KEMA Quality
a DEKRA company

Two Days Training

Quality System Requirements for Medical Device Manufacturers

In vitro Diagnostica

For the medical device sector a controlled QM-system has to be in place to be able to bring safe devices to the market. How do you as a manufacturer cope with this basic requirement? With this course KEMA Quality | DEKRA provides detailed information about the ISO 13485, the particular standard for companies developing and manufacturing medical devices. Focus of the second day will be on the European regulations for In-vitro Diagnostica, the German law for Medical Devices and In-vitro Diagnostica, and practical experiences with establishment of a flexible QM-System in a fast growing company.

The two training days can be booked separately!

Who should attend?

- QA/RA managers, responsible for keeping up the quality system and meeting the laws and regulations for medical devices
- CEOs and members of start-up companies
- Specialists in the field of In-Vitro Diagnostica

Description of the training

First Day: After a basic introduction to Quality System Standard ISO 13485, which is the most applicable standard for manufacturers of medical devices and In Vitro Diagnostica, Alex Laan, Senior Project Manager of KEMA Quality | DEKRA, gives an overview over what happens in an audit, what should the QM Manager prepare to guarantee a smooth process during the audit day and a proper follow-up of findings afterwards. In a workshop you will be able to activate your knowledge and to discuss special points. Think outside of the box: QM-Systems in the automotive sector have been developed to a similar extend compared to the Medical Device's world. Dr. Kai Nitsche, experienced in establishment of quality systems in the automotive industry will tell about what have been the drivers for this development in the Automotive industry Can we learn from each other?

Second Day:

The market for devices to diagnose diseases and to measure disease parameters has developed dramatically in the past years. This development will continue in the near future. How about the basics of in-vitro-diagnostica Directive 98/79/EC? Is this directive still up to date? How about the new regulations especially in Germany? Answers to these questions will be provided during the second day.

Dr. Andreas Calatzis, CEO of Multiplate Group, will present his own experiences with establishing a QM-System in the IVD field.

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General Information about the training

Date:	November 3 and 4, 2010, 8h30 to 17h30
Language:	English /German
Location:	Multiplate group Headquarters Reichenbachstraβe 27, 80469 Munich, Germany
Price:	The two days of the course can be booked separately: Two days 1.000 Euro per participant, one day 550 Euro per participant. In case that more persons from one organization attend the course, a reduced fee of 25% (750 Euro for two days and 412 Euro for one day) is granted for the 2nd to 4rth participant.

What's included?

Training fee, training documentation, additional training material for download on USB stick, coffee breaks and lunch, training certificate for your training records.

Further information and contact

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Schedule

Day 1: Nov 3, 2010 – Multiplate group Headquarters

Quality System Requirements Seminar and Workshop

08h30	Arrival and Welcome Coffee	
09h00	**Introduction to the ISO13485:2003**	**Alex Laan**
10h00	Coffee Break	
10h30	**The Audit (ISO19011 process)**	**Alex Laan**
12h00	Lunch Break	
13h00	**Quality Management**	
	– lessons from the automotive industry	**Dr. Kai Nitsche**
		BMW Group
14h30	Coffee Break	
15h00	**Workshop ISO13485:2003**	**Alex Laan**
17h00	Open questions / Discussion	
17h30	End of seminar	

Day 2: Nov 4, 2010 – Multiplate group Headquarters

In Vitro Diagnostica Seminar and Workshop

08h30	Arrival and Welcome Coffee	
09h00	**Introduction to the IVDD**	**Alex Laan**
10h00	Coffee Break	
10h30	**Introduction to the IVDD II**	**Alex Laan**
12h00	Lunch Break	
13h00	**The German MPG**	**Dr. Franziska Baumgarten**
13h30	**New developments in products and regulations**	**Alex Laan**
14h00	**Experiences with the introduction of a more elaborated QM**	
	including external audits	**Dr. Andreas Calatzis**
		Multiplate group
14h30	Coffee Break	
15h00	**Workshop IVDD**	**Alex Laan**
17h00	Open questions / Discussion	
17h30	End of seminar	