

Device Clinical Studies in Europe and the US: Regulatory Framework and Best Practices

One-Day Seminar

16 June 2010, ROME, ITALY

Lecturers:

Daniela Karrer

Director, Clinical Affairs
Donawa Lifescience Consulting

Tami Abudi

Senior Associate, Clinical Affairs
Donawa Lifescience Consulting

This seminar is offered to personnel working in medical device companies involved in planning, designing, managing, conduct and reporting of clinical studies

- Clinical Project Managers
- Clinical Monitors
- Regulatory Affairs
- Medical Affairs
- Senior Executives of start-ups

Daniela Karrer is responsible for Donawa Lifescience Consulting medical device and pharmaceutical clinical study services. She has nearly 20 years' experience in preclinical and clinical research, and has worked at Serono and most recently at Covance Clinical Services Ltd where she served as Director of Project Management and, previously, that of manager of Clinical Operations for Southern Europe.

Tami Abudi has over 15 years' experience in the area of clinical research. She began her career as a Senior CRA in a medical device company, then served as Director of Clinical Research at Medinol Ltd., Israel, a leading manufacturer of Class III medical devices. Ms. Abudi has extensive experience in planning, designing, managing and publishing clinical studies, including the various steps involved in device development to support worldwide registrations, and post-market clinical activities.

Seminar description:

Strategic planning and proper conduct of medical device clinical studies are not trivial matters. Effective study design and planning, thorough knowledge of international and national regulations and achievement of enrolment goals within given deadlines all are crucial to success. This course will provide an overview of clinical study requirements and best practices for conducting clinical studies in Europe and the US, with an emphasis on practical tips and methods for successfully achieving business objectives.

Program Outline:

- EU and US regulatory framework for clinical studies
 - EU: MDD, AIMDD and new requirements according to revising Directive 2007/47/EC
 - US: 21 CFR Parts 50, 54, 56, 812
 - Regulatory pathway for CE marking process and US product clearance or approval (pre-IDE process, IDE, 510K and PMA)
- Good clinical practices for device studies
 - Analysis of revised ISO 14155 DIS.2
- Key aspects of device clinical research, EU vs US
 - Is a clinical study needed? The clinical evaluation process
 - Clinical plan and study design
 - Types of clinical studies (pilot, pivotal, post-marketing)
- The journey from study design to successful clinical report, EU vs US
 - Protocol development
 - Site/country selection and successful patient enrolment
 - Ethics Committee and Competent Authority submissions
 - Study monitoring, safety reporting, complaint handling
- Discussion of case studies proposed by the participants

About Donawa Lifescience Consulting

Donawa Lifescience Consulting is a full service clinical research organization (CRO) for medical devices and pharmaceuticals and regulatory consultancy in the fields of medical devices, pharmaceuticals and combination products.

Location	Donawa Lifescience Consulting office Piazza Albania 10, 00153 Rome, Italy (Rome Historic Center)
Date	Wednesday, 16 June 2010
Time	09:00 – 17:30 (with lunch break)
Language	English
Registration Fee	Euro 500 + VAT (if applicable) - includes lunch and refreshments
Registration Deadline	1 June 2010 – Book early as seminar is limited to 15 attendees

For further information please contact:

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Visit our website at www.donawa.com.



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Please register me for the seminar “Device Clinical Studies in Europe and the US: Regulatory Framework and Best Practices”, on Wednesday, 16 June 2010

First name	Family name
Title	Organization
Address	City
Address	E-mail
Country	VAT No.
Telephone	Mobile
Date	Signature

Seminar Fee:

- registration and payment after 15 April 2010
Euro 500 + 20% VAT, if applicable

Lunch and refreshments included

Payment at time of registration required!

Payment and Registration Deadline:

1 June 2010

Payment by bank transfer to:

Bank: Banca Nazionale del Lavoro
Address: Agenzia n. 19, Via S. Prisca 28, 00153 Rome, Italy
Account name: Donawa Lifescience Consulting Srl
IBAN: IT20 S 01005 03219 000000024935
Account no.: 24935 Swift/BIC: BNLIITRR

Please provide billing address if different from address above:

Cancellation Policy:

Over 14 days prior to the Seminar: cancellation fee Euro 50.00.

7-14 days prior to the Seminar: 50% of the Seminar fee.

Fewer than 7 days, or if no notification received: registrant liable to pay FULL Seminar fee.

NB: Cancellations must be sent in writing to

sara@donawa.com

Donawa Lifescience Consulting reserves the right to alter the programme, speakers, date or venue in the event of circumstances beyond its control.

Please return this registration form, with payment details, to:

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