2nd UPIP-VAPI Yearly GDP Certification Training

Dear members,

The UPIP-VAPI board starts to organize a yearly training on the

Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (2013/C 343/01)

The training will also explain the principles of GDP for API's, as set forth in the

Guidelines of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01)

This session will be held on Thursday 25 January 2018 at JANSSEN PHARMACEUTICA
Rue du Bois de la Hutte 7, in 7110 La Louvière

Why we organize this training

Section 2.4. Training of the GDP guidelines of 5 Nov 2013 clearly states the requirement of continuous education:

- **All personnel involved in wholesale distribution activities should be trained on the requirements of GDP.** They should have the appropriate competence and experience prior to commencing their tasks.
- Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme.
- **The responsible person should also maintain their competence in GDP through regular training.**
- In addition, training should include aspects of product identification and avoidance of falsified medicines entering the supply chain.
- Personnel dealing with any products which require more stringent handling conditions should receive specific training.

Chapter 3. Personnel of the GDP guidelines for API's states similar requirements:

- **The personnel should be trained on the requirements of GDP for active substances.** They should have the appropriate competence and experience to ensure that active substances are properly handled, stored and distributed.
- Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme.

Furthermore, both guidelines require that “A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented”.

What is the content of the training

The training is set up to satisfy the requirements of continuous education as stated by the GDP guidelines. It will consist of 3 parts that cover the following topics:

PART 1: A theoretical part on the principles of the *GDP Quality Management System* as defined by the two GDP guidelines. This will be an interactive session that will answer questions such as:

a. What are the specific roles and functions of the GDP RP
b. Which procedures are required for full GDP compliance
c. How to apply risk management in GDP
d. Special handling conditions for temperature sensitive products
e. How to cope with section 6.4 on Falsified Medicinal Products
f. What is the status of the implementation of the unique barcodes

PART 2: A practical part presenting real-life situations during storage and transport of pharmaceutical products. This will cover situations such as:

a. Power Fail in storage facilities
b. Vehicle breakdown during transport
c. Handling of temperature alarms
d. Missing temperature measurements

Who should attend the training

The GDP guidelines clearly state that **all personnel** – not only key personnel – needs to receive GDP training when they are involved in GDP activities. This applies to personnel involved in storage and distribution, and even to brokers.

Many of the UPIP-VAPI members are **Responsible Person for GDP,** and are therefore ideally placed to train the personnel of the company for which they are GDP RP. This training session can serve as basis for the yearly GDP certification of your personnel.

Your personnel is of course also welcome, and for this reason the member price will be applicable for all persons of a company that are accompanied by an UPIP-VAPI member.

This “Train the Trainer” concept is however not applicable for the **GDP RP** him/herself. And the GDP guidelines clearly state that **“The responsible person should also maintain their competence in GDP through regular training”.** This is the reason why each GDP RP should attend regular training in order to remain up to date with the latest developments in this field.

Manufacturers with a GMP license also receive a GDP license for the products they manufacture. This means that they do not need to apply for a separate wholesale license, but does not exempt them from the GDP requirements, including regular training. Therefore this training is also aimed at **GMP Qualified Persons** because they are often involved in storage and distribution activities, and may be involved in the handling of falsified medicines.

The training will end with a **GDP Quiz**, whereby you can obtain a **GDP training certificate** when successfully passing the test.

Speakers

PART 1 of the training session will be chaired by two UPIP-VAPI board members:

Frank Peeters, Pharmacist, Ph.D.
UPIP—VAPI President

GDP RP & GMP QP
Visiting Professor KU Leuven

TOBEAS, Mechelen
Managing Director

Ludwig Everaert, Pharmacist
UPIP-VAPI Board Member

GDP RP

ARCHEMIN – MPI, Mechelen
Managing Director

PART 2 of the training session will be hosted by **Raes Pharmaceutical Logistics, Drongen**, specialised in distribution of temperature-sensitive pharmaceutical products.

Booking Information

GDP Certification Training

25th Jan 2018

Venue:

JANSSEN PHARMACEUTICA
Rue du Bois de la Hutte 7,
7110 La Louvière

VAPI-UPIP member 350€ (incl. VAT) - Non VAPI-UPIP member 450€ (incl. VAT)
Non-members accompanied by an UPIP-VAPI member of that company pay the member price.

Included: Course notes, Training Certificate, Sandwiches and Drinks.

Training begins at 13h30 and finishes at 17h30
Please register by email to info@upip-vapi.be with the attached registration form.