Quality by Design for Active Substances – a New Paradigm?

23rd November 2006
Basle, Switzerland
Course No. 6058

Target Group

Key personnel involved in the development and manufacture of both API and drug product, in API sourcing, quality control, change management and regulatory affairs.
# Quality by Design for Active Substances – a New Paradigm?
A seminar organised by the APV focus group “Drug Regulatory Affairs”

## Programme

**Thursday, 23rd November 2006**
**10.00 to 16.30 h**

**Welcome and introduction**
Jean-Louis Robert, PhD
Laboratoire National de Santé, Luxembourg, Luxembourg
Wolfgang Steuer, PhD
Boehringer Ingelheim GmbH, Ingelheim, Germany

**Critical product quality parameters of active substances**
Lisa Matzen
Boehringer Ingelheim GmbH, Ingelheim, Germany

**Impact of starting material on the manufacturing process and quality of the active substance**
Philippe Lefèvre, PhD
AFSSAPS, Saint Denis Cedex, France

**Comparison of the starting material definition in the US and the EU and their impact**
Wolfgang Steuer, PhD

**Responsibilities of finished product manufacturers – which information do they need on the synthesis and quality of the active ingredient? Practical examples of what can go wrong**
Santiago Alonso, PhD
Sandoz International GmbH, Holzkirchen, Germany

**Quality Risk Management – economical considerations in selecting an active ingredient supplier**
Thilo Fuchs, PhD
Hexal Pharmaforschung GmbH, Holzkirchen, Germany

**Panel discussion with all speakers (in English)**

Programme is subject to change

## Objectives

“Quality has to be built and not tested into a product” is nowadays a well accepted concept.

“Quality by Design” is becoming more and more important when developing a medicinal product. The same approach is equally valid for the manufacturing of an active pharmaceutical ingredient (API). As a consequence, industry is proposing to develop a guideline similar to ICH Q8 “Pharmaceutical Development” for APIs.

The seminar intends to present the important elements of “Quality by Design” for APIs, to understand the benefit and to discuss the implications for existing active substances. The API is not only often the most decisive starting material of the drug product but also the most critical compound in the formulation. This is in particular important for generic manufacturers who mostly do not synthesise their own material, but also for innovators who source out API manufacturing for their established products. The potential impact of changes in source materials of APIs on the quality of the API and the drug product will be discussed from a quality and from an economical point of view.

## Registration

**Registration fee**
- APV member: 860 EUR
- Non-member: 990 EUR

(free of VAT according to § 4.22 UStG)

Coffee breaks, lunch and proceedings included.

**Accounts**
- Dresdner Bank AG Mainz
  - Account No. 2 325 159 00
  - Bank Code 550 800 65
- Postbank Frankfurt/M.
  - Account No. 127 35-606
  - Bank Code 500 100 60

**Registration**
APV-Geschäftstelle
Kurfürstenstraße 59
55118 Mainz/Germany

Phone: ++49/6131/9769-0
Telefax: ++49/6131/9769-69

e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Members of authorities pay half of the APV member’s and non-member’s registration fee respectively.

**Hotel reservation**
Novotel Basel
Schönaustraße 10
4058 Basle, Switzerland

Phone: ++41/61/6957-000
Fax: ++41/61/6957-100

Participants must make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 23rd October 2006.

Special rate: Single room incl. breakfast buffet CHF 202,00 per night.

Mainz, June 2006