

Seminar Outline

Seminar Title

"Medical Device Adverse Event Investigation and Management"

Date: 06 - 08 March 2017

Time: 09:00 – 17:00

Venue: Village Hotel Bugis, Singapore

Speaker: Mr. Eric Woo, Regional Director of ECRI Institute, Asia Pacific

Introduction

This training provides a detailed curriculum on medical device accidents, hazards, and problems focusing on applicable investigation techniques, problem reporting, management, and information resources. It is intended to help attendees perform investigations more effectively and efficiently.

There will also be a session on Cybersecurity, a relevant area of special concern.

Instruction begins with a broad review of why and how medical device accidents happen highlighting equipment design and user error issues. Device testing, documentation, problem reporting programs are then addressed in detail along with incentives and methods for performing effective accident investigations and the roles of various hospital departments, governmental agencies, and third parties in this process. Investigation techniques for accidents and hazards specific to certain classes of technology are presented (e.g., monitoring, respiratory care, blood processing, anesthesia), as are techniques for investigation of generic classes of injury or accidents (e.g., skin "burns", gas embolism, medical device fires). In all sessions, numerous case examples of actual incidents and investigate approaches are given.

Also presented is an overview of ethical and legal issues associated with selecting, using, managing high risk medical devices. Risk management strategies for reducing harm and potential liability are explored. Case examples and hypotheticals, with a focus on identifying and managing device related risks are offered. All sessions are interactive; questions and case examples from the attendees are encouraged.

WHO SHOULD ATTEND

This training is intended for persons involved in medical technology management and regulation. It is specifically indicated for those who may play a role in medical device-related accident investigation or hazard and problem reporting programmes, including:

- Clinical and biomedical engineers
- Governmental regulatory affairs personnel
- Quality assurance personnel
- Physicians
- Risk managers
- Quality assurance managers
- Safety officers
- Hospital and service organization administrators
- Materials managers
- Operating room directors
- Critical care unit directors
- Nursing managers and nurses.

Attendance is also indicated for administrative and governmental personnel responsible for equipment purchasing and for those who must assess the risks of a technology during the tendering process.

EDUCATIONAL OBJECTIVES

This is a formal three days training programme on medical device accident investigation. The educational goals are to help the attendees provide a capability for dealing with device-related adverse events on behalf of a healthcare facility, healthcare ministry, or device supplier.

Following are the specific educational objectives:

- Learn causes of medical device accidents and how they injure patients.
- Learn general accident investigation protocols and techniques.
- Discuss in detail technology-specific accidents and those accidents of generic etiologies, along with the related techniques for investigation.
- Understand how to apply the available information resources to an investigation.
- Understand risk management techniques for preventing incidents.
- Understand the hospital's ethical and legal responsibilities for selecting and managing medical technology.

SPEAKER PROFILE



Mr. Eric Woo is the Regional Director of ECRI Institute, Asia Pacific. He has over 20 years of experience in healthcare industry having learnt and built various business for medical device organisations in Asia Pacific. He brings with him wealth of skills, knowledge and experience of medical technology, hospital operations, and strategic organization development and management.

ORGANIZED JOINTLY BY

TÜV Rheinland Singapore Pte Ltd

MDnet.Regulatory Consultants

REGISTRATION & FEES

Registration Fee	Early Bird Before 13 Jan 2017	Normal 14 Jan 2017 – 24 Feb 2017
Before 7% GST	S\$ 2,250	S\$ 2,500
After 7% GST Amount Payable	S\$ 2,407.50	S\$ 2,675

- Prices are in Singapore Dollar (SGD)
- Registration closes on **24 Feb 2017** or when maximum attendee capacity is full
- Lunch and refreshment breaks on each day of the training seminar are included
- 10% early bird discount for registration before 13 Jan 2017

Registration will be accepted with the attached registration form and can e-mail to liz.tan@tuv.com

Kindly contact us for further information at 6562-8750 ext 3364.

REGISTRATION FORM

Course Title	Medical Device Adverse Event Investigation and Management		
Date	06 – 08 March 2017	Time	09:00 – 17:00
Venue	Village Hotel Bugis, 390 Victoria Street, Singapore 188061		

Please register the following participants(s) for the above programme with full name indicated clearly.

Meal served will be halal certified. Vegetarian meals are available upon request.

Please tick in below check box if vegetarian meal is required.

	Full Name	Designation	Email address	Request for vegetarian meal
1.	_____	_____	_____	<input type="checkbox"/>
2.	_____	_____	_____	<input type="checkbox"/>
3.	_____	_____	_____	<input type="checkbox"/>
4.	_____	_____	_____	<input type="checkbox"/>

PAYMENT

Please indicate below information clearly for billing purposes.

Company Name in Full			
Billing Address			
Contact Person			
Designation			
Telephone (Office)		Fax:	
Email Address			
Payment must be made in full before the seminar			
Cheque payment	S\$	Cheque No.	

Payment Terms

By placing your signature, you will be agreeing to the following:

No refund once payment is made as seats are limited but **replacements are permitted** should the confirmed participant is unable to attend. All payment shall be made in Singapore Dollars in cheque and made payable to **TÜV Rheinland Singapore Pte. Ltd.** and sent to :

TÜV Rheinland Singapore Pte. Ltd.

25 International Business Park, #01-57/58 German Centre
Singapore 609916

Once the seminar is confirmed, TÜV Rheinland Singapore Pte. Ltd reserves the right to cancel or amend the training due to unforeseen circumstances. Refunds of payments received will be given only in this circumstance.

Signature

Company Stamp

Date

Name