Vendor Oversight in a regulatory environment

Regulatory affairs, vigilance and other GxP areas

**Topics**

- Local vs global outsourcing
- Quality management and quality assurance in outsourcing activities
- How to implement an effective worldwide regulatory vendor oversight programme
- Budget control and KPI monitoring
- Legal, contractual and liability aspects

**Your speakers**

- Dr Susanne Enslin  
  Lundbeck GmbH, Hamburg, Germany
- Stephan Hütter  
  PharmaLex GmbH  
  Office Mannheim, Germany
- Dr Dr Adem Koyuncu  
  Law firm Covington & Burling LLP, Brussels & Frankfurt

8 – 9 October 2019 in Berlin
Vendor Oversight in a regulatory environment

Aims and objectives

Many healthcare companies are choosing to outsource regulated activities in regulatory affairs, vigilance and other GxP areas. They remain responsible for ensuring that the services are in compliance with contractual and regulatory requirements. Our seminar and workshop will explain how to implement an effective regulatory vendor oversight programme in your company and how to monitor quality, KPIs, budget and compliance.

Who should attend?

This seminar addresses the needs of those working in the pharma and healthcare industries. It will particularly benefit the following departments involved in outsourced regulatory activities:
- Regulatory Affairs;
- Pharmacovigilance;
- QA and QC; and
- Business Development.

Providers are also invited to attend this seminar to exchange experiences. The optional workshop on day 2 will provide practical insights into operational issues and specific cases.

Your benefits

After the seminar, you will be able to:
- find and qualify the right vendor;
- identify the necessary elements for an effective worldwide regulatory vendor oversight programme;
- define and monitor KPIs for vendor performance; and
- effectively oversee the important elements of vendor contracts.

Your speakers

Dr Susanne Enslin  
Lundbeck GmbH, Hamburg, Germany  
Senior Manager Quality Assurance/Regulatory Affairs/Pharmacovigilance Manager BAC

Stephan Hütter  
PharmaLex GmbH  
Office Mannheim, Germany  
Senior Manager Regulatory Affairs  
Portfolio Maintenance Outsourcing

Dr Dr Adem Koyuncu  
Law firm Covington & Burling LLP, Brussels & Frankfurt  
Lawyer and Medical Doctor, Partner in the Brussels and Frankfurt offices

Optional workshop day 2

9 October 2019, 09:00 - 16:00  
Dr Susanne Enslin, Stephan Hütter

- KPIs for vendor oversight
- Budget control in detail
- Training for vendors
  - Who, when, what
- Risk based vendor audits
  - Points to consider
- Creation of a long-term audit plan
- Set-up a vendor oversight programme
- Finding the right vendor
Your programme: Seminar 8 October 2019

> 09:00

**Vendor oversight**

*Dr Susanne Enslin*

- Finding the right vendor
- Local vs global outsourcing
- Vendor qualification
- Risk management and risk minimisation

> 10:00

**Quality management and quality assurance**

*Dr Susanne Enslin*

- Interface with internal GxP functions

> 11:00 Coffee break

> 11:15

**How to implement an effective worldwide regulatory vendor oversight programme**

*Stephan Hütter*

- Elements of a vendor oversight programme
- Useful and necessary databases for a regulatory environment

> 12:45 Lunch

> 13:45

**Financial and performance aspects**

*Stephan Hütter*

- Budget control
- How to define and monitor KPIs
- Psychological factors

> 15:00 Coffee break

> 15:15

**Monitoring collaboration in practice**

*Stephan Hütter*

- Essential SOPs and training
- Vendor audit: Establish a risk-based approach

> 16:00

**Legal, contractual and liability aspects**

*Dr Dr Adem Koyuncu*

- Outsourcing regulated activities: Options and limitations
- Legal and GxP obligations
- Who is liable in cases of non-compliance?
- Typical practical issues and challenges of vendor oversight
- Contracts with vendors: Key elements and recommendations

> 17:15 End of day 1
Registration under service@forum-institut.com or Fax +49 6221 500-555

Registration Form

Yes, I will attend:
☐ Seminar + Workshop (08.-09.10.2019)
☐ Seminar (08.10.2019)

☐ Yes, I agree that FORUM Institut may inform me about events and relevant expert content by: ☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name
Position, department
Company
Street
Post code, city, country
Tel. no.
E-mail
Contact person at office
Date, signature

How to register

Registration: +49 6221 500-500
Conference no.: 19 10 203
Website:
www.forum-institut.com

Date and venue
8 – 9 October 2019 in Berlin
Day 1: 09:00-17:15; Day 2: 09:00-16:00
Adina Apartment Hotel Checkpoint Charlie
Krausenstr. 35-36 · 10117 Berlin
Tel. +49 30 200 767 0 · Fax +49 30 200 767 599

Fee
€ 990.00 (+ German VAT) Seminar
€ 1690.00 (+ German VAT) Seminar + Workshop
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Cancellation Policy

Our general terms and conditions (as of 1 January 2016) apply and are available upon request.
We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

Any Further Questions?

Please feel free to contact me if you have any questions.
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