

JOIN US

The Virtual Life Science Company and the FDA

The upward trend for pharmaceutical, biotech, device and other life science companies to outsource critical functions presents new regulatory compliance challenges.

This breakfast briefing will address business and regulatory strategies to meet these challenges.

WEDNESDAY, MAY 15, 2013

8:00 a.m. – 8:30 a.m. | Breakfast and Registration

8:30 a.m. – 10:00 a.m. | Program

Arcadia University

1150 First Avenue, Suite 700
King of Prussia, PA 19406

This is the first in a four-part executive series for senior professionals in the life sciences industry.

Discussion topics include:

- How FDA enforcement has evolved with the move to increased outsourcing
- How virtual relationships affect issues associated with clinical trial submissions and manufacturing processes
- Limitations on contracting parties managing recalls and other FDA post-approval issues
- Inherent conflicts between contract researchers and manufacturers and new drug application owners
- Risk reducing quality controls and other procedures
- Finding value in strategic relationships beyond project-by project engagement

Course Objective(s):

To explain business and regulatory strategies that will help attendees meet the new regulatory compliance challenges posed by pharmaceutical, biotech, device and other life science companies outsourcing critical functions.

Learning Outcome(s):

 Participants will be able to:

- Understand the regulatory compliance challenges posed by outsourcing critical functions;
- Identify strategies to mitigate these challenges.

Panelists:

Luis T. Gutierrez, Jr. – Executive Vice President and Chief Commercial Officer, Aptiv Solutions

Mark D. Myslinski – Senior Vice President and Chief Commercial Officer, Saladax Biomedical, Inc.

Robert Radie – President and CEO, Egalet, Ltd

Dana Smith, CPA, CFF – Partner, EisnerAmper

Moderator:

Edward John Allera – Chairman of the FDA & Pharmaceutical Practice Group, Buchanan Ingersoll & Rooney PC

To Register, contact:

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215-665-3602

This has been approved for 1.5 General CLE Credit in DE, NJ, NY, & PA.

1.5 CPE credit in the field of Specialized Knowledge and Applications

Delivery Method: Group-Live

Level: Basic

Prerequisites: None

Advanced Preparation: None



There is no fee to attend this course. For more information regarding administrative policies such as cancellations and complaints, please contact Rob Levine at 212.891.4034.

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