILITY 10993.1

22.11.2024 SOFTWARE MANAGEMENT 62304

23.11.2024 SOFTWARE CYBERSECURITY, ARTIFICIAL INTELLIGENCE

29.11.2024 DEVICE LABELING AND INSTRUCTIONS FOR USE + EXERCISE, DEVICE VIGILANCE AND POST MARKET + EXERCISE

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CARAQA Study Plan
2024-2025 UCLouvain

Dates & Topics

2 - QUALITY

06.12.2024 ARCHITECTURE AND DEPLOYMENT QMS + ISO 13485:2016, ISO 13485 - CHAPTERS 4

07.12.2024 QSR, FDA AUDITS

13.12.2024 ISO 13485 - CHAPTER 6 RESOURCE MANAGEMENT, ISO 13485 - CHAPTERS 7 P&P CONTROL

14.12.2024 MDSAP

20.12.2024 13485 (CH 7) PRODUCT REALIZATION: DESIGN AND DEVELOPMENT

10.01.2025 ISO 13485 - CHAPTER 7 PRODUCT REALIZATION: PROCESS VALIDATION, CHAPTERS 8 CAPA

11.01.2025 13485 (CH 7) PRODUCT REALIZATION: PURCHASING & SUPPLIERS

17.01.2025 MANAGEMENT INNOVATION, 13485 (CH 7) PRODUCT REALIZATION: CUSTOMER-RELATED PROCESSES, 13485 (CH 5) MANAGEMENT REQUIREMENTS

CARAQA Study Plan
2024-2025 UCLouvain

Dates & Topics

3 - CLINICAL

24.01.2025 CLINICAL EVALUATION OF MEDICAL DEVICES + CASE STUDY

25.01.2025 PMPF & PMCF

31.01.2025 CLINICAL EVALUATION OF IVD + CASE STUDY

07.02.2025 CLINICAL INVESTIGATION: STUDY DESIGN, INVESTIGATIONAL STRATEGIES

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.

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