

**UIP-VAPI Yearly GDP Certification Training
Basic & Advanced GDP Module**

Dear members,

The UIP-VAPI board is organizing it's yearly training on the Guidelines of 5 November 2013 (2013/C 343/01) on Good Distribution Practice of Medicinal Products for Human Use

The Advance Training part will also handle the GDP for API's (2015/C 95/01) and GDP for Medical Devices (FAGG Guide Distributers Version 1.5).

This session will be held on Monday 30 September 2019 from 13h30 to 17h30 at the J&J European Distribution Center, Rue du Bois de la hutte 5, B-7110 La Louvière

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 cover the following topics:

An initial refresher module on the GDP's including:

- The roles, functions and responsibilities of the GDP RP
- Current status of the Falsified Medicines implementation (unique barcodes), also presenting the issues relating to aggregation barcoding
- GDP Deviation management & CAPA handling
 - o vehicle breakdown during transport
 - o Handling of temperature alarms
 - o Missing temperature measurements

After these introductory sessions, the audience will split into two parts:

Basic Module Hosted by Ludwig Everaert	Advanced Module Hosted by Frank Peeters
Overview of the GDP chapters and the procedures required for GDP compliance.	Round table discussion between peers on the current issues relating to the GDPs. <i>Please feel free to send in your topics or questions in advance.</i>
Which products need more stringent handling conditions, and how to handle them.	GDP for API's. GDP for Medical Devices.

The afternoon will end with a tour of the warehouses of the J&J European Distribution Center.

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 persons 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".

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.

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.

Your personnel handling pharmaceutical ingredients & products or medical devices is of course also welcome. In case a person is not yet a member of our association, he/she will pay a membership fee but will then immediately benefit from the member price.

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

Speakers



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

Booking Information

Basic & Advanced GDP Certification Training

Monday 30th Sep 2019

Training begins at 13h30 and finishes at 17h30

Venue:

J&J European Distribution Center
Rue du Bois de la hutte 5 , B-7110 La Louvière

VAPI-UPIP member 350€ (incl. VAT)
Non VAPI-UPIP member 455€ (incl. VAT- allowing free membership for 2019)

Included: Course notes & Training Certificate, Drinks.

Please register by email to info@upip-vapi.be with the attached registration form.