



MEDICAL DEVICE HALF-DAY SEMINAR

Monday 18th October 2010

Crowne Plaza Hotel, Hayarkon Street, Tel Aviv

Presenters:

Maria Donawa, M.D., President
Roger Gray, BSc, CEng, MIMechE
VP, Quality and Regulatory
Tami Abudi, BSc, Senior Associate,
Clinical Affairs

Successful Strategies for Medical Device Market Clearance: Management Guide to Avoiding Common Pitfalls

Maria E. Donawa has nearly 30 years' medical device regulatory experience. She is a former US FDA Official in the area of medical device regulation, and since 1986, she has assisted many life science companies in meeting both US and European regulatory and quality system requirements. She is a former Board Member of the Regulatory Affairs Professionals Society (RAPS), and a regular columnist for European Medical Device Technology magazine.

Roger Gray has over 30 years' experience in the medical device industry, specializing in European and US regulatory and quality management requirements. He was Chairman of the UK ABHI Technical Committee and a member of COCIR Technical Committee during development of European Medical Devices Directive and has assisted numerous companies with regulatory strategies and submissions.

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 substantial 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.

PROGRAM

08:30 – 09:15 Registration and Welcome Breakfast

09:15 – 09:30 Introductions – Maria Donawa

09:30 – 10:00 **MANAGEMENT CHALLENGES – Maria Donawa**
The multiple hurdles faced by Israeli entrepreneurs in reaching the major device markets and what is needed to overcome them

10:00 – 10:55 **REGULATORY PATHWAYS - Roger Gray**
How device classification and other regulatory factors affect marketing decisions, costs and timelines

10:55 – 11:15 Coffee Break

11:15 – 12:00 **CLINICAL STUDY REALITIES - Tami Abudi**
Critical top level issues for understanding the need, timescale and costs of clinical studies

12:00 - 12:40 **QUALITY SYSTEM NECESSITIES - Roger Gray**
What top management needs to know about quality systems and how they apply to new device design and manufacture

12:40 – 13:00 Questions and Answers

13:00 Close, followed by one-to-one meetings*

Seminar Language: English

Location: Crowne Plaza Hotel, Hayarkon Street, 63453 Tel Aviv

Cost: NIS 175 per participant

About Donawa Lifescience Consulting:

Donawa Lifescience Consulting is a regulatory and quality system consultancy in the fields of medical devices, pharmaceuticals and combination products, and a full service clinical research organization (CRO) for medical devices and pharmaceuticals. Donawa Lifescience Consulting has offices in Italy, Switzerland, UK and USA, and has been active in Israel since 2002, assisting both established and early-phase companies with strategies and submissions for the US and European markets.

Please visit our website at www.donawa.com to see the full range of services available and access to multiple regulatory resources.

This seminar is organized by Donawa Lifescience Consulting in cooperation with Signal Business Development.

Attendance is limited to 30 participants, so book early to avoid disappointment.



To reserve your place at this seminar, please contact:

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* To arrange a one-to-one meeting after the seminar, please contact:

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