



"Your Partner for Innovation"

## Training Seminars

### Join Us in Ireland 2006!

*Is your company trying to enter the U.S. Biopharmaceutical or Medical Device Industry?  
Do you need training?*

#### **CGMP Training Seminar for BioPharma**

*In collaboration with University College Cork*

**Dates:** June 1st and 2nd, 2006

**Venue:** University College Cork

**Lecturers:** Dr. Antonio Moreira, CEO of SPI USA, Inc.

**Guest Lecturer:** Dr. Colman Casey, University College Cork

*\*Special presentation on comparison of EU and US CGMPs*

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#### SEMINAR TOPICS

- CGMPs and the FDA
- GLPs
- Quality
- CGMP Documentation
- Prevention of Contamination
- Case Studies
- Fundamentals and Essentials of Validation
- Controls
- FDA Inspections and Investigations
- International CGMPs
- Recent FDA Developments
- Case Studies

#### **FDA Medical Devices Regulations and Approval Process**

*In collaboration with CardioMed Device Consultants, LLC*

**Dates:** June 8th and 9th, 2006

**Venue:** [Morrison Hotel](#)

Ormond Quay  
Dublin, 1 Ireland

*\*Special hotel room rates available: 175 Euros per night.  
Call hotel for details at +353 1 887 2457 and reference SPI USA event.*

**Lecturers:** Dr. Semih Oktay, Former Scientific Reviewer for FDA & President of CardioMed Device Consultants

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#### SEMINAR TOPICS

- FDA Overview, History and Organization
- Device Classification and Regulatory Requirements
- The FDA Approval Process for Medical Devices
- Pre-market Notification [510(k)] Applications
- Pre-market Approval (PMA) Applications
- Investigational Device Exemptions (IDE)
- Pre-clinical studies (In vivo and In vitro)
- Combination Products - FDA's perspective of combination product verification process
- Case Study - Drug Eluting Stents
- How do we plan for successful performance testing to ensure device safety and improved product design?

#### Benefits of attending:

- Small class size for more instructor-student interaction
- Network with colleagues and peers
- Gain valuable insights that are directly applicable in the real world

- Receive 1.2 Continuing Education Units for participating in both days of each two day seminar

### Tuition includes:

- comprehensive course notes
- certificate of completion
- certificate of continuing education units
- continental breakfast
- lunch
- refreshment breaks

### How to Register:

[Download a CGMP registration form](#)

[Download a Medical Device registration form](#)

Fax to 443.543.5533 or Email to [seminars@usaspi.com](mailto:seminars@usaspi.com)

***\*Special rates available for Academic, Government, and Groups.***

### Questions or comments? Contact us at:

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Tel: 443.543.5530 - Fax: 443.543.5533 - Email: [info@usaspi.com](mailto:info@usaspi.com)

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