

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

Effective oversight of outsourced activities in the healthcare sector

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

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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.

Any Further Questions?



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

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