Teaching New Areas at the University or Not?[1]

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INTRODUCTION

In the French Pharmacy curriculum are included two years of specialization: in community pharmacy and in pharmaceutical industry. This specialization corresponds to a third cycle of the curriculum and lasts two years.

For pharmaceutical industry, the first year of this specialization generally includes topics which are related to various industrial and regulatory issues. As a rule, this first year is compulsory for all the students who have chosen this path of study. It includes eight different courses which are fundamental to work in a pharmaceutical company because they are the basis of the knowledge and vocabulary needed by those in industrial pharmacy. These courses are summarized in Table I.

The second part of this industrial specialization is selected by the students themselves because the courses are optional. Students must make a choice of one of the five career paths corresponding to those described by E.C. Guidelines for Pharmacists in the pharmaceutical industry. These ways correspond to: (*i*) Drug development (chemical, pharmacological, pharmaceutical-technological and/or analytical); (*ii*) Control (analytical), Quality Control; (*iii*) Pharmaceutical Manufacturing; (*iv*) Drug Information, Drug Marketing, Management; and (*v*) Drug Wholesale Supply (drug wholesale suppliers or agents).

The students must choose among the 25 hours of courses proposed, but only eight hours must correspond to the choice of their path of study. This second year is completed with a six months' training in a department in the pharmaceutical company corresponding to the path of specialization chosen. This allows students the opportunity to evaluate their interest for this specialization and/or to begin their career in this department.

For the students who choose the area of Pharmaceutical Manufacturing, new courses have been proposed which correspond to a new diploma we plan to introduce for pharmaceutical technicians that will be called "Pharmaceutical Engineers." For those with interest in Marketing and Pharmaceutical Development, another new course, Drug Dosage Form Design will be introduced. Explanations about these new areas of study are given below.

PHARMACEUTICAL ENGINEERS

In faculties such as Nancy, Montpellier and now, Lyon, students coming from the industry specialization have the opportunity during their last two years to follow, at the same time, the pharmaceutical courses corresponding to this curriculum and courses from the classical schools of engineers, *i.e.* mathematics, data processing, organic chemistry, mineral chemistry, analysis methods, thermodynamics and energetics, transport phenomena, heat exchange and separation methods, chemical reaction engineering, dynamics of systems, chemical engineering, polymerization engineering, analysis and design of industrial processes (Figure 1).

The courses which are taught from these schools of engineers allow the pharmacists to become also engineers but general ones and not specialized in the pharmaceutical field. Consequently, in Clermont-Ferrand we decided to propose to the pharmaceutical students and to the technicians involved in the pharmaceutical industry, a pharmaceutical engineering diploma the aim of which is to allow them in addition to the pharmaceutical knowledge, to understand the constraints of the pharmaceutical industry. Two levels are programmed during two years and correspond each to 865 hours of courses and practicals. In the case of Continuing Education, the two years may be extended up to three years.

The first level is related to the pharmaceutical working environment and operating conditions, *e.g.*, sterilization, build-up of clean rooms and maintenance, engineering problems of water and automatic manufacturing processes. The first level consist of seven teaching units about a special topic and of an industrial traineeship during which the students

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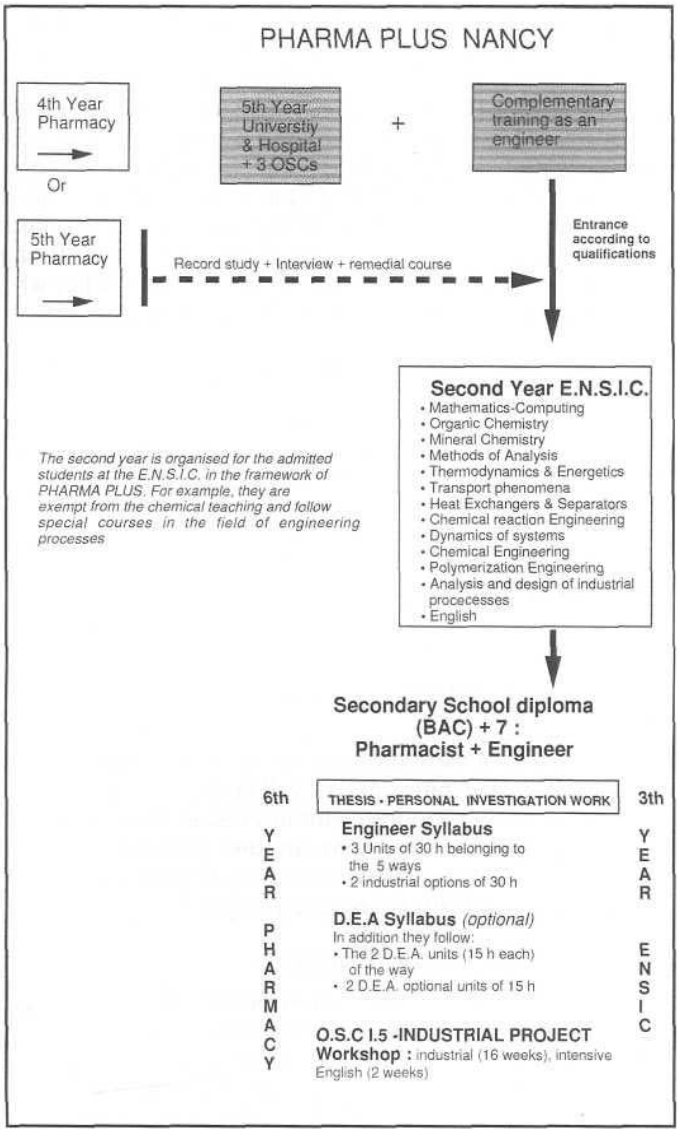

Fig. 1.

work on a specific project, write a report, and present it orally for validation. The teaching units are listed in Table II.

The second level is dedicated to ther automatic manufacturing processes of every dosage form: powders, granules, granulates, tablets, hard gelatin capsules, soft gelatin capsules, suppositories, ointments, transdermal systems and others. This second level, whose content is presently not completely resolved, will be offered in one year. It deals not only with the operation of machines, their installation in the working area and in the clean rooms, but also with automatic processes. Another teaching part is dedicated to the biopharmaceutical evaluation of the products and to the controls in process to be done. The second level teaching units are listed in Table III.

All these teaching units are taught as follows: one week every month for each course followed by a six months training in a pharmaceutical company with specialized work. The latter six-month training experience is presented orally for validation.

TEACHERS

For the first level, 60 percent of the teachers come from industry or companies specialized in equipment manufacturing or in building facilities. Courses are given at the university (50 percent) or in facilities corresponding with the topics to give students a direct application with its problems. For example, participants learn how to dress themselves to work in the clean rooms, how to clean a clean-

Table II. Teaching units in the first level

1. Industrial microbiology
   - Vehicles of micro-organisms
   - Sterilization methods
   - Elimination of endotoxines
   - Disinfection and disinfectants
   - Validation and sterilization
   - Regulation aspect and microbiology
   - Industrial hygiene
2. Contamination control
   - particle, biological and chemical contamination
   - controlled-contamination areas: aerobic, structure and conception
   - work station: laminar air flow and checkpoint
   - Clothes: material, equipment and cleaning
   - Cleaning and disinfecting of surface areas
   - Fluids: manufacturing and distribution
   - Filtration: theory of filtration
   - Filters for gas and liquids and their controls
   - Controls: standards, material and use
   - Staff: choice, training, capacitation and monitoring
3. Water and pharmaceutical industry
   - Water, drinking water: definition, obtaining and treatment
   - Setting-up of a water production unit
   - Production of distilled water: the various techniques
   - Industrial vapor, clean vapor
   - Network design
   - Chemical and microbiological water controls
   - Validation and maintenance of the water network
   - Regulatory aspects of water in the pharmaceutical industry
4. Packaging
   - Packaging materials: origin, nature, control
   - Main packaging types and their implementation
   - packaging machines
   - Control of the packaging items on receipt
   - Packaging of preparations in aerosol and/or spray form
   - Packaging of sterile products
   - Pharmaceutical design notion
5. Good Manufacturing Practices and relationships with engineering: quality assurance and validation
   - Quality assurance systems
   - Good Manufacturing Practices and engineering
   - Good Manufacturing Practices applied to development
   - Good Manufacturing Practices applied to dried drug dosage forms
   - Good Manufacturing Practices applied to sterility
   - Good Manufacturing Practices applied to packaging
   - Application examples of Good Manufacturing Practices and quality assurance
   - Statistics, validation and analysis
   - Metrology
   - Good Manufacturing Practices and ISO standardization
6. Notion of automation of systems and in process control (Automation and pharmaceutical field)
   - Notion of automation
   - Robotics and laboratory automate: definition, examples and application to dissolution tests
   - CIP/SIP (cleaning in place/sterilization in place)
   - Validation and automation
7. English language: practical and technical

Table III. Second level specific teaching units

Management of production
Architecture of the production systems
Part and means of the production management
computer-assisted production management
Quality
Quality construction
Quality and management
Mathematics-Statistics-Computing
Probabilities-Statistics
Computing
Technologies of industrialization
Robotics
Manufacturing techniques
Dynamic evaluation of production systems (Simulation and analytical modeling)
Analytical methods for production systems
Simulation of production systems
Application of automation to the pharmaceutical processes
Processes
Implementation of automation
Automation constraints related to fluids, facilities with mechanics of fluids and water
Powders
Fully automated production of drug dosage forms, cosmetic and food products
Solid dosage forms
Liquid dosage forms
Sterile dosage forms
Various cosmetic forms
Various types of industrial food
Control and supervision of systems

room, change filters, etc. They also carry out contamination tests, water controls and other quality assurance procedures.

The organization of the second level of the diploma will be done exactly as for the first level and be mainly given by industrial people (60 percent). The teaching is in good balance with the practical and theoretical components of the curriculum, but presently, in Europe, a discussion about apprenticeship for this kind of diploma arises.

DRUG DOSAGE FORM DESIGN

Drug dosage design is a second new teaching area. This is a relatively original notion as it seems to be essential to take into account dose design during the process of drug development. In fact, design allows one to improve the product coherence between the prescription requirements the pharmacists need, and the patients wants. The design of drug dosage forms is becoming more important due to an increase drug use by elderly people, and young children who, in both cases, require drug dosage forms adaptable to the special problems of their age groups.

An example is the division of liquids in the form of drops to provide the correct dose of medication for elderly people. It is now possible to use either a syringe or a special spoon with a tube to get a volume that corresponds to the correct number of drops for those who have difficulty obtaining the proper dose by the older method.

Other dosage forms present some use difficulties that have specific methods of administration and require patient education to take the drug. An example is the use of metered-dose inhalers or new powder-dose inhalers for which the presentation is very delicate and a detailed explanation to the patient is necessary.

The drug design instruction consists of 20 hours and is given in a period of one week. The course is taught by designers. Only one designer had specialized experience in the pharmaceutical field. The other instructors were designers who came from private agencies. Obviously, industrial people involved in the development of pharmaceutical drug products participate in this course to present the problems with which they have been faced. An example is a special device developed to distribute only one tablet for the elderly people to avoid an overdose. Another example of a problem is the white oval shaped tablets which are very similar and bring confusion to some in identifying what drug they are taking. Students are also asked to bring solutions to a project. As an example, they were asked to present a syrup for children according to the following requirements: no spoon required, a dose able to be carried on oneself.

CONCLUSION

In France, at our University, we have introduced into the pharmacy curriculum new teaching areas for specialization in pharmaceutical industry that may be selected by the students. It seems important that these new teaching areas be mostly given by professional people and that students be responsible for projects in order to be implicated exactly as if they were working. These projects should be presented orally by students, which is how they will be expected to perform in a pharmaceutical company when they are employed.

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