



PHARMANAGER

development



Qualiopi
processus certifié
RÉPUBLIQUE FRANÇAISE

WELCOME BOOKLET

FACE-TO-FACE OR DISTANCE LEARNING (WEBINAR)

Training organization registered under the activity declaration number: 52 49 03216 49





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1. RECEPTION

The entire Pharmanager Development team welcomes you.

This welcome booklet is intended to give you as much information and benchmarks as possible in order to answer your questions.

2. PRESENTATION OF THE COMPANY

Pharmanager Development is a consulting company, created in 2004, located at 24 Rue Max Richard in Angers (France).

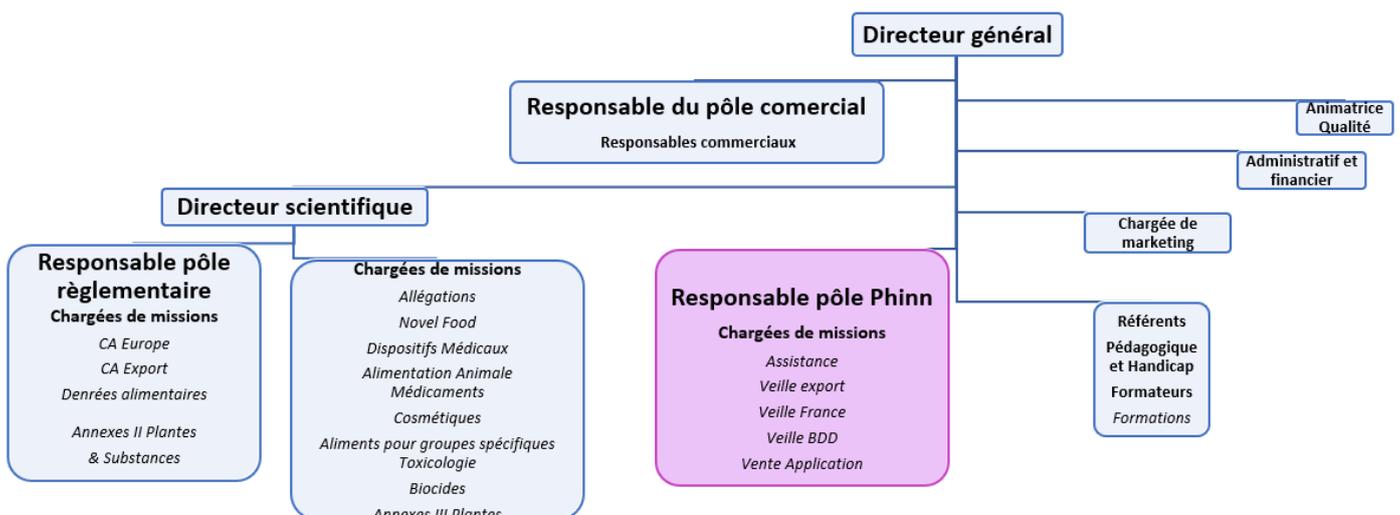
Our scientific and regulatory consulting services are spread over 4 areas of expertise: Product development, Scientific justification, Regulatory procedures, Training and audits; on 5 sectors of activity:

- Alimentary
- Pharmaceutical
- Cosmetic
- Biocide
- Animal nutrition.

We also offer an online scientific and regulatory application (PhInn®): Provision in the form of subscriptions of scientific and regulatory data.

a) Organization of the company

Functional organization chart (*Organizational chart: see annex*):





b) Administrative and functional interlocutors

Mr Mano: Managing Director,

Ms. Louveau: Administrative and Financial Manager,

Miss François: Scientific Director,

Miss Brillant, Mrs Dubin, Mrs Dupin: Business Unit Managers.

Training Pole:

Mr. Dalifard: Accounting Assistant, Administrative Manager/Referent,

Miss Pozza: Pedagogical and disability referent.

3. THE TRAINING OFFER

With its regulatory and scientific experience in providing concrete and comprehensive support to many players in the nutrition-health market and interactions with the authorities, Pharmanager Development offers training in the following areas:

- Food: Food supplements and foodstuffs, Nutrition and health claims, Foods for specific groups, Novel Food...
- Pharmaceutical: Herbal medicines, Medical devices,
- Cosmetics,
- Biocidal products,
- Feed: Animal nutrition.

They concern anyone involved in the process of developing and/or marketing products in their fields (DG, project manager, R&D, regulatory or marketing departments).

4. Our commitment to quality

Pharmanager Development has obtained the certification of its quality system (including training management) within the framework of the ISO 9001 standard, and is [qualiopi certified](#) by AFNOR certification for its training actions.





5. ORGANIZATION OF TRAINING

a) Training Information

When you register for the training program you are going to follow, you have informed (or your employer) your individual expectations and objectives.

You were also able to identify training adaptation needs related to a disability situation. An adaptation by agreement was previously considered on a case-by-case basis.

The detailed program of the training presents the training objectives, the teaching methods used, the means of supervision and the methods of assessing the achievements and satisfaction of the participants.

The place and times of training are also specified in the training program: either in our premises (24 rue Max Richard, Angers), or relocated to a room rented for this purpose, or remotely (via the COMPUTER tool TEAMS). The exact place, date and time of start of the training are recalled in the convocation sent upon validation of your registration.

Lunch breaks are included in the training offer when the training is carried out face-to-face (in Angers or relocated to another city).

b) Logistical means

The training takes place in our training room (maximum 12 people) when it takes place in Angers with wifi access. When it is relocated to another city, the rented training room (adapted in size to the number of participants) also has Wifi access.

Remotely, the computer platform used for training is the TEAMS tool. No need to have this tool installed on your computer to use it. Indeed, in the TEAMS invitation sent before the training, a connection link is integrated and if it detects the absence of installation of TEAMS on your computer, it will ask you to install a temporary plug-in (2 min of installation) allowing you to use TEAMS for the duration of the training.

c) Rights and duties of participants

Each participant in the trainings (face-to-face or remote) must read the rules of procedure and comply with them. This is annexed to this welcome booklet.

Each participant is required to respect professional discretion (inside and outside the establishment).

Each participant must respect the rules of hygiene and civility.

The participant being an actor of his training, the richness of it will depend on his own dynamism and his personal involvement.

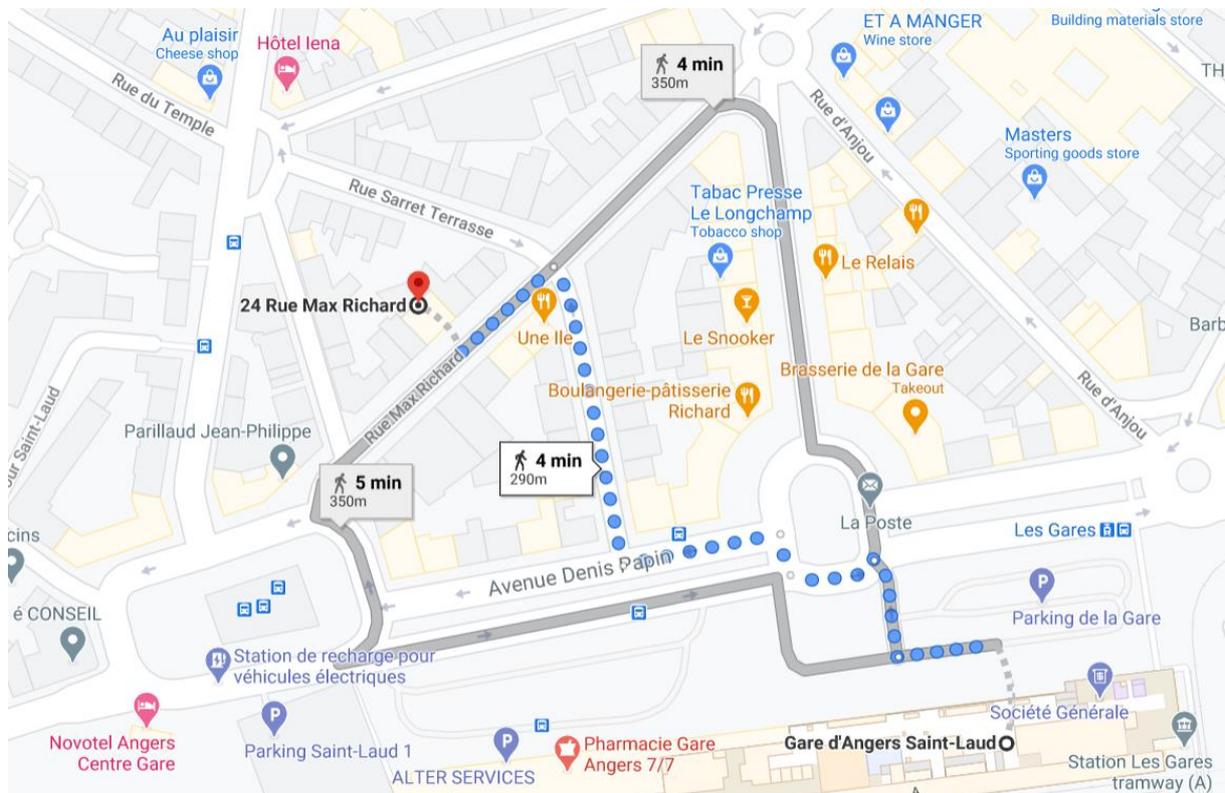
6. PRACTICAL LIFE

a) Access map

The premises of Pharmedge Development, located at 24 rue Max Richard (300 m walk from the Angers St Laud SNCF station), are accessible to people with reduced mobility (access ramp, training room on the ground floor, WC to “person with reduced mobility” standards).

NB: When the training courses are relocated to another city, accessibility for people with reduced mobility is a sine qua non condition for renting the training room.

A doorbell is available during the day at the main entrance at 24 Rue Max Richard.



b) Hotel and parking (Angers)

- [Hotel de Champagne](#): Accessibility for people with reduced mobility is not indicated on their website.
- [Hotel Le Progrès](#): Hôtel not easily accessible to people with reduced mobility.
- [Novotel Angers Centre Gare](#): Hotel accessible to people with reduced mobility.

Car park on “rue Max Richard” is subject to a fee (parking meter at the foot of the premises). Otherwise several paid car parks are available nearby:

- The Park St Laud 1 and 2,
- Marengo Park,
- The Haras Park.



7. SAFETY RULES

Participants must ensure their personal safety and that of others by respecting the general safety and hygiene instructions in force at the training site.

Any accident or incident occurring during the training (face-to-face) must be immediately reported by the injured participant or by the witnesses to the person in charge of the training or his representative.

Participants are prohibited from bringing firearms and products of a flammable or toxic nature into the premises.

Fire instructions, including a plan for locating fire extinguishers and emergency exits, are posted on the training rooms so that they are known to all trainees.

The latter are obliged to execute without delay the evacuation order given by the trainer or his representative.

8. ANNEXES

- a) Organizational chart
- b) Rules of Procedure

a) Organizational chart



b) Rules of Procedure

See next page.

Rules of Procedure of the training organization established in accordance with the Articles L6352-3 and L6352-4 and R6352-1 to R6352-15 of the French Labour Code

PREAMBLE

Article 1 – Subject matter and scope of the Regulation

This Regulation shall apply to all persons participating in a training action organised by PHARMANAGER DEVELOPMENT. A copy is given to each trainee.

The Regulation lays down the rules of health and safety, the general and permanent rules relating to discipline and the nature and scale of the sanctions that may be imposed on trainees who contravene them and the procedural guarantees applicable when a sanction is envisaged.

Every person must comply with the terms of this Regulation throughout the duration of the training action.

SECTION 1: HEALTH AND SAFETY RULES

Article 2 – General principles

The prevention of the risks of accidents and diseases is imperative and requires everyone to respect:

- the health and safety requirements applicable at the training sites;
- any instructions imposed either by the management of the training organisation or by the manufacturer or trainer, in particular as regards the use of the equipment made available.

Each trainee must thus ensure his personal safety and that of others by respecting, according to his training, the general and particular instructions in terms of hygiene and safety.

If he notices a malfunction of the safety system, he shall immediately notify the management of the training organization.

Failure to comply with these instructions exposes the person to disciplinary sanctions.

Article 3 – Fire instructions

Fire instructions and in particular a plan for locating fire extinguishers and emergency exits are posted on the premises of the training organisation (in the entrance hall next to the door of the training room). The trainee must read it.

In the event of an alert, the trainee must cease all training activities and calmly follow the instructions of the authorized representative of the training organization or the emergency services.

Any trainee who witnesses the start of a fire must immediately call for help by dialing 18 from a landline phone or 112 from a mobile phone and alert a representative of the training organization.

Article 4 – Alcoholic beverages and drugs

The introduction or consumption of drugs or alcoholic beverages on the premises is strictly prohibited. Trainees are prohibited from entering or staying drunk or under the influence of drugs in the training organization.

Interns will have access during breaks to non-alcoholic beverage distribution stations.

Article 5 – Prohibition of smoking

It is strictly forbidden to smoke in the training rooms and more generally within the premises of the training organization.

Article 6 – Accident

The trainee who is the victim of an accident - occurring during the training or during the travel time between the place of training and his home or place of work - or the witness of this accident shall immediately notify the management of the training organization.

The head of the training organization takes the appropriate steps in terms of care and makes the declaration to the competent social security fund.

Article 7 – Place of training

The training will take place either in the premises of PHARMANAGER DEVELOPMENT or in external premises. The provisions of these Regulations are applicable not only within the premises of PHARMANAGER DEVELOPMENT, but also in any room or space ancillary to the organization.

Where the training takes place in an undertaking or establishment which already has internal regulations, the health and safety measures applicable to trainees shall be those of the latter regulation.

In the context of distance learning, it is also imperative to respect the health and safety rules of the place where the training action is carried out, in particular the trainee's company.

The training organization can not be held responsible for incidents or accidents occurring remotely during training hours and in particular related to the use of computer and internet tools.

SECTION 2: GENERAL DISCIPLINE

Article 8 – Attendance of the trainee in training

Article 8.1. – Training schedules

Trainees must comply with the schedules set and communicated in advance by the training organization. Failure to comply with these schedules may result in penalties.

Except in exceptional circumstances, trainees may not be absent during internship hours.

Article 8.2. – Absences, delays or early departures

In the event of absence, delay or departure before the scheduled time, trainees must notify the training organization and justify it.

The training organization immediately informs the funder (employer, administration, Fongecif, Region, Pôle emploi...) of that event.

Any event not justified by particular circumstances constitutes misconduct punishable by disciplinary sanctions.

In addition, in accordance with Article R6341-45 of the Labor Code, the intern – whose remuneration is borne by the public authorities – is exposed to a deduction from his internship remuneration proportional to the duration of the absence.

Article 8.3. – Formalism attached to the follow-up of the training

The trainee is required to fill in the registration sheet as the action progresses. He may be asked to carry out an assessment of the training.

At the end of the training action, he is given a certificate of completion of training and a certificate of attendance at the internship to be transmitted, as the case may be, to his employer / administration or to the body that finances the action.

The trainee submits, as soon as possible, to the training organization the documents that he must fill in as a service provider (request for remuneration or coverage of the costs related to the training ; certificates of registration or entry into an internship ...).

Article 9 – Access to training premises

Unless expressly authorized by the management of the training organization, the trainee may not:

- enter or remain in the training premises for purposes other than training,
- introduce, cause to be introduced or facilitate the introduction of persons outside the body,
- proceed, in the latter, to the sale of goods or services.

The training organization declines all responsibility in the event of loss, theft or deterioration of personal objects of any kind, deposited by the trainees in its premises.

Article 10 – Outfit

The intern is invited to present himself to the organization in correct dress.

Article 11 – Conduct

All trainees are required to behave in a manner that guarantees compliance with the elementary rules of knowing how to live, knowing how to be in a community and the smooth running of training.

Article 12 – Use of equipment

Unless otherwise authorized by the management of the training organization, the use of the training material is made at the training sites and is exclusively reserved for the training activity. The use of the material for personal purposes is prohibited.

The trainee is required to keep in good condition the equipment entrusted to him for the training. He must make use of it in accordance with its purpose and according to the rules issued by the trainer.

The trainee shall immediately report to the trainer any anomaly in the equipment.

SECTION 3: DISCIPLINARY MEASURES

Article 13 – Disciplinary sanctions

Any failure by the trainee to comply with any of the requirements of these rules of procedure may be subject to a sanction pronounced by the head of the training organization or his representative.

Any act considered to be at fault may, depending on its nature and gravity, be subject to one of the following sanctions:

- call to order;
- written warning by the director of the training organization or his representative;
- blame;
- temporary exclusion from training;
- permanent exclusion from training.

Fines or other financial penalties are prohibited.

**Rules of Procedure of the training organization established in accordance with the Articles
L6352-3 and L6352-4 and R6352-1 to R6352-15 of the French Labour Code**

The head of the training organization or his representative shall inform of the sanction imposed:

- the employer of the trainee employee or the administration of the trainee staff member;
- and/or the funder of the internship.

Article 14 – Disciplinary guarantees

Article 14.1. – Information of the trainee

No penalty may be imposed on the trainee unless he has been informed in advance of the complaints raised against him.

However, where an act, considered to be wrongful, has made a precautionary measure of temporary exclusion with immediate effect indispensable, no definitive sanction relating to that conduct may be taken unless the trainee has been informed in advance of the complaints raised against him and, possibly, the procedure described below has been complied with.

Article 14.2. – Convocation for an interview

Where the director of the training organisation or his representative intends to impose a sanction, the following procedure shall be followed:

- he summons the trainee – by registered letter with request for acknowledgment of receipt or delivery to the interested party against discharge – indicating the subject of the convocation;
- the convocation shall also indicate the date, time and place of the interview and the possibility of being assisted by a person of his choice who is a trainee or employee of the training organization.

Article 14.3. – Possible assistance during maintenance

During the interview, the trainee may be assisted by a person of his choice, in particular the traineeship delegate.

The director or his representative shall indicate the reason for the sanction envisaged and shall obtain the trainee's explanations.

Article 14.4. – Imposition of the sanction

The penalty may not be imposed less than one clear day or more than fifteen days after the interview.

The sanction is the subject of a written and reasoned notification to the trainee in the form of a registered letter or delivered against discharge.

Done at ANGERS

on NOVEMBER 24th 2020

[Signature Director Training Organization]

Jean-Christophe MANO