GMP/GDP auditor training course

Frankfurt, November 20th and 21st 2018

INTRODUCTION

Asociación Forum Auditorías (AFA) is providing 3rd party audit services since 2005 to pharmaceutical companies. Since the roots of its foundation, AFA is the result of the agreement between pharma companies looking for a win-win approach to the development of supplier's qualification plans, always considering the acceptance with the Health Authorities and the alignment with the latest regulations and guidelines. Since 2013, AFA is accredited as an ISO 17020 GMP and GDP Inspection Body, by the official accreditation body ENAC.

Throughout its 13 years of history, AFA has become an outstanding reference in 3rd party auditing, initially in the EU, nowadays in more than 40 countries, with more than 400 customers.

AFA record encompasses more than 1,400 audits performed to:

- API manufacturers
- Excipient manufacturers
- Packaging materials manufacturers
- Registered Starting Materials manufacturers
- API distributors
- Wholesalers
- Carriers of medicines and API
- Analytical Services providers
- Software development and integration
- IT Hosting and Cloud systems

The high level of competence of our auditors is a key point for AFA being a reference entity in 3rd party auditing. Continuous training is essential to achieve and sustain this high level of competence; it is one of the bases in our Quality System.

In AFA, we have shared our auditing experience through several Auditor's training courses in Barcelona, Shanghai and Mumbai. Because of the great demand of customers located in Europe, we have planned a training course to be held in Frankfurt, Germany.

The course is organized in two days, from 9:00 am to 5:00 pm. The following topics will be covered during the sessions:

- Audit organization and realisation
- Auditing API manufacturers
- Auditing Excipient manufacturers

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- Auditing GDP agents (Distributors and Carriers)

The course is designed to be as interactive as possible, fostering the participation of attendants to the maximum effectiveness, knowledge transmission and experiences sharing.

INTENDED AUDIENCE

This course is aimed to professionals operating in the Pharmaceutical business wishing to improve their resources and knowledge on performing effective supplier audits.

SPEAKERS

- Dr. Octavi Colomina, AFA President
- Dr. Eduard Cayón, AFA Director
- Ms. Carla Peraferrer AFA Audit Technical Manager

AFA AUDITOR CERTIFICATION

AFA will issue a certificate of attendance to the course, which enables you as a candidate for becoming an *AFA Qualified Auditor*.

To finally become an *AFA Qualified Auditor*, the candidate should meet the following requirements:

- To attend the training course specialised on the auditing subject to be qualified.
- Professional background meeting the required profile.
- Participating in joint audits with Senior Qualified Auditors.
- Obtaining the approval of the AFA Board of Directors.

SCHEDULE

Day	Contents	Timetable
November 20th	Audit organization and realisation Auditing API manufacturers	9:00 to 17:00 h
November 21st	Auditing Excipient manufacturers Auditing *GDP relevant* companies (Distributors and Carriers)	9:00 to 17:00 h

ORGANISATION

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VENUE

Lindner Hotel & Sports Academy

Otto-Fleck-Schneise 8

60528 Frankfurt am Main, Germany

Rooms can be booked at special conditions with the code AFA TRAINING via

Phone: +49 69 339968 444

E-Mail: eingang.res-sportsacademy@lindner.de

LANGUAGE

Language of the Training Course will be English.

REGISTRATION FEE

One day:

- AFA affiliate members: 900 € net per delegate
- Non-AFA members: 1,080 € net per delegate
- Members of the EU GMP inspectorate: 400 € net per delegate

Two days:

- AFA affiliate members: 1,500 € net per delegate
- Non-AFA members: 1,800€ net per delegate
- Members of the EU GMP inspectorate: 600 € net per delegate

A 10% discount for the registration of a second delegate will be applied

Early bird registration: 10% (before September 7th).

Discounts are not cumulative only the highest discount will apply.

CANCELLATIONS

Cancellations received 10 days before the event, 85% of the registration fee will be refunded.

Cancellations received after this limit will not be refunded. However, registration rights can be transferred to another delegate from the same organisation.

CONTENTS & SCHEDULE

November 20th, 2018: From 9:00h to 17:00h

AUDIT ORGANIZATION AND REALISATION

Introduction

- **Pharmaceutical industry: current scenario**
- **Applicable current regulations**
- **Auditing process as part of the Pharmaceutical Quality System**

Audit methodology

- **Audit preparation**
- **Audit realisation. Time management**
- **Audit reporting**
- **CAPA plan follow up**

Auditor skills

- **Key aspects in the communication**
- **Auditor's role**
- **Disturbing factors**

AUDITING API MANUFACTURERS

Introduction

- **Regulatory framework and responsibilities**
- **Evolution of the requirements and maturity of manufacturers**
- **Key compliance indicators**

Workshop

- **Working in groups answering key questions**
- **Plenary and conclusions**

Documents for preparing the workshop, will be sent one week in advance for better preparation

Wrap up

- **Summary of main concepts**
- **How being effective during the audits?**

November 21st, 2018: From 09:00 to 17:00h

AUDITING EXCIPIENTS MANUFACTURERS

Introduction

- **Regulatory framework and responsibilities**
- **Excipient risk analysis**
- **Excipients manufacturers acceptance criteria**
- **Key compliance indicators**

Workshop

- **Group work answering key questions**
- **Plenary and conclusions**

Documents for preparing the workshop, will be sent one week in advance for better preparation

Wrap up

- **Summary of main concepts**
- **How being effective during the audits?**

AUDITING GDP RELEVANT COMPANIES (DISTRIBUTORS AND CARRIERS)

Introduction

- **Regulatory framework and responsibilities**
- **Raw Materials Supply Chain**
- **Medicines Supply Chain**
- **Key compliance indicators**

Workshop

- **Group working answering key questions**
- **Plenary and conclusions**

Documents for preparing the workshop, will be sent one week in advance for better preparation

Wrap up

- **Summary of main concepts**
- **Risk evaluation and management**
- **Technical agreements**

Registration form

Please, fill completely in capital letters and send to afadeutschland@forumauditorias.org or training_afa@forumauditorias.org

First name_____ Last name _____

Position_____

AFA affiliate: ☐ Yes ☐ No

I request inscription to:

☐ November 20th: Audit Organization and realisation.
Auditing API manufacturers

☐ November 21st: Auditing Excipients manufacturers
Auditing *GDP relevant* companies (Distributors and Carriers)

Company _____

Business address _____
_____

City_____ Country:_____ Post code_____

Email address_____ Telephone:_____

VAT NUMBER: _____

☐ As a second delegate, I apply for a 10% discount of the registration fee.

Discounts are not cumulative and only the highest discount will apply

Payment method

☐ By Bank transfer to the following bank account:

La Caixa 2100 3042 15 2200459287
IBAN: ES11 2100 3042 1522 00459287
SWIFT: CAIXESBBXXX

☐ Payment on receipt of invoice:

Invoice Address:
_____
_____
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