

# Vendor Oversight in a regulatory environment

Oversight of outsourced activities in the healthcare sector

## 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

Regulatory affairs,  
vigilance and other  
GxP areas

## Your speakers

Dr Constanze  
Burkhardt  
PharmaLex GmbH,  
Office Berlin, Germany

Dr Susanne Enslin  
Lundbeck GmbH,  
Hamburg, Germany

Dr Dr Adem Koyuncu  
Law firm Covington &  
Burling LLP, Brussels  
and Frankfurt offices

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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 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.

## 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 and implement them;
- define and monitor KPIs for vendor performance; and
- effectively oversee the important elements of vendor contracts.

## Your speakers



**Dr Constanze Burkhardt**  
PharmaLex GmbH,  
Office Berlin, Germany

Senior Director Strategic Outsourcing



**Dr Susanne Enslin**  
Lundbeck GmbH, Hamburg,  
Germany

Senior Manager Quality Assurance/  
Regulatory Affairs/Pharmacovigilance  
Manager BAC



**Dr Dr Adem Koyuncu**  
Law firm Covington &  
Burling LLP

Lawyer and Medical Doctor,  
Partner in the Brussels and Frankfurt offices

## Quality guaranteed!

We follow the IMI quality criteria and, as a signatory, we are an active partner in further developing and optimising the quality standards. An aggregate evaluation of participants' feedback on all FORUM's healthcare training courses (evaluation period from 10.2016 - 09.2017) produced a result of 1.6 (based on a school grading system of 1-6).

## Your programme

> 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

*Dr Constanze Burkhardt*

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

> 12:45 Lunch

> 13:45

### Financial and performance aspects

*Dr Constanze Burkhardt*

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

> 15:00 Coffee break

> 15:15

### Monitoring collaboration in practice

*Dr Constanze Burkhardt*

- 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 seminar

# Vendor Oversight in a regulatory environment

Registration under  
service@forum-institut.com or  
Fax +49 6221 500-555

## Registration Form

Yes, I will attend the seminar

Vendor Oversight in a regulatory environment

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.: 18 10 204**

**Website:**

[www.forum-institut.com](http://www.forum-institut.com)

**Date and venue**

Monday, 15 October 2018 in Berlin

08:30 registration; 09:00-17:15 seminar

ARCOTEL John F Berlin

Werderscher Markt 11 · 10117 Berlin

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**Fee**

€ 990.00 (+ German VAT)

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.

**Jessica Jegodka**

Conference Manager

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