

**Medical Device  
Seminar:  
Striving for  
Regulatory  
Success In  
A Changing  
Environment**

Sponsored by

**Hyman, Phelps &  
McNamara, P.C.**

**February 8, 2008  
The Island Hotel  
Newport Beach, CA**

 **Hyman, Phelps  
& McNamara<sub>PC</sub>**

**REGISTRATION FORM**

**Register early – Space is limited!**

**Registration Fee:** \$225 for HPM's current clients; \$300 for non-clients; by check or money order. Registrations submitted after January 18 are subject to an additional \$50 fee. Sorry, no credit cards can be accepted. Registration includes a continental breakfast, and a copy of the program materials.

**Conference Location:**

The Island Hotel  
690 Newport Center Drive  
Newport Beach, CA 92660  
Phone: (949) 759-0808

**Cancellation Policy:** Substitutions for attendees can be made at any time. Cancellations made on or before February 5 will be subject to a 20% service fee.

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Company Name: \_\_\_\_\_

Company Address: \_\_\_\_\_

City, State: \_\_\_\_\_

Zip: \_\_\_\_\_

Telephone: \_\_\_\_\_

Fax: \_\_\_\_\_

E-mail: \_\_\_\_\_

**Continued on next panel →**

**REGISTRATION FORM (continued)**

**Please make checks payable to:**  
Hyman, Phelps & McNamara, P.C.  
Tax ID # 521212184.

**Please mail the completed registration and check to:**

Hyman, Phelps & McNamara, P.C.  
2603 Main Street, Suite 760  
Irvine, California 92614  
(949) 553-7400

You may also register by faxing the registration form to (949) 553-7433. Once we have received your payment, you will be sent a confirmation of your registration by either fax or e-mail. If you have further questions, please call Brian Donato or Toby Young at (949) 553-7400 (West Coast contacts) **or** Laura Murray at (202) 724-1740 (East Coast contact).

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Fax (949) 553-7433

**Medical Device Seminar:  
“Striving For Regulatory Success In  
A Changing Environment”**

This morning seminar will highlight the key current regulatory issues that can help device companies achieve success. The conference will integrate the new developments that directly affect device companies: the new FDA Amendment Act, approvals of devices, post-market controls and safety reports, FDA enforcement, government investigations of the device industry, and clinical studies. Speakers from the law firm of Hyman, Phelps & McNamara, P.C. (HPM) will update attendees on these crucial regulatory areas.

**FRIDAY, February 8, 2008**

7:45 - 9:00 AM Registration and Continental Breakfast

9:00 AM - 12:30 PM Program

**Moderator:** Brian J. Donato

**Key Recent Regulatory Developments: A Top Ten List**

Speaker: Jeffrey N. Gibbs

- Advertising and promotion
- Developments in product approvals
- Product jurisdiction/combination products
- Product approvals

**FDA Amendments Act: What Does it Mean to You?**

Speaker: Jeffrey K. Shapiro

- MDRs
- User fees
- Tracking
- Registration

**Clinical Studies: New Developments**

Speaker: Anne Marie Murphy

- FDA’s BioResearch Monitoring Program
- Enrollment incentives for subjects and patients
- Informed consent

**FDA Enforcement: A More Dangerous Landscape**

Speaker: Douglas B. Farquhar

- FDA Litigation and enforcement trends
- Inspections
- Department of Justice subpoenas

**Speakers:**

Brian Donato is a Director at HPM and has headed HPM’s California office for 17 years.

Jeffrey Gibbs is a Director at HPM, and was formerly an Associate Chief Counsel of Enforcement at FDA. Mr. Gibbs specializes in device regulatory issues.

Jeffrey Shapiro is a Director at HPM, who specializes in device regulatory issues. He is the author of numerous FDA-related publications.

Anne Marie Murphy is an Associate at HPM and specializes in clinical study-related issues. She is currently a member of a university Institutional Review Board.

Doug Farquhar, a former Assistant United States Attorney, is a Director at HPM who specializes in FDA enforcement and litigation.