University of Applied Sciences and Arts Northwestern Switzerland
School of Life Sciences

medídee®



CAS CARAQA
Clinical, Regulatory and Quality Affairs for Medical Devices and In-Vitro Diagnostics

Program 2020

Date	Time		Module	Topic	Lecturer	Location
07.01.2020	9:00	10:00		Introduction	Hradetzky, David (FHNW)	12.O.01
	10:00	12:00	Introduction to world of devices	Intro: MedTech Products Overview	Hradetzky, David (FHNW)	12.O.01
	12:00	13:00		Intro: Interaction with Notified Bodies	Etter, Philippe (medidee)	12.O.01
	14:00	16:00		Intro: MedTech Market	Visarius, Heiko (VISARTIS Healthcare GmbH)	12.O.01
	16:00	17:00		Intro: MedTech Operations	Visarius, Heiko (VISARTIS Healthcare GmbH)	12.O.01
	17:00	18:00		Intro: MedTech Operations	Hediger, Michael (Zühlke Group)	12.O.01
14.01.2020	9:00	12:00	Regulatory affairs, design and submissions	CE regulation: Overview	Etter, Philippe (medidee)	12.S.25
	13:00	18:00		CE regulation: State of the art	Etter, Philippe (medidee)	12.S.25
21.01.2020	9:00	13:00	Regulatory affairs, design and submissions	CE regulation: Device Classification (MDR)	Riedwyl, Hansjörg (ISS AG)	12.S.25
	9:00	13:00		CE regulation: Device Classification (IVDR)	Ritz, Alicja (Bühlmann Laboratories AG)	12.S.25
	14:00	16:00		CE regulation: Conformity Assessment Procedures	Maier, Michael (medidee)	12.S.25
28.01.2020	9:00	13:00	Regulatory affairs, design and submissions	CE regulation: Device Vigilance	Schulze, Karin (Solutions for Life Sciences SFL)	12.S.25
	14:00	18:00		CE regulation: Technical Documentation	Klaus, Sebastian (Biotronik)	12.S.25
04.02.2020	9:00	11:00	Regulatory affairs, design and submissions	China Regulations	Xu, Chao (J MedTec)	12.S.25
	11:00	13:00		US Regulation: Overview	Enns-Bray, William (medidee)	12.S.25
	14:00	17:00		US Regulation: Overview	Enns-Bray, William (medidee)	12.S.25
11.02.2020	9:00	12:00	Regulatory affairs, design and submissions	Regulation: Risk Management	Göttsche, Thorsten (Osypka AG)	12.S.25
	13:00	16:00		Regulation: Risk Management	Göttsche, Thorsten (Osypka AG) and	12.S.25

Date	Time		Module	Topic	Lecturer	Location
					Zoethout, Jurjen (medidee)	
18.02.2020	9:00	16:00	Regulatory affairs, design and submissions	Regulation: Sterilization	Dumba, Arthur ()	04.O.08
25.02.2020	9:00	18:00	Regulatory affairs, design and submissions	Regulation: Software Management	Enns-Bray, William (medidee)	04.O.08
03.03.2020	9:00	17:00	Regulatory affairs, design and submissions	Regulation: Risk Management	Göttsche, Thorsten (Osypka AG) and Seiler, Daniel (FHNW)	04.O.08
10.03.2020	9:00	12:00	Regulatory affairs, design and submissions	Regulation: Hardware and Software Process Validation	Razaname, Cedric (medidee)	04.O.08
	13:00	16:00		Regulation: Electrical Safety and Electromagnetic Compatibility	Charrotton, Yannick (Lambda Health System)	04.O.08
17.03.2020	9:00	12:00	Regulatory affairs, design and submissions	Regulation: Usability	Medidee, Employee (medidee)	04.O.08
	13:00	18:00		Regulation: Device labeling and Instructions for Use	Medidee, Employee (medidee)	04.O.08
24.03.2020	9:00	13:00	Regulatory affairs, design and submissions	Regulation: Biocompatibility	Medidee, Employee (medidee)	04.O.08
	14:00	16:00		Regulation: Controlled Environment	Klaus, Sebastian (Biotronik)	04.O.08
31.03.2020	9:00	13:00	Quality Management	QMS: Architecture	Paray, Edouard (medidee)	04.O.08
	14:00	17:00		EU QMS: ISO 13485:2016	Paray, Edouard (medidee)	04.O.08
07.04.2020	9:00	13:00	Quality Management	US QMS: Quality System Requirements	Lucano, Elena (medidee)	04.O.08
	14:00	16:00		Expectations on Thesis	Lucano, Elena (medidee) and Hradetzky, David (FHNW)	04.O.08
21.04.2020	9:00	12:00	Quality Management	QMS: Audits	Razaname, Cedric (medidee)	04.O.08
	13:00	16:00		QMS SubSys: Management	Snétivy, Daniel (Thommen Medical)	04.O.08
28.04.2020	9:00	11:00	Quality Management	QMS SubSys: Resources	Feigenwinter, Gregor (Synthes GmbH)	04.O.08

Date	Time		Module	Topic	Lecturer	Location
	11:00	16:00		QMS SubSys: Design & Development	Göttsche, Thorsten (Osypka AG)	04.O.08
05.05.2020	9:00	13:00	Quality Management	QMS SubSys: Design & Development	Göttsche, Thorsten (Osypka AG)	04.O.08
	14:00	18:00		QMS SubSys: Purchasing & Suppliers	Medidee, Employee (medidee)	04.O.08
12.05.2020	9:00	13:00	Quality Management	QMS: Management Innovation	Etter, Philippe (medidee)	04.O.08
	14:00	16:00		QMS: Management Innovation	Etter, Philippe (medidee)	04.O.08
	16:00	18:00		Thesis: Q&A session	Etter, Philippe (medidee)	04.O.08
19.05.2020	9:00	13:00	Quality Management	QMS SubSys: CAPA and Non-Conformances	Tsanaka, Amalia (medidee)	04.O.08
	14:00	18:00	Quality Management	QMS SubSys: CAPA and Non-Conformances	Tsanaka, Amalia (medidee)	04.O.08
26.05.2020	9:00	12:00	Quality Management	QMS SubSys: Documentation and Records	Medidee, Employee (medidee)	04.O.08
	13:00	16:00		QMS SubSys: Customer Processes	Medidee, Employee (medidee)	04.O.08
02.06.2020	9:00	16:00	Quality Management	QM Subsys: Production and Process Controls	Medidee, Employee (medidee)	12.O.01
	16:00	17:00		Thesis Kick-off (Submission of thesis plan)	Lucano, Elena (medidee) and Hradetzky, David (FHNW)	12.O.01
09.06.2020	9:00	13:00	Clinical Affairs	Clinical: MDDs Evaluation	Bobela, Wojciech (medidee)	04.O.08
	14:00	16:00		Clinical: MDDs Evaluation	Bobela, Wojciech (medidee)	04.O.08
16.06.2020	9:00	13:00	Clinical Affairs	Clinical: IVDs Evaluation	Scarabelli, Silvia (medidee)	04.O.08
	14:00	17:00		Clinical: Study Design	Janikowska, Karolina (medidee)	04.O.08
23.06.2020	9:00	14:00	Clinical Affairs	Clinical: Investigational Strategies & Organization	Janikowska, Karolina (medidee)	04.O.08
	14:00	17:00		Clinical: Investigational Strategies & Organization	Janikowska, Karolina (medidee)	04.O.08
30.06.2020	10:00	11:00	Clinical Affairs	Clinical: Post Market (IVDR)	Messerli, Camilla (Bühlmann Laboratories AG)	04.O.08

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	11:00	16:00		Clinical: Post Market (MDR)	Matern, Ulrich (Matern Consult)	04.O.08
	16:00	18:00		Wrap up + questions	Etter, Philippe (medidee)	04.O.08
14.07.2020	9:00	11:00		Final exams	Etter, Philippe (medidee) and Hradetzky, David (FHNW)	04.O.08
28.07.2020				Submission of final thesis		
08.09.2020	9:00	18:00		Defense	Etter, Philippe (medidee) and Hradetzky, David (FHNW)	04.O.08
09.09.2020	9:00	18:00		Defense	Hradetzky, David (FHNW) and Etter, Philippe (medidee)	04.O.08