

Medical Seminar: June 7th 2011

Find the answers to your questions with TÜV Rheinland Nederland

- Met welke wet- en regelgeving krijgt u te maken wanneer u een medisch product op de markt wilt brengen?
- Hoe kunt u belangrijke zaken als certificatie en registratie van uw medisch product, zo efficiënt mogelijk organiseren?
- Hoe werkt dit binnen, maar vooral ook buiten de grenzen van Europa?

Gedurende dit seminar zal TÜV Rheinland Nederland waardevolle informatie geven over de stappen die gezet dienen te worden om een medisch product wereldwijd op de markt te brengen. TÜV Rheinland Nederland nodigt u hierbij van harte uit!

TÜV Rheinland Nederland B.V.

Worldwide support in testing and certification of medical devices

Program Medical Seminar June 7th 2011:

Compliance with European and other Global Requirements

Speaker: Mr. Ties Koning (TÜV Rheinland EPS B.V.)

Certification Processes inside and outside Europe

Speaker: Mr. Luca Boniardi (TÜV Rheinland Italy)

Compliance and Registration in Europe

Speaker: Mr. Clemens Mohr (MT Promedt Consulting GmbH)

The ethics of Quality and professional behavior

Speaker: Mr. Boi Jongejan (Managing Director of the Orange Cross)

Are you ready for the future?

Speaker: Mr. Ulrich Jakobautzki (TÜV Rheinland Nederland B.V.)



Detailed Content Program:

Compliance with European and other Global Requirements

Compliance with various Global Requirements is a fact and therefore an issue to be considered from the beginning of the evolution process of a medical product. At design level, almost on the drawing table many compliance issues can be solved or at least being reduced by starting early. For example the EMC and Safety matters can be solved by using EMC or Safety experience from your EMC/Safety partner. Taking into account that some basic electronic laws are also valid for Solving EMC emission problems and that the PCB layout engineer at forehand can eliminate Safety and EMC problems. Therefore, knowledge concerning the given subjects is time- and therefore cost- saving at the end.

Speaker: Mr. Ties Koning (TÜV Rheinland EPS B.V.: EMC Senior Engineer)

Certification Processes inside and outside Europe

Topics of this session are the different approval processes to several countries inside as well as outside Europe. The focus will be answers on how to document the compliance with the applied requirements. What is essential to be establish a Technical File? Which aspects regarding clinical data are to be considered in the different countries? And how to maintain conformity with the regulations in case, applied standards are amended or replaced? Is a full re-test required (e.g. 3rd edition of the EN 60601-1?)

Speaker: Mr. Luca Boniardi (TÜV Rheinland Italy: Auditor)

Compliance and Registration in Europe

With the revision of the MDD93/42/EEC and the related implementation into national law, several EU member- states have modified their notification system as well. Some member-states require additional notification and ask for additional documentation. Medical Devices registration have been established in some member states and the registration of the devices is mandatory before the product can be placed on the market. This applies to all MD's incl. IVD's. Also here the different authorities have different expectations from the manufacturer. The lecture will give you an overview about the national registration process and national distinctions and language requirements in selected European member states as for example Italy, Spain, Germany and others. The European Medical Device Vigilance System requires the reporting of Incidents and Field Safety Corrective Actions(Recall) to the relevant competent authorities. This lectures will give you an overview about the expectations of the competent authorities in regard to your investigation, documents submitted and the implementation of the corrective actions.

Speaker: Mr. Clemens Mohr (MT Promedt Consulting GmbH: European Authorized Representative and Safety Officer for Non-European Manufacturers)

The ethics of Quality and professional behavior

The title might surprise you, but you probably ar a professional in your field of work. From time to time, you also think about your values you put into your work. Mr. Boi Jongejan: My goal is to put forward the significance of making those values explicit. Whether you work with an organization which seeks sustainable growth, or which has a policy to enhance continue quality improvement.

Is it corresponding with your own value and those of your colleagues and customers?

Speaker: Mr. Boi Jongejan (Managing director of the Orange Cross, member of the board of: the National Resuscitation Council, the Carnegie trust fund, the National Disaster Fund, the platform for WMO-council)

Are you ready for the future?

Different global registration procedures require flexible processes within the management system of a manufacturer. Due to different registration requirements in the member states you will learn about aspects to be considered when selecting Certification Bodies and Testing Agencies (Laboratories). It is essential to prepare the at an early stage, to be ready for compliance with various certification and registration processes.

Speaker: Mr. Ulrich Jakobautzki (TÜV Rheinland Nederland B.V.: Head of Medical Devices Netherlands and Technical Coordinator Medical Devices Western)



Belangrijke informatie Seminar

Het Seminar vindt plaats op 7 Juni 2011 van 9.30u tot 17.00u bij TÜV Rheinland Nederland aan de Josink Esweg 10, 7545 PN, te Enschede. Er zal worden gezorgd voor een lunch en een afsluitende borrel. De presentaties zullen worden verzorgd in het Engels.

Aanmelden

De kosten voor dit seminar bedragen € 225,- excl. BTW per persoon inclusief lunch en informatiepakket.

AANBIEDING: Indien u zich aanmeldt **vóór 17 Mei 2011**, betaald u een gereduceerd tarief van slechts **€ 150,-**.

U kunt zich tot uiterlijk 1 Juni 2010 aanmelden door middel van onderstaand inschrijfformulier.

Het belooft een inspirerende en informatieve dag te worden, welke zeer interessant is voor fabrikanten, distributeurs als ook voor consultants en andere partijen die te maken hebben met het op de markt brengen van medische apparatuur.

Wij begroeten u graag op 7 juni 2011!

Meer informatie

Voor meer informatie over dit Seminar kunt u contact opnemen met:

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Laurens Bervoets
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Inschrijfformulier - Medical Seminar 7 Juni te Enschede

**Graag uw aanmelding versturen per email naar laurens.bervoets@nl.tuv.com
of faxen naar: 088 888 7 859**

Voorletter: _____ Tussenvoegsel: _____ Achternaam: _____

Bedrijf: _____ Functie: _____

Adres: _____ Postcode: _____

Plaats: _____

Factuur adres (indien afwijkend): _____

Telefoon: _____ Email: _____

Eventuele dieetwensen (i.v.m. lunch): _____