COORDINATED DESIGN AND IMPLEMENTATION OF "BIOENGINEERING DESIGN" AND "MEDTECH" COURSES BY MEANS OF CDIO PROJECTS LINKED TO MEDICAL DEVICES

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ABSTRACT

Biomedical engineering is aimed at the application of engineering principles, methods and design concepts to medicine and biology for healthcare purposes, mainly as a support for preventive, diagnostic or therapeutic tasks, and is directly connected with professional practice in the medical device development sector. Industrial and management engineers, due to their broad education and global view, can significantly contribute to the advances in the biomedical field, especially if they learn some essential biomedical concepts and train specific professional skills during their higher education degrees.

In this study we present the coordinated design and implementation of two courses devoted to the biomedical engineering field, namely "Bioengineering Design" and "MedTech", included in the Master's Degree in Industrial Engineering and in the Master's Degree in Engineering Management respectively, both at the ETSI Industriales from Universidad Politecnica de Madrid. These courses follow the framework established by the Industriales Ingenia Initiative, which is completely aligned with the spirit of the International CDIO Initiative, as presented in recent CDIO Conferences. Students from both courses collaborate in teams and live through the complete development life cycle of innovative medical devices (linked to relevant health concerns), from the product planning and specification stages, through the conceptual and basic engineering phases, including final validations with real prototypes, towards pre-production and commercialization considerations. These projects stand out for their degree of complexity and counting with such multidisciplinary teams, in which students from different backgrounds and with varied skills intimately collaborate, constitutes an interesting strategy for addressing the life cycle of innovative biodevices with a holistic approach. Socio-economic issues, technical considerations, environmental sustainability and overall viability are among the key aspects assessed by the students following systematic (bio)engineering design methodologies.

The team of professors has also lived somehow through a complete and challenging CDIO cycle, during the conception, curricular design, first implementation and assessment of these synchronized teaching-learning experiences, but the improvement of students' learning outcomes and the inspiring ambience of collaboration created are worth the efforts. Main benefits, lessons learned and future challenges, linked to these courses and to the collaborative presented strategy, are analyzed, taking account of the available results from 2017-2018 academic year.

KEYWORDS

CDIO implementation, Case studies & best practices, Integrated learning experiences, Active learning. (Standards: 1, 3, 7, 8).

INTRODUCTION

Biomedical engineering is aimed at the application of engineering principles, methods and design concepts to medicine and biology for healthcare purposes, mainly as a support for preventive, diagnostic or therapeutic tasks, and is directly connected with professional practice in the medical device development sector. Industrial and management engineers, due to their broad education and global view, can significantly contribute to the advances in the biomedical field, especially if they learn some essential biomedical concepts and train specific professional skills during their higher education degrees. Being a recent field of study, with its first Master's Programmes appearing in the US in the late 1950s (Fagette, 1999) –and the first ones in countries such as Spain just dating back three decades-, the teaching-learning approaches to this field have been continuously evolving, as has happened also with the enormous advances in biomedical technologies, during the last decades.

According to the Biomedical Engineering Society, a biomedical engineer uses traditional engineering expertise to analyze and solve problems in Biology and Medicine, providing an overall enhancement of healthcare. Students choose the Biomedical Engineering field to be of service to people, to partake of the excitement of working with living systems and to apply advanced technology to the complex problems of medical care. The biomedical engineer works with other healthcare professionals including physicians, nurses, therapists and technician. Biomedical Engineers may be called upon in a wide range of capacities: to design instruments, devices and software, to bring together knowledge from many technical sources, to develop new procedures, or to conduct research needed to solve clinical problems (BMES).

The aforementioned duties are directly connected to the traditional corpus of Industrial Engineering (in its broadest sense) and, being applied tasks in direct relation with real and complex problems (pathologies) and systems (human body), can potentially be taught and promoted by means of project-based learning CDIO-related approaches (Crawley, 2007), both within Biomedical Engineering programmes, and in more traditional ones. However, very relevant and multifaceted issues, connected with all aspects of Engineering Management, also arise in any real project devoted to the development of real biomedical devices for addressing relevant health concerns. These aspects (project and team management, conflict resolution, quality and safety promotion, prediction of costs and revenues, production organization, management of the supply chain, ethical and professional aspects, among others) are linked to all stages of the CDIO cycle and need to be analyzed in detail for successfully reaching market and patients. Consequently, the collaboration between academic programmes and between professionals with different backgrounds is relevant in Biomedical Engineering, towards more holistic approaches, as required by a field, whose complexity is continuously growing.

In this study we present the coordinated design and implementation of two courses devoted to the biomedical engineering field, namely "Bioengineering Design" and "MedTech", included in the Master's Degree in Industrial Engineering and in the Master's Degree in Engineering Management respectively, both at the ETSI Industriales from Universidad Politecnica de Madrid. These courses follow the framework established by the Industriales Ingenia Initiative, which is completely aligned with the spirit of the International CDIO Initiative, as presented in recent CDIO Conferences (Lumbreras, 2015, 2016) and the "Bioengineering Design" course is adapted from previous experiences (Díaz Lantada, 2014, 2015, 2016) to be integrated together with "MedTech".

THE “INGENIA” INITIATIVE: INTEGRATED PROMOTION OF CDIO AT THE ETSI INDUSTRIALES FROM UNIVERSIDAD POLITÉCNICA DE MADRID

The implementation of Bologna process has culminated at the ETSI Industriales from Universidad Politécnica de Madrid with the beginning of the Master’s Degree in Industrial Engineering, in current academic year 2014-15. The program was successfully approved in 2014 by the Spanish Agency for Accreditation (ANECA), with the inclusion of a set of subjects based upon the CDIO methodology denominated generally “INGENIA”, an acronym from the Spanish verb “*ingeniar*” (to provide ingenious solutions), also related etymologically in Spanish with the word “*ingeniero*” (engineer). INGENIA students experience the complete development process of a complex product or system and there are different kinds of subjects (and projects), within the initiative, covering most of the engineering majors at the ETSI Industriales from Universidad Politécnica de Madrid. Students choose among the different INGENIA subjects (and projects), depending on their personal interests.

The INGENIA subjects are compulsory for all students enrolled in the first year of the Master’s Degree program at the ETSI Industriales from Universidad Politécnica de Madrid (a two-year program with 120 ECTS after a four-year Grade in Industrial Technologies with 240 ECTS). The subjects (with a similar CDIO orientation but offering different topics and projects) are 12 ECTS equivalent, which correspond to a student workload between 300 to 360 hours, distributed along two semesters with the following structure: 120 hours of supervised work plus between 180 to 240 hours of personal student work, organised usually in teamworks. Professor supervised part of the subjects is divided into 30 hours dedicated to adapt basic theoretical knowledge derived from other subjects to those directly related with the project, and a second set of 60 hours is devoted to practical work in the lab, with professor supervised sessions. Students also receive two seminars of 15 hours; one oriented to transversal outcomes, in particular, workshops on teamwork, communication skills and creativity techniques, and the other one about social responsibility issues such as environmental impact, social, political, security, health, etc. These lectures, practical sessions, seminars and workshops, are distributed along the 28 weeks of the two semesters of the first year, resulting in 5 hours per week of lectures or practical sessions in the regular schedule of students. Placing the INGENIA subjects in the first year of a 120 ECTS program is indeed interesting, as additional 12 ECTS are devoted to the final degree thesis normally during the second year. Therefore, at least 20% of the whole Master’s Degree is devoted to project-based learning aimed at the complete development of engineering products and systems. Program structure is detailed in Figure 1 and the integration of CDIO activities can be easily appreciated (INGENIA subjects in pale blue and Final Master’s Thesis in pale green).

Hours/week	THIRD SEMESTER	ECTS	Hours/week	FOURTH SEMESTER	ECTS
	Final Master's Thesis	6		Final Master's Thesis	6
6	Curricular configuration	9	6	Curricular configuration	9
2	3 specialization subjects (Automation & Electronical,	3	2	3 specialization subjects (Automation & Electronical,	3
2	Chemical, Electrical, Energetic, Materials,	3	2	Chemical, Electrical, Energetic, Materials,	3
2	Mechanical, Construction, Org.)	3	2	Mechanical, Construction, Org.)	3
2	1 subject on Industrial Installations	3	2	1 subject on Industrial Management	3
2	1 subject on Industrial Technologies	3	2	1 subject on Industrial Technologies	3

Hours/week	FIRST SEMESTER	ECTS	Hours/week	SECOND SEMESTER	ECTS
4	INGENIA (first part)	6	4	INGENIA (second part)	6
2	2 subjects on Industrial Management	3	2	2 subjects on Industrial Management	3
2		3	2		3
2	2 subjects on Industrial Installations	3	2	2 subjects on Industrial Installations	3
2		3	2		3
2	4 subjects on Industrial Technologies	3	2	4 subjects on Industrial Technologies	3
2		3	2		3
2		3	2		3
2		3	2		3

Figure 1. Program structure (Master’s Degree in Industrial Engineering).
120 ECTS program with at least 20% devotion to project-based learning activities.

In addition, the INGENIA subjects are helping us to complement our competence-based strategy, in accordance with CDIO Standards 1, 3, 7 & 8, by placing special emphasis on several professional skills difficult to obtain in more traditional teacher-centred activities, such as conventional master classes and expert talks. Expected outcomes include the promotion of: students' ability to apply knowledge of mathematics, science and engineering, students' ability to design experiments and interpret data, students' ability to design engineering systems and components to meet desired goals, students' ability to communicate effectively and to work in multidisciplinary teams, or students' ability to use modern resources, in accordance with the ABET professional skills our program tries to promote (Shuman, et al. 2005). Different subjects within the INGENIA framework cover diverse disciplines such as: automotive engineering, mechanical engineering, automation and electronics, construction, materials science, energy engineering and biomedical engineering.

Regarding students' assessment, it is important to note that the proposed engineering systems to be developed within INGENIA courses are complex enough to promote positive interdependence between members of the teams, so that each of the members is needed for the overall success and that there is enough workload to let all students work hard and enjoy the experience, thanks to continued learning. Furthermore, individual assessment can be promoted, by complementing the teamwork activities with individual deliveries and by means of public presentations of their final results and individualized questions (which account typically for a 20-30% of the global qualification). The evaluation of professional skills counts with the help of *ad hoc* designed rubrics or evaluation sheets, as part of an integral framework for the promotion of engineering education beyond technical skills, consequence of recent educational innovation projects (Hernández Bayo, et al., 2014), and in some cases peer-evaluation strategies have been introduced (for just a 10% of the global mark).

Thanks to implementing the CDIO approach in these INGENIA courses, students taking part in these formative programmes are living, in many cases for the first time (excluding their previous Bachelor's theses), through the complete development process of real engineering systems and are getting now better prepared for their final theses and for their future professional practice, as students themselves have highlighted in several occasions during and after these courses.

Next sections describe and analyze the implementation and first experience with our coordinated courses on "Biomedical Engineering Design" (or "Bioengineering Design") and MedTECH, as a relevant examples of success within the INGENIA framework and as a quite singular example of the benefits and potentials of coordinated courses among different academic programmes, which at least in our country is something quite unusual. They are developed upon previous experiences, as the "Bioengineering Design" course was already within the Industriales INGENIA Initiative (Díaz Lantada, 2014, 2015, 2016), but with a radically innovative approach, providing the first example of coordinated complete CDIO experiences within the Industriales INGENIA Initiative and one of the very first examples of project-based learning experiences in the biomedical engineering field with such a broad scope and holistic approach. Some recommendations for successful project-based teaching-learning experiences have been taken into account for their coordinated implementation (Díaz Lantada, 2013) and the experience of involved professors, with complementary expertise covering the whole life cycle of medical devices, has been fundamental for the aforementioned successful execution.

COORDINATED DESIGN AND IMPLEMENTATION OF "BIOENGINEERING DESIGN" AND "MEDTECH" COURSES: MAIN RESULTS AND CHALLENGES

According to the mentioned holistic vision of the Biomedical Engineering field we would like our students to acquire, the two courses, namely "Bioengineering Design" and "MedTECH", share some fundamental lessons and common topics along the two semesters, while some specific lessons also help to differentiate according to the different backgrounds and motivations of the students. Those from "Bioengineering Design" take part in the Master's Degree in Industrial Engineering and prefer to deepen in aspects linked to design, simulation and manufacturing technologies, while those from "MedTECH" belong to the Master's Degree in Engineering Management and are more interested in strategic and business aspects, together with topics related to the organization of production and to the supply chain management.

In short, both courses go in parallel and share several general lessons, while a 40% of the lessons are devoted to the more specific aspects with the students from different Master's degrees separated. Each team counts with students from both Master's degrees and all students work together and are responsible for the successful conception, design, implementation and operation of an innovative medical device, although the different skills and backgrounds make them share and distribute tasks according to their experiences and expectations. Globally speaking, conceive and design stages are covered during the first semester and implementation and operation stages are covered during the second one. Figure 2 helps to summarize the organization of both courses and to highlight their mutual interaction.

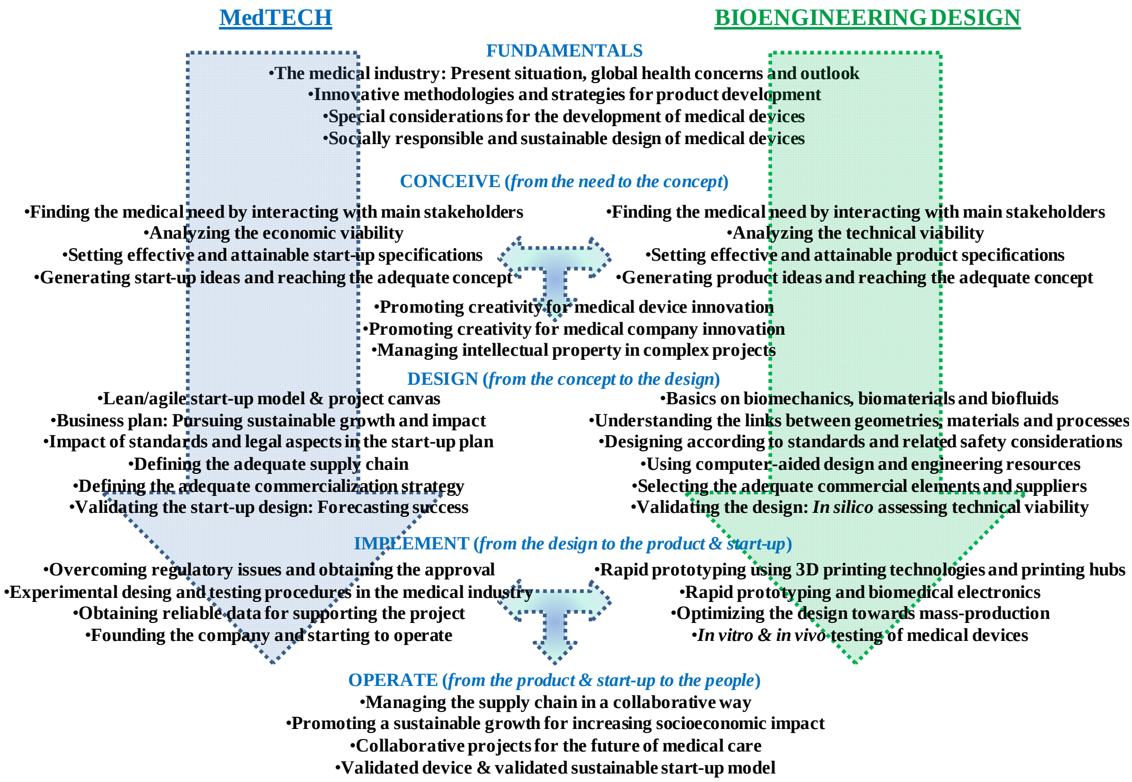

Figure 2. Collaborative scheme among "Bioengineering Design" and "MedTECH". The topics to the left represent the "MedTECH" track and the topics to the right the "Bioengineering Design" track, while the central topics are common. The fundamentals and conceive and design stages are covered during the first semester, while implementation and operate stages correspond to the second semester.

During the first year with both subjects running in parallel (academic year 2017-2018) a total of 35 students from “Bioengineering Design” –Master’s Degree in Industrial Engineering- and a total of 15 students from “MedTECH” –Master’s Degree in Engineering Management- enrolled in these courses implemented according to the Industriales INGENIA Initiative, each counting with 12 ECTS, which corresponds to a total dedication of around 300 hours of student personal dedication (including lessons and work outside the classroom in laboratories, at home and devoted to teamwork).

At the beginning of the course, students were divided into 6 teams of around 8 students and each team counts with components of the different involved degrees and, consequently, of different backgrounds, so as to better fulfill the expectations regarding the whole CDIO cycle with the selected medical devices. Each team proposed several medical needs and related potential biodevices to be developed and, after a voting session, 8 different ideas were distributed among the different teams, including: a sensorized vest for detecting and alerting about fallen patients, a sensorized t-shirt for detecting wrong positions during working, an instrumented pill dispenser, an ergonomic aid for applying droplets to the eyes, a use-and-throw amnioscope, an a system for training injured hands. At the current state of development, student groups have already completed their product specification and conceptual designs (according to the images shown as examples in Figure 3) and in the following months the devices will be prototyped and tested. In our opinion, the multidisciplinarity of the teams is leading to very interesting results, with much more professional devices than those from previous experiences (Díaz Lantada, 2015, 2016) and we expect to present the final results, together with data from the assessment during the 14th International CDIO Conference of Kanazawa. In addition, according to preliminary evaluations, student and professor motivation has been importantly promoted thanks to the collaborative approach.

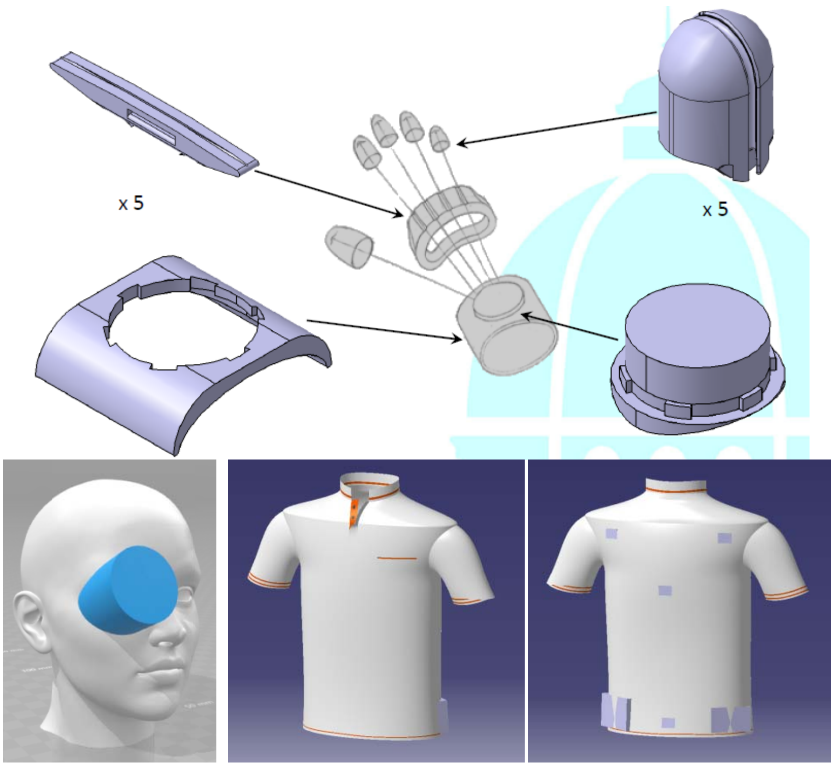

Figure 3. Some examples of the proposed concepts and designs.
a) Device for training hand after injure. b) Ergonomic eye-droplet supplier.
c) Sensorized vest for detecting wrong working positions.

CONCLUSIONS

In this study we have presented the coordinated design and implementation of two courses devoted to the biomedical engineering field, namely “Bioengineering Design” and “MedTech”, included in the Master’s Degree in Industrial Engineering and in the Master’s Degree in Engineering Management respectively, both given at the ETSI Industriales from Universidad Politecnica de Madrid. These courses are following the framework established by the Industriales Ingenia Initiative, which is completely aligned with the spirit of the International CDIO Initiative and constitute a source of motivation, both for students and professors, who see their scientific-technological background applied to solving real problems. During this first coordinated implementation, students are benefiting from a more global point of view, in connection with the biomedical engineering field and with the engineering design of biomedical devices, taking also account of the existing regulatory framework and of relevant socio-economic issues, which condition the technical decisions. The results obtained so far motivate us to continue with this coordinated and more holistic approach, which will let us hopefully reach medical professionals and patients for improved social impacts in the near future.

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BIOGRAPHICAL INFORMATION

Andrés Díaz Lantada is Professor in the Department of Mechanical Engineering at ETSI Industriales – UPM. His research activities are aimed at the development of biodevices using modern design, modeling and manufacturing technologies and he incorporates these results to subjects linked to product development. He is Editorial Board Member of the International Journal of Engineering Education and CDIO contact at UPM. He has received the “TU Madrid Young Researcher Award” and the “TU Madrid Teaching Innovation Award” in 2014 and the “Medal of the Spanish Academy of Engineering to Young Researchers” in 2015.

Luis Ignacio Ballesteros Sánchez is Professor in the Department of Industrial Management, Business Administration and Statistics at ETSI Industriales – UPM. He is focused on systematic project management procedures and on the resolution of conflicts in multidisciplinary teams, hence supporting both courses and mentoring the adequate progress of the different teams.

Enrique Chacón Tanarro is Professor in the Department of Mechanical Engineering at ETSI Industriales – UPM. His research activities are linked to several fields of Mechanical Engineering, including most areas of tribology and contact phenomena, machine performance assessment and systematic product development.

Ana Moreno Romero is Professor in the Department of Industrial Management, Business Administration and Statistics at ETSI Industriales – UPM. She is currently Deputy Vice-Dean for Social Responsibility and is especially focused on the management of change in complex organizations and on professional development.

Rafael Borge García is Professor in the Department of Chemical Engineering at ETSI Industriales – UPM. He is our expert on sustainable engineering design and supports both courses with the systematic assessment of products’ life-cycles for enhanced selection and definition of geometries, materials and processes.

Miguel Ángel Peláez García is Professor in the Department of Industrial Management, Business Administration and Statistics at ETSI Industriales – UPM. He supports these subjects by means of his expertise in medical device regulation towards optimized marketability processes.

Rafael Ramos Díaz is Professor in the Department of Industrial Management, Business Administration and Statistics at ETSI Industriales – UPM. He supports both courses with innovative approaches to entrepreneurship.

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