

The Qualified Person Forum Pre-Conference Session

QP Challenges in the Veterinary Industry

Hamburg, Germany 21 November 2012

GMP Fitness for Purpose
Complaints and Pharmacovigilance
Routine Batch Release



Speakers:

Dr Pierre-Jean Consalvi
Meriel, France

Dr Afshin Hosseiny
Tabriz Consulting, U.K.

Dr Dr Dierk Rebeski
Lohmann Animal Health, Germany

Background

The regulation for manufacture and supply of medicinal products for human and veterinary medicines are very similar. Whereas many medicines supplied to human are sold via authorised pharmacists based on the prescriptions drawn out by the physicians, many veterinary medicines are marketed directly to the animal owners. Such an approach creates tremendous impact on the QP decision making process in particular when releasing products on borderline compliance status or quality attributes, putting the QP in the mist of dealing with customer demands as well as sales and marketing expectations.

Programme

Batch Release Process

The Batch Release Process require review and assessment of the impact of the deviations from the GMP procedures on the finished batch and sound reasoning to justify release or rejection of the batch.

- The participants are confronted with a number of findings deviating from standardised batch production, quality control testing, labeling, including those upon delivery at final destination of product. What will be your corrective and preventive action?

Complaint Management System

In general, release of quality assured veterinary drugs produced and tested under well qualified and validated conditions will most certainly prevent complaints from customers. However, are you prepared to address key elements of an efficient Complaint Management System if serious complaint is received?

- The participants are invited to sketch out an efficient complaint management process for various complaints.

The QP's Position in the Company

From the quality and economical perspective, the veterinary pharmaceutical company is well advised to position the QP and related quality assurance and control functions (including regulatory affairs) independent from sales and marketing to ensure the fitness for purpose (usefulness) and use (reliability) of GMP procedures.

- The session will elaborate how the aforementioned functions could be best arranged within the company's organization structure in line with the GMP guide

Premises and Equipment

The daily routine of the QP is the judgment on the finished product quality. This requires profound knowledge of the production site and facilities.

- The participants will identify pitfalls of clean zones, hygiene monitoring programs, risk of cross-contamination by raw material encountered at the production facility.

Target Audience

Qualified Persons and QA Managers from the veterinary medicines industry

Moderator

Dr Afshin Hosseiny

Speakers

Dr Pierre-Jean Consalvi, Merial, France,

Qualified Person for veterinary products

After graduating of the National Veterinary School of Maisons-Alfort, Pierre-Jean Consalvi worked within the French Ministry of Agriculture. In 1988 he joined Rhône Mérieux (Director of Pharmaceutical Development). At Merial he was Chief Regulatory Affairs, EMEA (Europe, Middle East, Africa), Director and General Manager of the production site in Toulouse. He has been Merial Qualified Person since 2006, and was recently appointed as Chief Quality Officer of the Company.

Dr Afshin Hosseiny, Tabriz Consulting, U.K.,

Qualified Person and Managing Director

Dr Hosseiny was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. He is a QP via permanent provision is a member of the UK standards committee for development of the ISO GMP standards for packaging components and a visiting lecturer at the London Metropolitan University.

Dr Dierk Rebeski, Lohmann Animal Health, Germany,

Qualified Person and Acting Director of Quality Control Vaccines

Before becoming a QP, Dr. Dierk Rebeski was Head of Business Development for Vaccines and Biologicals and Director of R&D Poultry Vaccines. He also worked as Project Leader at Bommeli Diagnostics / Intervet, Bern, Switzerland. He studied Veterinary Medicine in Hanover, Germany and gained a second Ph.D. at Utrecht University (Netherlands).

Date ½ Day Pre-Conference Session:**QP Challenges in the Veterinary Industry**

Wednesday, 21 November 2012, 13.30 – 18.00
(Registration, snacks and coffee: 13.00 – 13.30)

Welcome Reception for all participants

Wednesday, 21 November 2012, 18.00 – 19.00

Date QP Forum

Thursday, 22 November 2012, 9.00 – 18.00

(Registration: Wednesday, 21 November 18.00 – 19.00 and
Thursday 22 November 2012, 08.00 – 9.00)

Friday, 23 November 2012, 8.30 – 15.00

Venue

Sofitel Hamburg Alter Wall
Alter Wall 40
20457 Hamburg
Germany
Tel.: +49 (0)40 36950 0

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation or be sure to mention QP Association to receive the specially negotiated rate (single room € 180,- per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 20 September 2012. Early reservation is recommended.

Fees for ½ Day Pre-Conference Session:**QP Challenges in the Veterinary Industry**

€ 590,- per delegate plus VAT.

The fee is payable in advance after receipt of invoice and includes electronic conference documentation, welcome reception and all refreshments. VAT is reclaimable.

Fees for QP Forum

QP Association Members € 1.590,- per delegate plus VAT.

EU GMP Inspectorates € 895,- per delegate plus VAT.

Non-QP Association Members € 1.790,- per delegate plus VAT.

The conference fee is payable in advance after receipt of invoice and includes electronic conference documentation, welcome reception, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Saving Opportunities!**Book both the QP Forum and a Pre-Conference Session:**

Delegates who attend the QP Forum and a Pre-Conference Session will get a discount of 200€ on the QP Forum.

Please visit www.qp-forum.org for more information.

Registration

Via the attached reservation form, by e-mail to info@qp-association.eu or by fax to +49 6221 / 84 44 34 . Or you register online at www.qp-forum.org.

Conference Language

The official conference language will be English.

Important Information!

The presentations of the QP Forum and the Pre-Conference Workshop/ Session will be available for download and your print-out 1 week before the conference. You will also receive a USB memo stick when you register in Budapest. **Note: there will be no print-outs available during the conference.**

Organisation / Contact

CONCEPT HEIDELBERG
P.O. Box 10 17 64
D-69007 Heidelberg, Germany
Phone +49 (0) 62 21/84 44-0, Fax +49 (0) 62 21/84 44 34
E-mail: info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content:

Mr Wolfgang Schmitt (Operations Director) at +49-62 21 / 84 44 39,
or per e-mail at w.schmitt@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc:

Ms Marion Grimm (Organisation Manager) at +49 (0) 62 21 / 84 44 18,
or per e-mail at grimm@concept-heidelberg.de.

General Terms of Business

If you cannot attend the conference you have two options:

1. We are happy to welcome a substitute colleague at any time.

2. If you have to cancel entirely, we must charge the following processing fees: Cancellation

- until 2 weeks prior to the conference 10 % of the registration fee.
- until 1 week prior to the conference 50 % of the registration fee.
- within 1 week prior to the conference 100 % of the registration fee.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event. If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid.

CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.

Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message. In case you do not appear at the event without having informed us, you will have to pay the full registration fee even if you have not made the payment yet. You are not entitled to participate in the conference until we have received your payment (receipt of payment will not be confirmed)!

About the European QP Association

The European Qualified Person (QP) Association was founded on 7 July 2006 by the European Compliance Academy's (ECA) Advisory Board Members. With this unique association the ECA wants to provide QPs in Europe with a platform allowing them to exchange their experience, discuss the latest regulatory requirements, to identify and address difficulties and challenges and to support a harmonised European approach.

More information about the QP Association and a membership application form are available at www.qp-association.eu.

About CONCEPT HEIDELBERG

Founded in 1978, CONCEPT HEIDELBERG is the leading organiser of seminars on pharmaceutical production, quality control, quality assurance and GMP in Europe. This year more than 240 events will be organised by CONCEPT HEIDELBERG. The European QP Association has entrusted CONCEPT HEIDELBERG with the organisation of its events.

If the bill-to-address deviates from the specification to the right, please fill out here:

Reservation Form (Please complete in full)

Qualified Person Forum 2012. Pre-Conference Session "QP Challenges in the Veterinary Industry"
Hamburg, Germany, 21 November 2012

Qualified Person Forum 2012
Hamburg, Germany, 22-23 November 2012

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

P.O Number (if applicable)

Street / P.O. Box

City Zip Code Country

Phone / Fax

E-mail (Please fill in)

CONCEPT HEIDELBERG
Postfach 10 17 64
Fax 06221/84 44 34

D-69007 Heidelberg