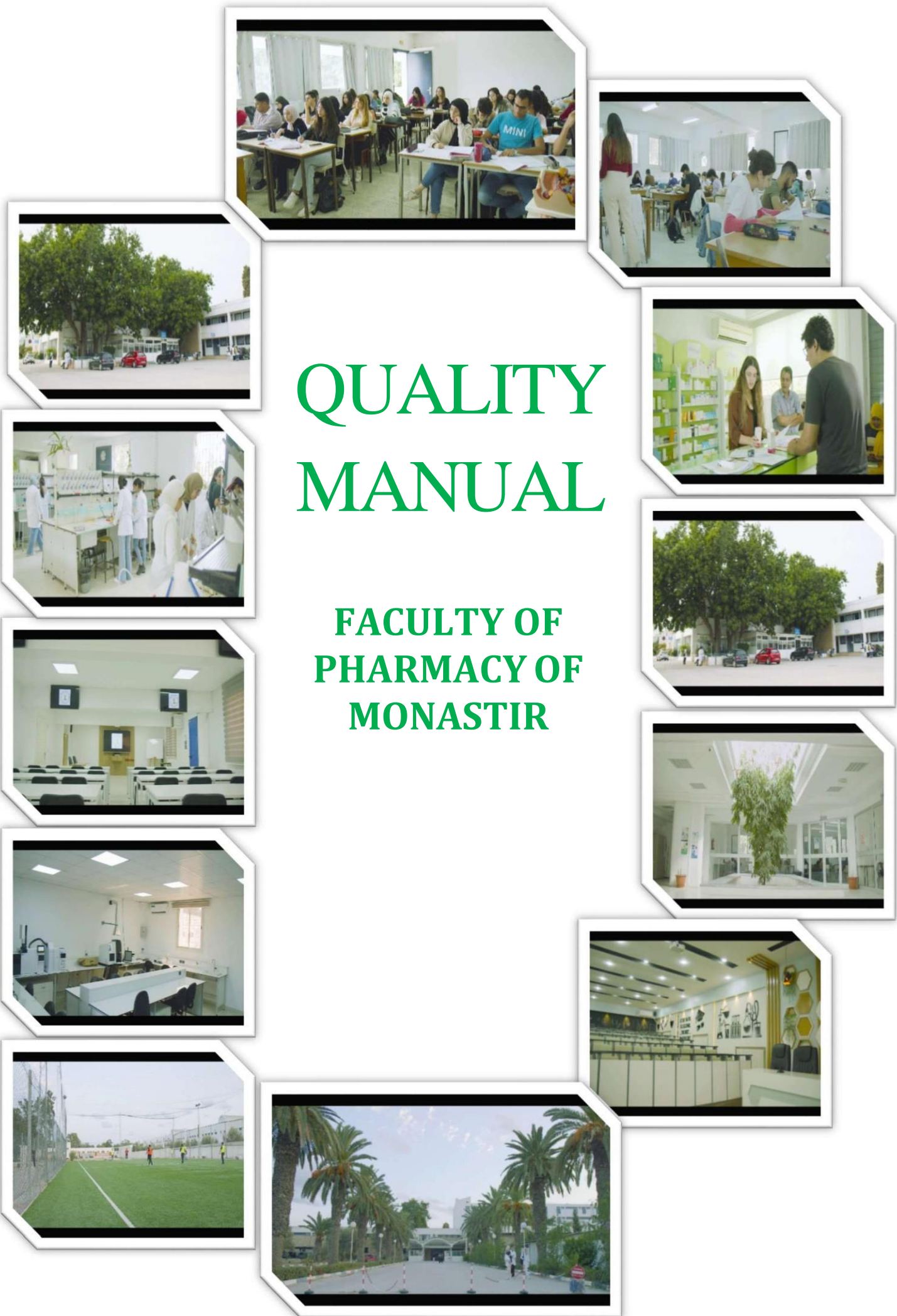

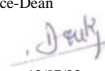


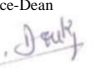



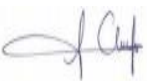


QUALITY MANUAL

FACULTY OF PHARMACY OF MONASTIR



History of modifications :

Indice d'évolution	Creation/Revision Date	Reason of modification	Whriter		Auditor		Approver	
			Name	Function/Visa	Name	Function/Visa	Name	Function/Visa
01	15/07/23	Creation	Fouzia MEHDIQUI	RMQ  Date : 10/07/23	Wahiba DOUKI	Vice-Dean  Date : 12/07/23	Mohsen HASSINE	Dean Le Doyen Pr. Mohsen Hassine  Date : 15/07/23
02	15/04/24	Updated mapping	Fouzia MEHDIQUI	RMQ  Date : 10/04/24	Wahiba DOUKI	Vice-Dean  Date : 11/04/24	Mohsen HASSINE	Dean Le Doyen Pr. Mohsen Hassine  Date : 15/04/24
03	15/02/2025	Pilots list process Field of application	RMQ	RMQ  13/01/2025	Sadek Zayene	General secretary 15/02/2025 	Cherifa CHAOUECH	Dean 15/02/2025 

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I. FPHM Presentation

The Faculty of Pharmacy of Monastir (FPHM) is the only faculty of pharmacy in the country. It was created in 1975 (law 75-72 of 11/14/1975) in Monastir.

It is attached to the Ministry of Higher Education and Scientific Research (MESRS) via the University of Monastir (decree 2004-2102 of 2 September 2004 establishing the University of Monastir). The University of Monastir is made up, in addition to other higher education institutions, of a network of health sciences which is composed of the faculty of pharmacy, the faculty of medicine, the faculty of dental medicine and the higher school of health sciences and techniques, all located in the city of Monastir.

Dual supervision (MESRS and ministry of Health) offers the advantage of a better integration by the faculty of the challenges and health needs of our country and the possibility of implementing training that meets international standards in terms of pedagogy and focusses on the patient and the needs of society.

The FPHM has a mission of basic training and continuing education in different pedagogical forms (face-to-face training, distance learning, training in a professional environment, etc.). It also provides scientific research, technological development and service provision in complementarity with all the production sectors of the country and as part of the opening on the economic, social and cultural environment.

The FPHM participates in the sociosanitary environment by training professionals who work in all health structures and administrations of the country (pharmacies, hospital pharmacies, clinics, polyclinics of the National Social Security Fund (CNSS), medical biology analysis laboratories, pharmaceutical industries, Directorate of Pharmacy and Medicine (DPM), regional health directorates, pharmaceutical inspection, central and regional administrations,...).

A-Academic programs

1- Doctor of Pharmacy Degree

It is obtained after six years of study governed by Decree No. 2004-1634 of 12 July 12, 2004, laying down the general framework for studies and the conditions for obtaining the national diploma of Doctor of Pharmacy, and its implementing decree of 30 April 30, 2018, setting out the regime for studies and exams. The courses are organised by discipline, or in multidisciplinary certificates,, coordinated certificates and optional certificates.

Studies in pharmacy include a first cycle (PCE) and a second cycle (DCEP). The PCE lasts two years. The DCEP lasts four years.

2. Residency in pharmacy to obtain the diploma of specialist pharmacist

The residency in pharmacy, lasting eight semesters, was established in 1980 for biology and then extended in 2000 to the Hospital and Industrial Pharmacy (PHI). The residency is governed by the decree of December 27, 2010. Access to the residence is through a competition.

Training is provided in several ways: academic training and internships reinforced by self-training, active participation in seminars, congresses and scientific conferences.

For residents, the faculty organizes mandatory Certificates of Specialized Studies (CES) (four for the biology option set up in 1981, and four for the PHI option).

3- Master's degree in research

Currently, the FPHM has two research masters with different backgrounds:

- a. Master's degree in medical biology and health technologies, with two courses: infectious diseases and immunology - immunotherapy
- b. Master's degree in drug development research, with four courses: analytical drug development, galenic drug development, pharmacological drug development and pharmaceutical chemistry.

4- Professional Master Degree

The FPHM currently has three professional master's degrees:

- hematobiology, transfusion and cell therapy,
- quality management in the field of health,
- Technological innovation, management and engineering applied to the pharmaceutical industry.

5- Doctoral thesis in pharmacy

The FPHM has been authorised, since 1993, for doctoral theses in pharmaceutical sciences and Habilitation to Supervise Research (HDR). The thesis and habilitation committee registers candidates taking into account the criteria specified in the text governing doctoral studies.

6- Other training

The FPHM organizes certifying training in various fields in the form of Certificates of Complementary Studies (CEC): Each commission that pilots a CEC establishes selection criteria accessible on the FPHM website. The FPHM also provides seminars, workshops and scientific days.

B- Scientific Research

Promoting scientific research in pharmaceutical, biological and environmental sciences is one of the objectives of the FPHM.

This is how the FPHM hosts five research laboratories whose activity falls within the priority areas of research at the scale regional, national and international.

II. Field of application

The Integrated Management System (IMS) of the Faculty of Pharmacy of Monastir (FPHM) applies to all the following pedagogical, scientific, administrative and logistical activities:

- **Education degrees :**
 - Doctor of Pharmacy Degree ;
 - Residency of Pharmacy
 - Professional and Research Master Degree
 - Doctoral thesis in pharmacy

- **Certifying and continuing education :**
 - Certificates of complementary studies (CEC);
 - Seminars, workshops and other continuing education activities.

- **Scientific research and national and international cooperation**, including research laboratories, scientific projects, publication and promotion.

- **Administrative management and support activities:**
 - Admission and subscription;
 - Educational planning;
 - Human resources management;
 - Infrastructure and procurement management;
 - Student services and student life.
 -

Geographical domain: The field of application covers all activities carried out **at the main FPHM site located in Monastir**, as well as educational, scientific and cooperation activities conducted in partnership with other institutions, in Tunisia and internationally.

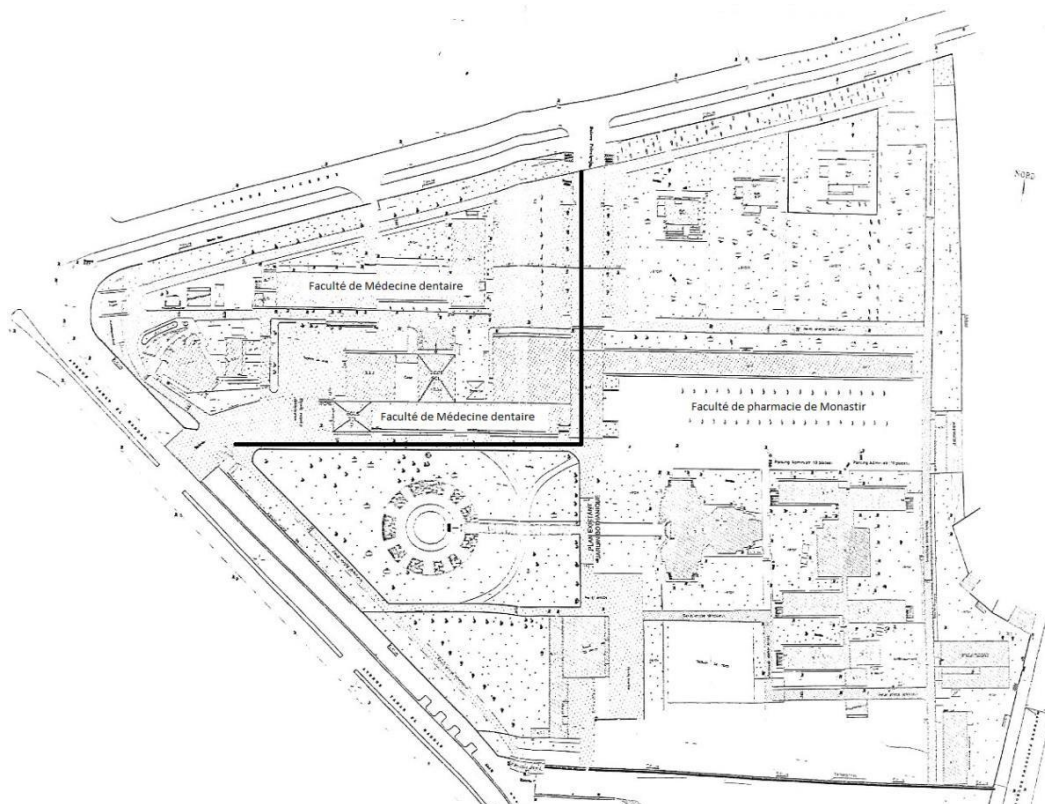


Figure n°1 : PPHM plan

Outsourced activities: Some activities are outsourced and subject to monitoring and control in accordance with IMS requirements. These include the following.

- Maintenance of infrastructure and equipment;
- of certain IT services;
- Catering or cleaning services, if applicable;
- Cooperation with educational or scientific partners.
- Internship places.

The identification of internal and external issues, risks and opportunities, as well as listening to stakeholders, allow for the definition of this scope and ensure compliance of the SMI with the requirements of ISO 9001:2015 and ISO 21001:2018 standards.

III. Useful information

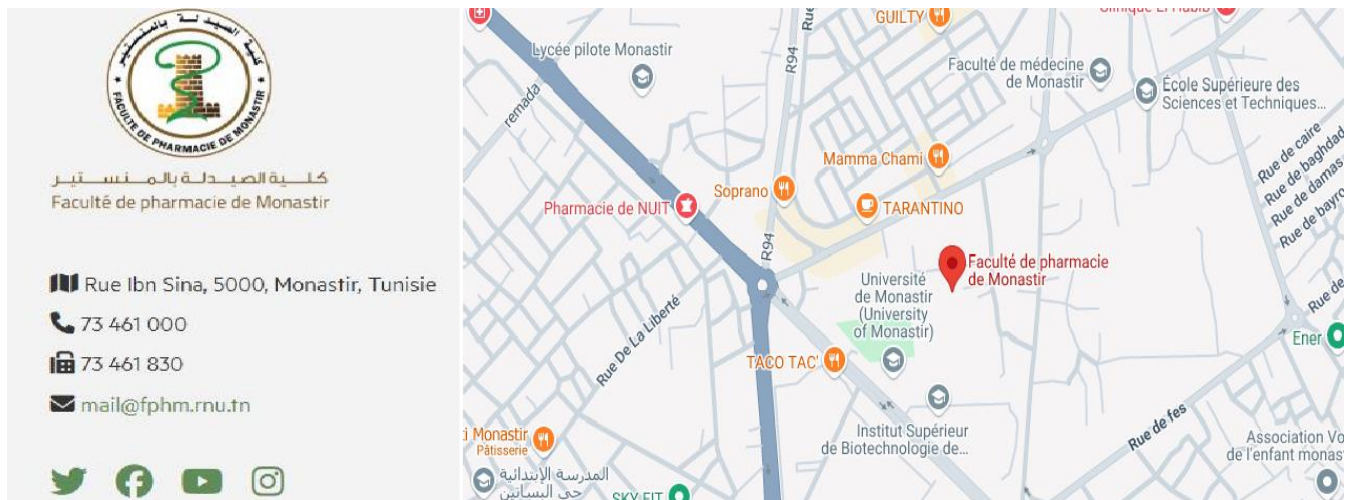


Figure n°2 : Useful information

IV. Exclusions

All the chapters of the two standards ISO 9001: 2015 and ISO 21001: 2018 are applicable.

V. Abbreviations

- PCEP : First cycle of pharmaceutical studies
- DCEP: First cycle of pharmaceutical studies
- CES : Certificate of specialized education
- CEC: Complementary study certificate
- SMI : integrated management system

VI. FPHM quality policy

The FPHM is committed to implementing and promoting an integrated management system, in compliance with the requirements of ISO 9001:2015 and ISO 21001:2018, as well as legal, regulatory and internal requirements, while continuously improving its efficiency and relevance.

Our commitment is based on a thorough understanding of the internal and external context, as well as the identification and consideration of relevant stakeholders: students, teachers, administrative staff, supervisory authorities, academic partners, and socio-economic.

In this perspective, the faculty strengthens its leadership through the active involvement of the management and mobilization of all employees to promote the vision and values of the institution.

The mission of the FPHM is to train competent and innovative professional pharmacists, with an emphasis on academic excellence, scientific research, and continuous professional development. This mission is reflected in quality pharmaceutical practices, focused on the patient and based on a culture of continuous improvement.

To ensure the sustainability of its activities and achieve its strategic objectives, the FPHM regularly analyses the risks and opportunities likely to influence the compliance of its services, the satisfaction of stakeholders, and the overall performance of the quality system.

Our quality policy is thus based on the following principles:

- Improve the satisfaction of learners and stakeholders by listening to their needs and anticipating their expectations.
- Strengthen student engagement and involvement in university life.
- Continuously improve the quality of educational services and services offered.
- Develop scientific research through national and international cooperation.
- Promote human capital and ensure favourable conditions for professional development.
- Modernize infrastructure and ensure the safety of all stakeholders.
- Mobilize all staff in the management dynamic through quality.
- Integrate social responsibility principles by promoting sustainability, inclusion and diversity.

We reaffirm our commitment to meet the applicable requirements, including those defined by the institution itself, and to regularly review this policy in order to adapt it to changes in context and expectations.

V. FPHM mapping

The mapping of SMI processes, ISO 9001 V2015 and ISO 21000 V 2018 presented below brings to the Faculty a structuring approach oriented learners, teachers and interested parties.

Integrated Management System Process

SMI

ISO 9001 V 2015

ISO 21000 V2018

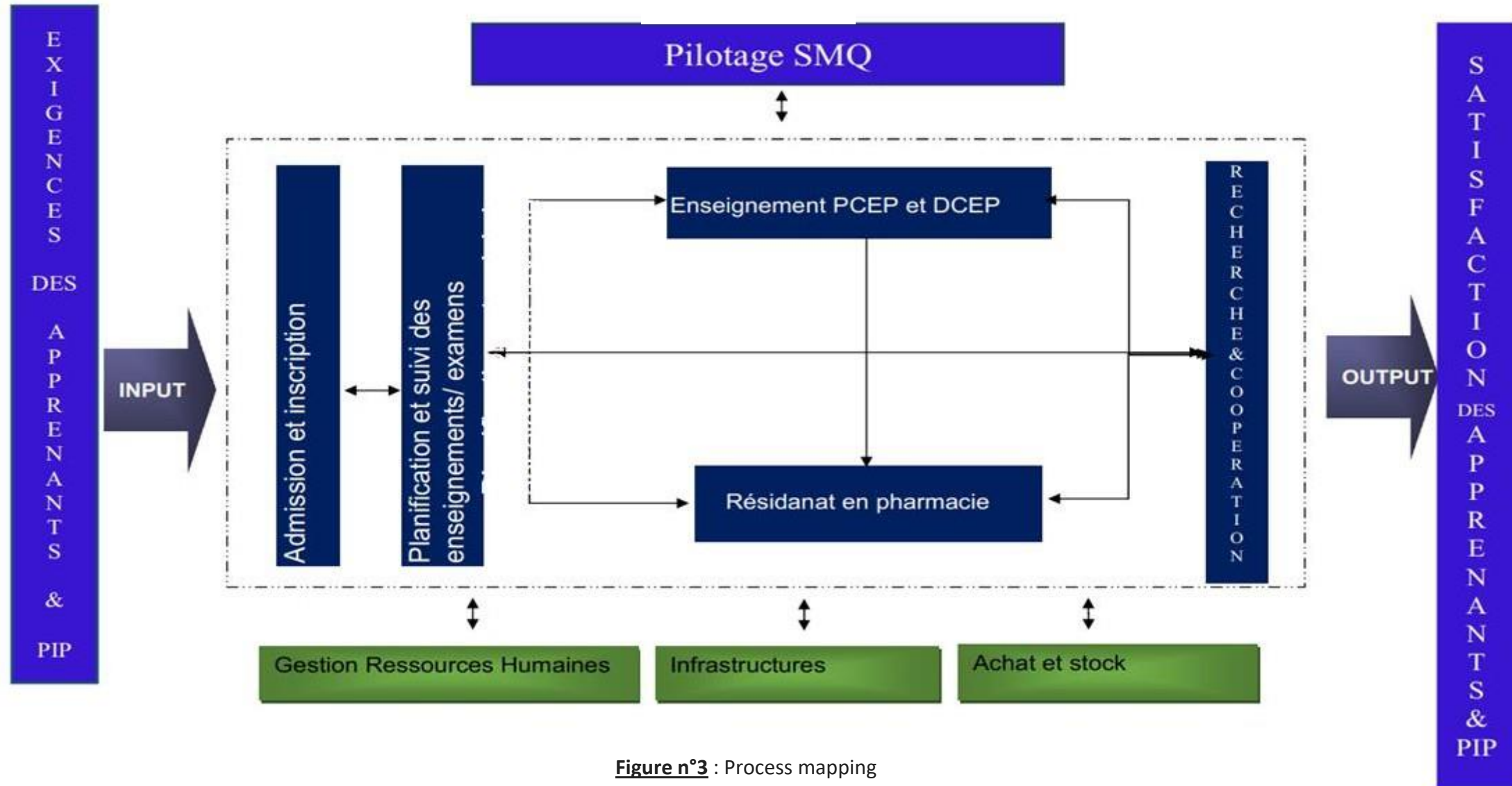




Figure n°3 : Process mapping

■ Process interactions



	Pilotage SMI	Admission et inscription	Planification et suivi des enseignements et examens	Enseignements PCEP et DCEP	Résidanat en pharmacie	Recherche et coopération	Gestion des ressources humaines	Infrastructures	Achat et stock
Pilotage SMI		Analyse Swot et PESTEL enjeux Politique qualité Objectifs qualité Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Actions d'amélioration Evènements FPHM Rapport cellule d'écoute	Analyse Swot et PESTEL enjeux Politique qualité Objectifs qualité Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Actions d'amélioration Calendrier universitaire Evènements FPHM Rapport cellule d'écoute	Analyse Swot et PESTEL enjeux Politique qualité Objectifs qualité Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Actions d'amélioration Cursus Rapport cellule d'écoute	Analyse Swot et PESTEL enjeux Politique qualité Objectifs qualité Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Actions d'amélioration Rapport cellule d'écoute	Analyse Swot et PESTEL enjeux Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Conventions de partenariat Rapport cellule d'écoute	Analyse Swot et PESTEL enjeux Politique qualité Objectifs qualité Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Organigramme Besoin en recrutement Actions d'amélioration	Analyse Swot et PESTEL enjeux Politique qualité Objectifs qualité Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Demande intervention Données à sauvegarder Actions d'amélioration	Analyse Swot et PESTEL enjeux Politique qualité Objectifs qualité Analyse des Risques Résultat des audits Résultat des enquêtes de satisfaction apprenants et autres PIP Plan de communication PV de la revue de direction Besoin Achat Actions d'amélioration
Admission et inscription	Fonctionnement de processus Besoins d'amélioration Liste des étudiants à besoin spécifique Nombre d'étudiants par groupe		Liste de groupe des étudiants inscrits par niveau d'étude Liste des étudiants à besoin spécifique	Liste de groupe des étudiants inscrits en PCEP et DCEP Liste d'émargement des examens Liste des étudiants à besoin spécifique	Liste des résidents inscrits par CES Liste d'émargement des examens	Attestation d'inscription en mastère/ thèse de doctorat national/ PCEP et DCEP	Besoin en formation Besoin en recrutement	Demande intervention Données à sauvegarder	Besoin Achat



	Pilotage SMI	Admission et inscription	Planification et suivi des enseignements et examens	Enseignements PCEP et DCEP	Résidanat en pharmacie	Recherche et coopération	Gestion des ressources humaines	Infrastructures	Achat et stock
Planification et suivi des enseignements et examens	Fonctionnement de processus Besoins d'amélioration Plan d'étude Nombre d'étudiants par groupe			Emploi de temps validé Calendrier des examens Calendrier des surveillances Planning des corrections d'examen	Planning des CES Note examen CES	-	Besoin en formation Besoin en recrutement	Demande intervention Données à sauvegarder	Besoin Achat
Enseignements PCEP et DCEP	Fonctionnement de processus Besoins d'amélioration Avancées technologiques et scientifiques Syllabus PCEP/DCEP	Liste de présence des groupes des étudiants inscrits en PCEP et DCEP PV délibérations	Demande de rattrapage/modification PV de surveillance Liste des étudiants non autorisés à passer l'examen Syllabus PCEP/DCEP		-	Besoin de visite de découverte des structures de recherche Demande d'exploitation du matériel de recherche	Besoin en formation Besoin en recrutement	Demande intervention Données à sauvegarder	Besoin Achat
Résidanat en pharmacie	Fonctionnement de processus Besoins d'amélioration Avancées technologiques et scientifiques Rapport évaluation enseignement Syllabus résidanat	Liste des résidents Liste des CES PV délibérations	Demande de rattrapage/modification PV de surveillance Liste des étudiants autorisés à passer l'examen Syllabus résidanat	-		Besoin de mise au point d'une méthode/procédé	Besoin en formation	Demande intervention Données à sauvegarder	Besoin Achat
Recherche et coopération	Fonctionnement de processus Besoins d'amélioration Avancées technologiques et scientifiques Dossier de création ou de reconduction de SR	-	-	Projet de recherche Articles publiés	Projet de recherche Articles publiés		Besoin en recrutement Besoin en formation	Demande intervention Données à sauvegarder	Besoin Achat Répartition du budget accordé



	Pilotage SMI	Admission et inscription	Planification et suivi des enseignements et examens	Enseignements PCEP et DCEP	Résidanat en pharmacie	Recherche et coopération	Gestion des ressources humaines	Infrastructures	Achat et stock
	Rapport annuel validé Rapport quadriennal								
Gestion des ressources humaines	Fonctionnement de processus Personnel recruté affecté Personnel formé Besoins d'amélioration	Personnel recruté affecté Personnel formé	Personnel recruté affecté Personnel formé Liste des enseignants	Personnel recruté affecté Personnel formé Liste des enseignants	Personnel recruté affecté Personnel formé Liste des enseignants	Personnel recruté affecté Personnel formé		Personnel recruté affecté Personnel formé Demande intervention Données à sauvegarder	Personnel recruté affecté Personnel formé Besoin Achat
Infrastructures	Fonctionnement de processus Infrastructure entretenu Intervention réalisée Données sauvegardés Besoins d'amélioration	Infrastructure entretenu Intervention réalisée Données sauvegardés	Infrastructure entretenu Intervention réalisée Données sauvegardés Liste des équipements	Infrastructure entretenu Intervention réalisée Données sauvegardés	Infrastructure entretenu Intervention réalisée Données sauvegardés	Infrastructure entretenu ESM étalonnés Intervention réalisée Données sauvegardés	Infrastructure entretenu Intervention réalisée Données sauvegardés		Infrastructure entretenu Intervention réalisée Données sauvegardés Besoin Achat
Achat et stock	Fonctionnement de processus Etat des réclamations fournisseurs Fonctionnement de processus Achats Bilan de performance	Besoin d'Achat satisfait Etat du stock	Besoin d'Achat satisfait Etat du stock	Besoin d'Achat satisfait Etat du stock	Besoin d'Achat satisfait Etat du stock	Besoin d'Achat satisfait Etat du stock	Besoin d'Achat satisfait Etat du stock	Besoin d'Achat satisfait Etat du stock Demande intervention Données à sauvegarder	

VI. List of employees and copilots of the different processes :

The FPHM's SMI processes are represented in the following table:

Table 1 : List of processes and pilots

Process	Pilots et co-pilots	E Mail
Management SMI	Cherifa Chaouch (Pilot) Manel Turki (copilot) Ferial Laouiti (Member)	cherifa18chaouch@gmail.com manel.turki2022@gmail.com faculte-pharmacie@fphm.rnu.tn
Admission and subscription	Amira Cherif (Pilot) Lamia Znati (copilot)	cherifamira79@gmail.com
Planning and monitoring of teaching and exams	Sameh Belgacem (Pilot) Boubakr Meksi/ Yassine Ben Soussia (copilots)	belgasam1503@yahoo.fr boubaker.meksi@fphm.rnu.tn bensoussiayassine@gmail.com
Learning (first and second cycle)	Mohamed Ali Soussi (Pilot) Imen Zrafi (copilot)	mohamedalisoussi@yahoo.fr imenzrafimachmoum@gmail.com
Residency in Pharmacy	Henda Mustapha (Pilot) Yomna Ben Lamine (Copilot)	henda_mustapha@live.fr yomnabenlamine@gmail.com
Third cycle training	Najoua Haouass (Pilot) Ibrahim Soud (copilot)	Najoua.h@laposte.net ibrahim.soud@fphm.u-monastir.tn
Research and Cooperation	Slim Mrad (Pilot) Hassen Ben Abdennebi (copilot)	selim.mrad@gnet.tn hbenabdennebi@yahoo.fr
Continuing professional development	Imen Ben Jdidia (Pilot) Asma Ben Abdelaziz (copilot)	benjdidiaimen@gmail.com asma_benabdelaziz@yahoo.fr
Human resources management	Ridha Neili (Pilot) Nabil Sakly (Copilot)	ridhanaili3@gmail.com saklynabil@yahoo.fr saklynabil@gmail.com
Infrastructures	Ridha Neili (Pilot) Rim Zitari (copilot) Riadh Bhar, Najeh Mdimegh, Wafa Bellazreg (copilot) IS informatics	ridhanaili3@gmail.com rymchatti3@gmail.com , rymzita@yahoo.fr wafabellazreg@gmail.com najahmdimeghfphm@gmail.com
Purchase and Stock	Besma Taleb (Pilot) Manel Hadj Ayed (Copilot)	besma_taleb@yahoo.fr hadjayedmanel@yahoo.fr

VII. Training environment:

The FPHM extends over approximately 20,000 m². The premises include different spaces:

- ✓ 06 Amphitheatres of different capacities;
- ✓ 06 TD Rooms;
- ✓ 02 Computer rooms;
- ✓ 03 Small group teaching rooms;
- ✓ Experimental pharmacy;
- ✓ 18 Practical work rooms;
- ✓ Continuous professional development complex;
- ✓ Library;
- ✓ Sports complex;
- ✓ Student space;
- ✓ 05 Research laboratories;
- ✓ Technical platform;
- ✓ Administration;
- ✓ Parking.

VIII. Student life

The faculty encourages student life by encouraging students to participate in sports, cultural and scientific activities. Thus, the faculty has made available to student associations (ATEP, ENACTUS, INNOVAMED, etc.) a space for students and the equipment necessary for its operation.

Some of these associations are partners in the organization of various scientific events of the FPHM. In the field of sports, the FPHM has participated in the majority of sporting events organized by the Tunisian federation of school and university sport. In addition, the physical education teacher, in partnership with ATEP, organises collective sports activities (basketball, handball, volleyball, football) and individual activities (tennis, ping-pong, running, etc.).

The support of FPHM to these student and sports associations is also manifested in a material contribution provided for in the institution's budget.