

# Kim Fowler's Tutorial: Medical Instrument Development - Abstract, Audience, and Bio

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## **Title:**

Medical Instrument Development

## **Abstract:**

This tutorial introduces the general processes to design and development medical instruments. It will cover 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 FDA.

The tutorial will include a case study from the presenter's own experience with medical device development. Finally the case study will provide rationale for the types and amounts of effort required to develop a medical instrument.

## **Target Audience:**

This tutorial is for advanced graduate students, academics, and practitioners considering medical device development as a new field of endeavor.

## **Biography:**

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.