

Regulatory Management Series

May 17-22nd | Irvine, California

No longer a “niche”
function...

*regulatory
affairs* impacts all
parts of any bioscience
company large or small.



Enhance your regulatory affairs knowledge...become current on the latest requirements from the FDA and other bodies... become more strategic in management of this critical area. KGI's Regulatory Management Series (RMS) consists of five information-rich days – each of which is devoted to a specific regulatory area. RMS provides attendees with sophisticated insights about key components of regulation as well as offering an invaluable opportunity to learn from and network with industry peers and subject matter experts.

KGI offers participants the opportunity to attend an individual class...or to select several courses that will help achieve his or her career, skill-enhancement, or other goals. Registrants who finish the entire five day series will receive a certificate of completion.



May 17, 2010.....	FDA Law and Regulatory Affairs
May 18, 2010	Quality Management
May 19, 2010.....	Risk Management
May 20, 2010	FDA Medical Devices
May 21, 2010.....	FDA Manufacturing

Regulatory Management Series

May 17 – 22nd | 8:30am – 4:30pm

2855 Michelle Drive, Ste 250 • Irvine • CA

Register at:

<https://www.regonline.com/regmgmt>

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FDA Law and Regulatory Affairs

Monday - May 17, 2010

Development of productive relationships with regulatory bodies takes more than an ability to conduct clinical trials and prepare documents. Strategy, relationships, context, and a variety of other “higher order” thinking are required.

- Overview of FDA and regulatory affairs including current status of FDA laws and FDA Modernization acts
- Product development phases: pre-clinical to reimbursement
- FDA regulatory approval process from design input stage through submission: BLA, 510(k) documentation and post-market approval requirements
- FDA interactions with applicants: enforcement, compliance, relationship mgmt

Quality Management

Tuesday - May 18, 2010

During the last several years, the FDA has issued numerous observations and warning letters to pharmaceutical and biotechnology companies for not having adequate quality systems in place. Every company needs quality systems.

- Review and compare industry guidance from the FDA, ICH Q10, and cGMP requirements
- Evaluate leading industry quality systems such as the Six-System Inspection Model
- How to implement a pharmaceutical quality system
- Gap analysis and system/process reviews

Risk Management

Wednesday - May 19, 2010

Risk of any form presents a significant decision-making conundrum to the organization – but especially to life science companies that rely heavily on future outcomes to grow their businesses. Risk in the regulatory arena requires a proactive approach.

- Overview of enterprise risk management and the background to FDA's developing interest in risk management
- Systems approach to risk management, explains the FDA's requirements, and addresses the issue of implementation
- Risk acceptance - when can risk be low enough and acceptable?
- Risk assessment and introduces a framework for using risk assessment tools

FDA Medical Devices

Thursday - May 20, 2010

As regulatory scrutiny increases around the globe, the medical device industry is experiencing significant pressure from enhanced requirements and expectations. An understanding of the new world of medical device regulation is necessary.

- Preamble to and detailed review of the Quality System Regulation
- Medical device clinical trials: clinical outcome studies, design control, post market surveillance
- Regulatory Requirements and FDA expectations
- Quality System Inspection Technique

FDA Manufacturing

Friday - May 21, 2010

Increased regulatory and lawmaker scrutiny focused on manufacturing and operations resulted in the closure of high profile plants. New uncertainty emphasizes the need for organizations to be knowledgeable about FDA manufacturing.

- FDA oversight of later stage efforts including small molecule, biologics, and contract manufacturing
- How the FDA approaches supply chain vs. commercialization
- Fill...finish...packaging requirements
- Distribution and customer service