



WORLD MEDICAL DEVICE ORGANIZATION

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WMDO USA
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South 8th Street, Minneapolis
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Online Training for Medical Device Professionals

Course Title:

Role of RA Specialist in the Design Process

Product ID: 154

Duration: 40 mins

SME: Adrienne Lenz

First Released On: 02/11/2011

Course Description:

This course focuses specifically on the responsibilities of the Regulatory Affairs (RA) specialist within the medical device manufacturer's design process.

It features a comprehensive illustration of the RA specialist's role in the following areas:

- Design control
- Regulatory documentation
- Submissions
- Product launch
- Design changes

Watch the Course Trailer:

Learning Objectives:

Upon successfully completing this course, trainees will be able to:

- Identify the RA specialist's function in the manufacturer's design process, including initial design, documentation, submissions, and launch
- Recognize the importance of the RA specialist in the following phases:
 - Early on in the design process
 - Throughout the device's development
 - Up until the product launch

Who Should Enroll:

Regulatory Affairs Associate, Quality Assurance Associate, Quality Assurance Engineer, Manufacturing Engineer, Supply Manager, Purchasing Manager, Design Engineer, Validation Engineer, Notified Body Auditor, Regulator, Electrical Safety Engineer, Internal Auditor, R&D Engineer, Clinical Affairs Director, Clinical Project Manager, and Human Resource Manager, and those interested in learning about the typical roles and responsibilities of RA specialists in the design process are all encouraged to enroll in this course.

Related Resources: Yes

Prerequisite Knowledge

There is no prerequisite knowledge required for this course; all areas of expertise are welcome.

Price:

Premium: €89.00.- **Basic:** €118.00.-

Course Format:

All WMDO professional online training courses are fully interactive and contain audio, video, graphic animation, online quizzes and include all necessary course materials. Trainees receive a minimum of 60 days of unlimited access in which to complete each course depending on course length and complexity. (See individual course descriptions for details). Courses include handouts, case studies, working documents and other useful links. After successful completion of your course, you will be able to download your WMDO Certificate of Completion for your training records.

Online courses are cross-browser compatible and require internet connection (minimum 300kbs) and Adobe Flash Player installed (Free download available at: <http://www.adobe.com/products/flashplayer>).



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Premium Account Holders:

Premium account holders enrolling in this course will receive complimentary email access to subject matter experts for any questions, clarifications or feedback they may have concerning this course and its contents, including free automatic course updates for 1 full year.