Virtual Firm in Biomedical Education: a Very Successful Experience

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Abstract— **In May 2006, the Institut Superieur d'Ingenieurs de Franche-Comté (ISIFC) launched its own virtual firm, which was named Biotika® by students. Virtual means that this company has no real legal status. It is a pedagogic model; however, the situation scenario for the ISIFC student engineers is real. They are currently working in real conditions on the development of new medical devices and on the modernization of medical products. The need for these innovative medical devices was identified by the students during their second-year (6 weeks) internship in hospitals. Biotika® is open between March and December every year. The students are "recruited" following an imitation job interview and each is then entrusted with a mission (engineer, project manager etc.) in one of the company's four departments: Research & Design, Quality-regulatory affairs, Clinical investigations, and Public relations-marketing. The personnel of Biotika® work on the development of innovative medical devices and/or the preparation of CE or FDA certification for 2 days per week. Since its launch, Biotika® has developed eight products and obtained many grants and prizes from French research and governmental organizations. It is also certified ISO 13485.**

I. Introduction

THE Institut Superieur d'Ingenieurs de Franche-Comté (ISIFC, or the High Institute of Engineers of Franche-Comte) is the internal engineering school of University of Besançon (France) and is accredited by the French Ministry of National Education [1],[2]. Since 2004, 216 biomedical engineering students have graduated from the ISIFC with skills to develop products for the prevention, diagnosis, and treatment of disease that can be used to rehabilitate patients and improve health. Its originality lies in its innovative course of studies, which trains engineers in the scientific and medical fields so that can gain competency in both. Therefore, the ISIFC collaborates with the University Hospital Centre of Besançon, biomedical companies, and national research centers. The teaching team consists mainly of lecturers, researchers, and biomedical and health industry professionals.

The ISIFC is an innovative engineering school that tries to understand the expectations of specific healthcare and medical devices markets. It trains engineers in 3 years (2400 hours per student), focusing on both medical and technical fields. The graduates will work for 80% in the biomedical industry, 15% in healthcare centers, and 5% in research laboratories. They master the entire life-cycle of a medical device, from the idea to its market launch. These people can help to improve product functionality, usability, safety, and quality.

Students may enter the program with a bachelor's degree in engineering or life sciences (3 years of training) or a license degree (2 years of training).

The majority of the graduates are employed by firms that produce and/or commercialize medical devices and health-oriented materials and equipment such as Alcis, Denstply, Imasonic, Johnson & Johnson, Statice Santé, Sophysa, Symbios, Praxim, Protheos, Tornier, and Zimmer.

II. What Is a Virtual Firm?

The nature of this innovative concept is based on the originality of the ISIFC, which is at the heart of an innovative process to accelerate device deployment in the market. The ISIFC requires strong interactions among academia, life sciences, technology, engineering, and industry.

To stimulate greater academia/business interactions, in 2006, the ISIFC created Biotika®, a virtual firm specialized in design engineering of innovative medical devices [3],[4]. ISIFC created an environment for innovation in healthcare to stimulate the commercialization of new medical devices, to reduce costs, and to deliver results faster. It focuses upon marketing, regulatory and clinical affairs, service support, accounting, and inventory (not on manufacturing or production engineering). This company was built based on a 7 European Credit Time System (ECTS) or 175 hours of a teaching model. It is divided into two parts: 3 ECTS in semester 4 (second year) and 4 ECTS in semester 5 (third year). However, it is not simply an educational entrepreneurship exercise to encourage students during their university course.

The purpose of this company is to provide students an insight into various aspects of their future jobs within a real-life professional framework, and to establish real new innovative businesses that enhance the research of academic researchers or support real start-up activities. The idea was to sensitize the students to innovation, entrepreneurship, quality approach, and project management using the specific angles of regulatory affairs, clinical investigations, financing of the innovation, industrial and intellectual properties, and market studies. The students (about a half of the class, *i.e.* 20 to 25 students per year) that are "recruited" by Biotika® work on real projects.

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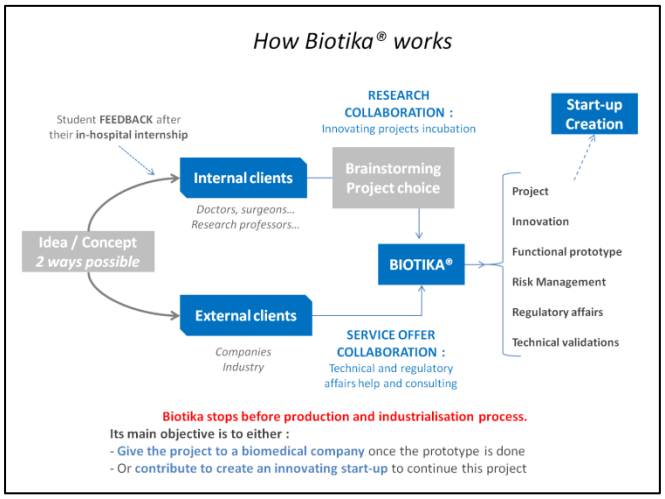

Figure 1. Life-cycle of a Biotika® project

Three ISIFC staff members pilot the virtual firm as the CEO, Human Resources manager, and quality assurance/regulatory affairs manager. They are assisted by university experts, physicians, a finance secretary, and a technician in electronics.

Every year, the students and the staff of the ISIFC decide upon the new project together. This brainstorming is performed soon after the students have completed a 6-week internship in a hospital, thereby allowing the ideas obtained by the students during their first working experience in contact with healthcare professionals to be integrated into the project (Fig. 1).

During each project, the students work in close cooperation with different categories of customers, such as patients, healthcare professionals (nurses, biomedical hospital engineers, physicians, and clinical researchers), and industrial professionals, as well as with scientists from research laboratories in the fields of engineering, microtechnology, or health. Thus, they benefit from the most recent scientific and technological innovations and have access to the up-to-date equipment that is available in these units (Fig. 2).

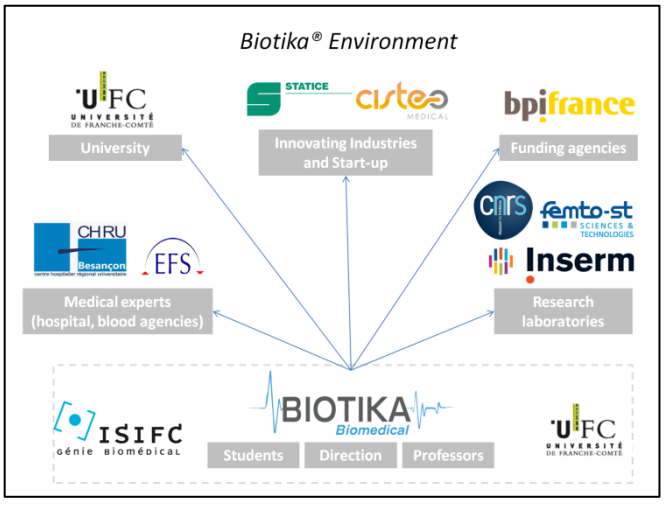

Figure 2. Structure of Biotika® and its partenrs

All staff is involved in the communication strategy of the company. By adopting this approach, the management team expects that every student will acquire communications skills with various interlocutors (physicians, senior engineers, patients, industrial professionals etc.).

The students are replaced with new recruits each year, which makes the written traceability of technical choices and communication activities particularly important.

Biotika® guarantees quality throughout its organization and is working to systemize the level of quality (according to ISO 13485). The name and logo were INPI-registered in 2007.

In addition to training students for the workplace, Biotika® has its own goals as a biomedical company:

- Develop and implement innovative medical devices.
- Establish a quality assurance system.
- Create a technical file on each product.
- Perform investigations and clinical trials.
- Ensure internal/external communication of the company and market analysis.
- Ensure financial and human resources management of the company.
- Transfer the concept to an academic or industrial partner that can guarantee the production (mission partnership and quality file) or create a real firm.

III. Practice

Every year, the student staff of Biotika® is replaced with new recruits. All posts are given to second-year students of ISIFC after they have been interviewed by industrial professionals and academic staff. The teaching staff usually comprises at least six people for the management team and technical supervision.

In 2008, for example, the Biotika® team comprised 30 persons, including 21 students. The permanent members of staff included a physician from Besançon University hospital as the Director for clinical investigations and four project managers (all teachers and researchers from the University of Franche-Comté). The students obtained the following positions: four Project Leaders, a Research and Development Engineer, a Logistics and Purchasing Manager, a Communications Project Manager, a position dealing with communication/marketing, a Quality Manager, a Regulatory Affairs Manager, a Quality Assurance Manager with suppliers, a Product Qualification Engineer, an Information Systems Engineer, a position dealing with clinical trials, and a Validation Engineer.

IV. Results and Projects

In less than 10 years, Biotika® has become a real partner of business-academic cooperation. It has been awarded five prizes from the French National Innovation Agency (OSEO) and the Regional Valorization Department.

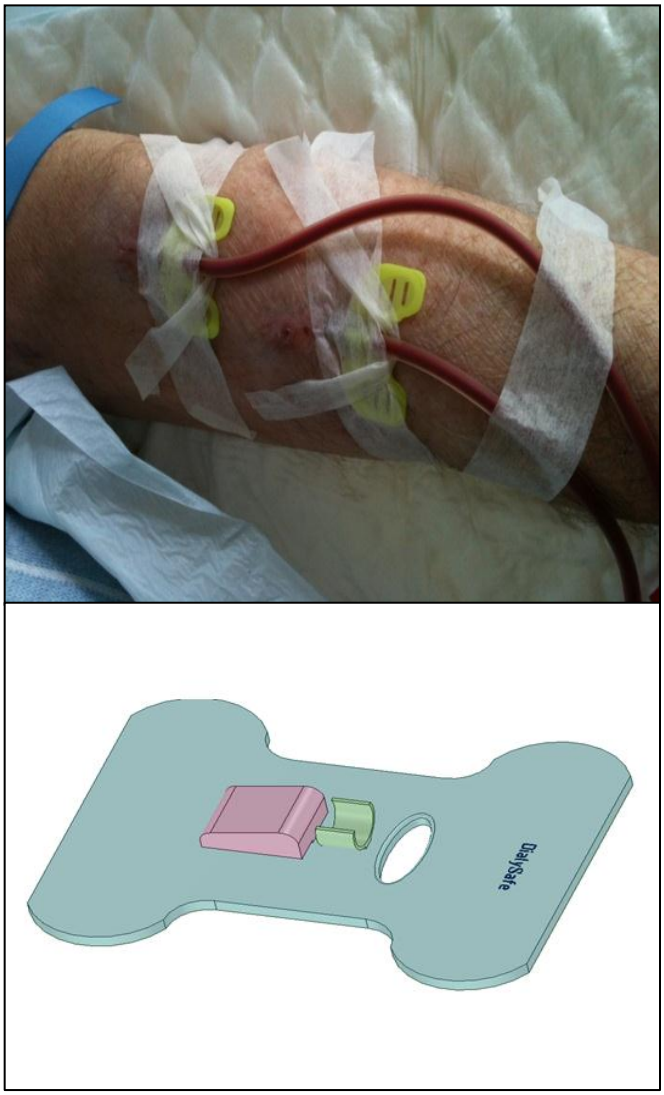

Figure 3. Photo needles placed in the arm of a patient under dyaslis (top) and prototype developped by Biotika® to facilitate the needles maintaining

Our students have participated in a European competition for innovative companies in the category INNOVACT Community (Reims, October 2006) and in industrial meetings such as MEDTEC FRANCE and MICRONORA every year. They have conducted five clinical trials. In 2010, the Biotika® project "S-Alive" obtained a grant from the ANR (French National Agency for Research). One start-up company has been created.

Two patents are under evaluation and four intellectual property letters (Soleau envelopes) have been registered by the INPI.

But probably the most important result of Biotika® was the creation of a real link between medical/clinical domain and R&D/business domain during the educational process. Indeed, the majority of projects are related to the topics explored by students during their internship in hospitals. We consider this point as crucial because giving to the students the opportunity to test scientific and managerial skills and facilitating their integration after the graduation. The procedure – from an idea to a project – is well established now; we developed 3 special forms to facilitate the discussion between academic staff, students and experts, especially during first steps of R&D process.

The example of DailySafe project is one the most eloquent. During the internship in Department of Nephrology, a student observed the efforts of paramedical staff to place and hold needles in patients under dialysis (Fig. 3). Biotika® staff developed the prototype of a disposable, easy-to-place and biocompatible device which, of course, allowed to hold needles in vessels (Fig. 3). Other issues were also identified such as the adaptability of the device for different types of needles, the importance of needles angle to maintain the blood flow etc.

As other examples, we have chosen four projects that were developed by Biotika® during the previous 5 years.

Hospital bed with voice recognition: The concept was based on the instrumentation of a motorized hospital bed that can be controlled by voice recognition. The working model was presented at MICRONORA 2006.

S-Alive®: The goal of this project is to develop a new distributor of artificial saliva for patients with xerostomia (dry mouth sensation) and/or oral dryness (lack of or a decrease in the production of saliva). In the majority of these patients, salivary glands were destructed during radiotherapy. This project is on-going and is supported by OSEO and ANR grants.

Visiotika®: This project aims to enable completely paralyzed patients, such as those suffering from locked-in syndrome, to regain some autonomy by giving them the ability to control their environment using their eyes. Currently, such solutions exist, but they are extremely expensive. Biotika® 2007 has made a device at low cost by simply using common materials.

Physiotika® was developed to measure pulse wave velocity (PWV), a strong predictor of cardiovascular risk. This innovative device measures PWV by using two infra-red probes that are placed on two artery sites.

Increased arterial stiffness is associated with an increased risk of cardiovascular events. For example, this risk appears to be far greater in patients with chronic renal failure than in the general population. Several methods are available to determine arterial stiffness, of which PWV appears to be the most accurate. The current gold standard to measure PWV is applanation tonometry. Although this method is non-invasive and predictive of adverse cardiovascular outcomes, the device is expensive and technically challenging to operate. Physiotika®, a non-invasive method, uses the principle of reflectance photoplethysmography to detect cardiovascular pulse waves. This is a common optical technique that is used to monitor peripheral pulsation.

We decided to extract this project from Biotika® and to transfer three prototypes to our academic partners for new international experiments.

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