



## “Regulatory Affairs BOOTCAMP for non-regulatory affairs employees”

### COURSE OVERVIEW

In May, 2009, MassMEDIC surveyed its member companies and asked them to identify specific knowledge gaps and training needs of their employees that are critical to their company’s product development and business success. Close to 94% (93.8%) of the respondents indicated that their employees, at all levels, need a greater understanding of the **role of regulatory affairs** in product design, development, approval, and ongoing product compliance.

In response to this overwhelming demand, MassMEDIC, with the help of its industry Advisory Committee\*, has developed a new 14-hour course that will be offered August 4<sup>th</sup> and 5<sup>th</sup>, in Waltham MA. The course is specifically targeted for medical device **ENGINEERS and QC EMPLOYEES.**

#### Participants will:

- Learn and understand the vernacular of regulatory affairs
- Learn the role of the FDA in the regulation of medical devices
- Learn the key regulatory considerations for medical devices and where they come into play during the product lifecycle

Over a two day period, the course will cover the following topics:

#### Introduction and Overview

- Mile high perspective on the FDA and its requirements for medical devices
- Careers in regulatory affairs

#### Regulation of medical devices in the United States (Course content)

- Medical devices, how they are regulated, and by whom
- FDA oversight of medical devices throughout the product lifecycle
- Criterion determining the degree of oversight
- Premarket requirements including preproduction design control
- Clinical trial considerations
- Post-market requirements including QSR compliance
- Where can employees find information?

The course will end with a **panel discussion** that reviews two device product submissions and the role that regulatory affairs played in their failures/successes.

The course will be taught by Rosina Robinson and Judy Andrews, from the Massachusetts-based Medical Device Consultants, Inc (MDCI). Both instructors have worked in the medical device regulatory affairs and QA/Compliance for over 20 years and have deep medical device as well as teaching experience.

**MassMEDIC is accepting applications from July 8 to July 31.**

If you are interested please complete the attached registration form and return it to:

Susan K. Moulton  
Project Manager  
[susankmoulton@hotmail.com](mailto:susankmoulton@hotmail.com)  
781-608-5114



**REGISTRATION FORM**

**Regulatory Affairs BOOTCAMP for non-regulatory affairs employees**

**NAME** \_\_\_\_\_

**e-MAIL** \_\_\_\_\_

**TELEPHONE #**  
Office \_\_\_\_\_ Cell \_\_\_\_\_

**COMPANY** \_\_\_\_\_

**ADDRESS**  
\_\_\_\_\_  
\_\_\_\_\_

**CURRENT JOB**  
Position \_\_\_\_\_

**DEPARTMENT** \_\_\_\_\_

**# OF YEARS IN**  
Current **JOB** \_\_\_\_\_

Do you have any knowledge of any FDA requirements for medical devices?

No \_\_\_\_\_ Yes \_\_\_\_\_ Limited \_\_\_\_\_

If YES, please describe

\_\_\_\_\_  
\_\_\_\_\_

**# OF YEARS AT**  
CURRENT **COMPANY** \_\_\_\_\_

**# OF YEARS IN MEDICAL**  
DEVICE **INDUSTRY** \_\_\_\_\_

Please complete form and fax to: