

# Good Distribution Practices (GDP)

## *Approaching Compliance*

Berlin, January 16<sup>th</sup> and 17<sup>th</sup> 2018

### OBJECTIVE OF THE EVENT

The Qualified Person (QP) is assuming the responsibility of GMP and GDP compliance of the entire processes that participate in the medicines supply chain: primary manufacturing (raw materials), transport, warehousing, distribution, secondary manufacturing (medicines), packaging and distribution to hospitals and pharmacies.

The objective of this event is to offer an opportunity to share the current requirements and practical interpretations, having open discussions on the different approaches than can be followed to meet the expectations of the authorities in a reasonable and efficient manner. The main conclusions of this meeting will constitute a valuable foundation for AFA to prepare the 2018 GDP Audit Plan for AFA customers in Central Europe.

### AFA INTRODUCTION

Asociación Forum Auditorias is an International Association of Pharmaceutical companies based in Barcelona providing 3<sup>rd</sup> party audit services to the Pharmaceutical Industry.

It was founded in 2005 with the aim of establishing an organized platform to perform joint audits to suppliers. AFA activities are ruled by an Intercompany Protocol approved by all affiliated members. AFA carries out all its activity under a Quality Management System, accredited under ISO 17020 as a “GMP & GDP Inspection Body”. Both constitute the pillar elements to ensure the quality, confidentiality and absence of conflict of interest for all AFA activities.

AFA is continuously improving processes and costs to provide the optimal service to assist pharmaceutical companies in their supply chain qualification activities. AFA operates on a “shared costs” basis, optimising the price of the audits by looking for the maximum number of sponsors to reduce the final price.

Originally, AFA started as group of local pharmaceutical companies to leverage and share the individual efforts they were spending to the control of the supply chain. The initiative resulted in a successful win-win platform, which is currently a reference worldwide. The result: AFA arrives to approximately 400 customers from 40 countries, having performed more than 1,500 audits in the last 12 years

## INTENDED AUDIENCE

Professionals from the API and medicines industry having responsibilities in:

- Qualified Person
- Quality Assurance and Supplier Qualification
- Logistics

## SPEAKERS

- Mr. Rico Schulze, GMP Inspector ZLG, Landesdirektion Sachsen
- Mr. Kaspar von Wedel, GDP Expert
- Dr. Eduard Cayón, Director AFA Asociación Forum Auditorías
- Dr. Octavi Colomina, President AFA Asociación Forum Auditorías

## EVENT PROCEEDINGS

Organizers will prepare the Meeting Proceedings that will summarize the main conclusions from the workshop exercise. This Meeting Proceedings will be available through the Forum Auditorías website.

## EVENT ORGANISATION

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## VENUE

Holiday Inn Berlin Airport  
Conference Centre

Hans-Grade-Allee 5  
12529 Schönefeld b. Berlin

+49 (0) 30 634 01 0  
[info@holidayinn-berlin.de](mailto:info@holidayinn-berlin.de)

Hotel rooms are available at a special AFA rate of EUR 90,00 and can be booked until 20.12.2017 under the code AFA GDP EVENT directly at the hotel via +49 30 63401820 or [info@holidayinn-berlin.de](mailto:info@holidayinn-berlin.de).

Rooms are available up from 14.00 h on 16<sup>th</sup> of January 2018.

## LANGUAGE

The meeting will be performed using German & English language.



## REGISTRATION FEE

- AFA affiliate members: 300 € per delegate, plus VAT
- Non-AFA members: 390 € per delegate, plus VAT
- EU GMP inspectorates: 200 € per delegate, plus VAT
- Second delegate has 10% discount

10% discount for early bird registration (before December 15<sup>th</sup>).

*Discounts are not cumulative and only the highest discount will apply.*

## CANCELLATIONS

In case of 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

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### January 16<sup>th</sup>, 2018: From 15:00h to 17:00h

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*Visit to a logistic centre: UNITAX PHARMALOGISTIK GMBH*

Pharmalager  
An den Gehren 1  
12529 Berlin-Schönefeld

- 15:00 – 15:15**    **Welcome**
- 15:15 – 17:00**    **Guided visit**
- 19:00 – open**    **Snack Buffet and Networking**
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### January 17<sup>th</sup>, 2018: From 08:30h to 17:00h

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*Venue: Holiday Inn Berlin Airport, Conference Centre*

Hans-Grade-Allee 5, 12529 Schönefeld b. Berlin. +49 (0) 30 634 01 0  
info@holidayinn-berlin.de

- 8:30 – 9:00**            **Reception / Welcome**
- 9:00 – 10:00**        **AFA Profile and Organization**  
*Dr. Octavi Colomina, AFA President*  
*Dr. Eduard Cayón, AFA Director*
- 10:00 – 12:00**        **Good Distribution Practices. General Overview**
- Supply Chain Characterization  
*Mr. Kaspar von Wedel, GDP Expert*
  - EU Regulatory frame  
*Mr. Rico Schulze, ZLG Landesdirektion Sachsen*
- 12:00 – 13:00**        *Lunch. Networking*
- 13:00 – 15:00**        **Workshop in groups about GDP applicable to API**
- Distributors approach
  - Carriers approach



<b>15:00 - 15:15</b>	<i>Coffee Break</i>
<b>15:00 - 16:00</b>	<b>Plenary Discussion</b>
<b>16:00 - 16:30</b>	<b>2018 AFA's GDP Audit Plan</b>
<b>16:30 - 17:00</b>	<b>Questions &amp; Answers</b>



## Registration form

Please, fill out completely in capital letters and send to [karen.schipke@forumauditorias.org](mailto:karen.schipke@forumauditorias.org)

First name \_\_\_\_\_ Last name \_\_\_\_\_

Job title  
\_\_\_\_\_

AFA affiliate:  Yes  No

Company  
\_\_\_\_\_

Business address  
\_\_\_\_\_  
\_\_\_\_\_

City \_\_\_\_\_ Country: \_\_\_\_\_ Post code \_\_\_\_\_

Email address \_\_\_\_\_ Telephone: \_\_\_\_\_

VAT NUMBER: \_\_\_\_\_

As a second delegate, I apply for 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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