

# SESSIONS

DAY ONE - 03/11/2018

Vendor Oversight for Biotech

Pre-Event Course | 3 - 4 November, 2018

AC Hotel Bella Sky  
Copenhagen

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## Registration and breakfast

08:00 - 09:00

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## Opening and introductions

09:00 - 09:15

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## Setting the scene

09:15 - 09:45

- History of Outsourcing
  - Expectations and alignment
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## Meeting regulatory expectations

09:45 - 10:30

- Examining EU and US regulatory expectations and requirements
  - Exploring the evolution of vendor oversight such as the increasing accountability of sponsors
  - Understanding transfer of obligations
  - How can sponsors manage regulatory expectations?
  - GDPR requirements
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## Break

10:30 - 11:00

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## Case study examples

11:00 - 12:30

Delegates will examine examples of cases where the sponsor has failed to comply with regulation / received warning letters. As a group, you will discuss these compliance failures to ensure you understand common pitfalls.

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## Lunch

12:30 - 13:30

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## Understanding different outsourcing models: What could work best for your organisation?

13:30 - 14:30

- Matching the needs of the company business with Research and Development strategies
  - Selecting the right model(s) for your organisation
  - Functional service providers, business process outsourcing
  - Full service preferred providers, Strategic alliances
  - Sole and multiple provider
  - Data Management and Analysis Vendor Management
  - Safety Management
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## Getting off on the right foot

14:30 - 15:00

- Selecting a partner or partners
  - Vendor capabilities assessment
  - Site inspections
  - Financial assessment and mock bids
  - Core elements for contracts
  - Identifying, understanding and managing risk
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## Break

15:00 - 15:30

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## Vendor management: What are the key components of vendor management?

15:30 - 17:00

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11:00	11:00 - Case study examples
12:00	12:30 - Lunch
13:00	13:30 - Understanding different outsourcing models: What could work best for your organisation?
14:00	14:30 - Getting off on the right foot
15:00	15:00 - Break 15:30 - Vendor management: What are the key components of vendor management?

# SESSIONS

DAY TWO: EXAMINE MONITORING STRATEGIES, BUSINESS RELATIONSHIPS AND PROJECT MANAGEMENT SKILLS - 04/11/2018

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## Vendor oversight: What are the key components of vendor oversight?

09:00 - 10:00

Practical Exercise:

- What is difference between vendor management and vendor oversight?
- What is defined as success for vendor oversight?
- Define your oversight philosophy
- Demonstrating control to inspectors
- Effective shared risk approaches to vendor oversight: 'Skin in the game'
- Hands on/hands off - does it matter?
- Auditing strategy: Reaffirmation of vendor capabilities and CAPA management

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## Changing monitoring strategies

10:00 - 10:30

- The cost of 100% monitoring
- Examining risk based monitoring
- Evaluating data driven monitoring
- How is quality developed and assessed?
- How targeted is targeted?
- Co-monitoring – benefits and challenges

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## Break

10:30 - 11:00

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## Maintaining healthy business relationships

11:00 - 12:30

- Success strategies for effective communication
- What is the alliance/relationship manager's real job?
- Assessing the right level of transparency
- Overcoming challenges with change management
- Case studies: Differing approaches taken by vendors

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## Lunch

12:30 - 13:30

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## Project management strategies

13:30 - 14:30

- Practical examples for developing risk management plans
- Keys considerations for timelines and processes
- Calculating value
- Cost implications and budget management

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## Vendor management and oversight in emerging economies

14:30 - 15:00

- Understanding and defining quality in emerging economies
- Exploring clinical research and patient safety
- Ensuring compliance with local affiliates
- Handling confidential information
- Dealing with corruption, bribery and fraud

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## Break

15:00 - 15:30

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## Group discussion

15:30 - 16:30

Reviewing responsibilities of the sponsor and debating the appropriate levels of oversight – what are the best strategies for managing multiple vendors with varying levels of risk and capabilities to ensure regulatory compliance?

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## Final summary and close

16:30 - 17:00

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13:00	13:30 - Project management strategies
14:00	14:30 - Vendor management and oversight in emerging economies
15:00	15:00 - Break 15:30 - Group discussion
16:00	16:30 - Final summary and close