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Tutorial Medical Instrument Development

by
Kim Fowler

ICCE 2012
2 July 2012
Seri Pacific Hotel
Kuala Lumpur, Malaysia



Kim Fowler

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Kim Fowler has spent 29 years developing medical, military, and satellite equipment. He co-founded a medical products company and worked in the aerospace industry. Kim consults on engineering processes in designing and developing products and systems. He is the President of the IEEE Instrumentation & Measurement Society for 2011.

Abstract

Medical Instrument Development

This tutorial introduces the general processes for the design and development of bio-medical instrumentation. It will include process stages such as standards, regulations, certification, development phases, documentation, plans, procedures, and reviews. The tutorial will also address concerns over configuration control, archiving, and traceability and how to meet and deal with the government bodies on food quality control such as the U.S. Food and Drug Administration. Finally, the tutorial will include a case study from the presenter's own experience with medical device development.

Program

09:00 am – 09:30am Registration
 09:30 am – 09:35am Recitation
 PART I:
 09:35am – 09:50am Opening Remarks
 10:00am – 11:00am

General processes to design and development medical instruments; covering standards, regulations, certification, development phases, documentation, plans, procedures, and reviews.

PART II:
 11:00 am – 11:15am Coffee/Tea Break

11:30 am – 01:00pm
 Configuration control, archiving, and traceability, case study from the Kim Fowler's own experience with medical device development, providing rationale for the types and amounts of effort required to develop a medical instrument.

01:00pm – 02:00pm Lunch Break and Certificates

Registration Form:

Name: _____

Postal Address: _____

Tel: _____

Fax: _____

Email: _____



Registration Fee:

The registration fee to be charged is detailed as under:

Category	Early*	After
Industry	RM600	RM800
IEEE Members	RM500	RM550
IEEE Students	RM300	RM350

*before 31 May 2012

Please pay the registration fees by a bank draft / crossed cheque / money order to "IEEE I&M Chapter". You may pay into Account No. 512316115511, Maybank Bandar Sunway Malaysia. And send email notification to Sherz at cnar32@yahoo.com or Sherz@iium.edu.my