Software engineering knowledge transfer channels between university and medical device industry: a gap analysis

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Abstract: This paper describes a number of different channels for bidirectional software engineering (SE) knowledge transfer between academia and medical device industry. The paper also brings the results of the gap analysis showing the discrepancy between the medical device industry needs and the curricula of relevant courses. We perform a case study of the Faculty of Organization and Informatics (FOI) at the University of Zagreb (Croatia).

Keywords: innovation; knowledge transfer; medical device industry; regulated industry; software engineering

1 Introduction

In today's world of industrial automation, connected devices, artificial intelligence and digital transformation, more than ever before, software engineering plays an important role in many industries. University education in software engineering as well as ongoing collaboration between university and industry can be viewed as one of success factors for development of innovative products in highly regulated industries such as pharmaceuticals, in-vitro diagnostics, and medical devices. On one hand, higher education institutions such as universities are preparing students to enter the workforce. On the other hand, regulated industries such as healthcare, pharmaceutics or automotive require special knowledge and skills. To close this gap, universities need to make their syllabuses more relevant to the needs of the job market.

In order to narrow this gap in the field of software engineering, we have witnessed few quite different approaches and points of view. For example, Ghezzi and Mandrioli discuss that in engineering *learning by studying at school* is not the same as *learning by doing at work*. They think that even if a field of study is rapidly evolving, education should put focus on principles and long-lasting concepts [GM06]. Oppositely to their point of view, to improve

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the education of software engineers, Lethbridge et al. are arguing that curricula should be forward-looking and industrial practices should be effectively communicated to students [Le07]. Third view is taken from Connor at al. who are focusing on requirements engineering to narrow the identified research-practice gap [CBP09]. When focusing on the internships, Almi at al. reveals that even a semester-long internship at companies is not enough for students to meet the industry requirements [Al11]. Similarly, Hanna et al. analyzed more than 1000 job listings to compare SE curricula and job requirements just to find out that academia is not aware of the existing very big discrepancy [Ha14]. A comprehensive meta-analysis trying to align industrial needs and SE education along with the most required skills was done by Garousi et al. who report that software requirements, design and testing are the most important skills and that the greatest gaps are in configuration management, SE models, methods, process, design, architecture and testing [Ga19a, Ga19b].

University-industry interactions include a wide range of channels for knowledge transfer and bring many benefits for both academia and regulated industry. The most common benefits for industry may include: bringing innovations [Re19], easier recruiting through strong cooperation with the universities, top talent retention, reduced initial training time of new employees who have completed an academic degree at the universities with curricula that highly match the industry needs. The benefits for academia may include: providing better education to students who aim to apply for positions in regulated industries, making universities more attractive to potential students, etc.

As part of our case study, we identify different channels of knowledge transfer between the university and medical device industry and examine the curricula of the following three university courses taught at FOI: Software Engineering, Software Analysis and Design, and Information Systems Security. Afterwards we conduct a gap analysis to identify the gaps between the syllabuses and medical device industry needs.

2 Knowledge transfer channels

FOI is a constituent part of the University of Zagreb and has been the first higher education (HE) institution in Croatia that combined information and organizational sciences. It could be considered as the leading HE institution in Croatia providing education in applied information technology and information sciences. Today, the faculty aims to develop its scientific and research activities in the following research fields and topics: ICT application in the private and public sector, information systems, Internet of everything, big data analytics, artificial intelligence, information security and open systems, organizational design, business process re-engineering, decision support (systems), e-learning, electronic and mobile business, software engineering, service-oriented architectures, biometrics, quantitative methods for decision making, risk analysis, project management, and strategic planning. FOI has been involved in several scientific, research and development, and commercial projects. The faculty has close cooperation with the IT companies and is also a co-owner of the Technology Park located in Varaždin.

FOI uses a number of different channels for bidirectional software engineering knowledge transfer between university and industry. In context of the medical device industry, we propose the following channels of knowledge transfer: publication of research results in CECIIS (Central European Conference on Information and Intelligent Systems) conference proceedings and JIOS (Journal of Information and Organizational Sciences) journal published by FOI, participation in CECIIS conference program committee, development of prototypes as part of the industry oriented development projects, student/faculty staff participation in pilot projects, co-patenting, innovation pitch awards, hackathons that aim to solve problem statements for specific industry themes, student internships, student theses, medical device manufacturers providing scholarships to students, innovation incubators at the faculty, medical device manufacturers founding university/academic spin-off companies that transform technological inventions developed from university research, keynotes from industry practitioners at the faculty, meet-ups with industry practitioners, presenting research results from the faculty to medical device manufacturers, attending at the software engineering conferences and workshops organized by the faculty, medical device company presentations at the job fairs organized by the faculty, cooperation with other similar universities/faculties, Erasmus student exchange programs, students conducting their professional practice in the medical device industry, cooperation of Student Support and Career Development Centre with medical device manufacturers, case studies from the medical device industry during faculty lectures and lab exercises, and cooperation with the Technology Park Varaždin.

A novel approach in knowledge transfer that was recently introduced to courses of Software Engineering and Software Analysis and Design, brings industry into classroom in forms of industry-defined project assignments, co-mentoring and infrastructural support [SČM19]. By working in close collaboration with partnering companies on industry-defined and co-mentored projects, students have chance to gain a first-hand insight into challenges, requirements and practices industry faces with, as well as to obtain knowledge and skills from the experienced software engineers.

3 Gap analysis

Medical device manufacturers may develop medical devices that contain software (including firmware) and/or software that is a medical device (including mobile medical applications). Software engineering knowledge that is specific for the medical device industry covers the following topics: global regulations for design and development of health software (e.g., quality (management) system according to ISO 13485 standard [IS16] and 21 CFR 820 [FD19], risk management covering safety and security risks according to ISO 14971 standard [IS19] and technical information report AAMI TIR57 [AA16], software life cycle processes according to IEC 62304 standard [Co06], safety and security of health software products according to IEC 82304-1 standard [Co16], usability engineering according to IEC 62366-1 standard [Co15], etc.), modern software architectures, requirements engineering,

software design specifications, traceability analysis, handling of software changes and bugs, configuration management, creating technical documentation for regulatory submissions, secure coding, applying coding styles, writing unit tests, software verification and validation, regression testing, conducting (peer) code reviews, using agile frameworks (e.g., Scrum, Kanban) and practices during the product development, software project management, cryptography, data protection and privacy, information security, penetration testing, etc.

Based on the medical device industry needs, we identified three related university courses taught at FOI (i.e., Software Engineering, Software Analysis and Design, and Information Systems Security) and compared syllabuses against the industry needs. The Software Engineering course provides a detailed overview of software engineering process and practices and teaches the students methodological approach to develop software products. On the other hand, the Software Analysis and Design course introduces students to the full modern software development life cycle, including domain analysis, requirements specifications, methods and techniques for software design, software development, software testing and debugging. In addition, students learn fundamental approaches that are used in development and engineering of complex software systems and modern tools and procedures that make this process easier.

In context of the medical device industry, the following gaps have been identified if taking into consideration the combined knowledge students get in these two courses: (1) global regulations for design and development of health software are mainly not covered, only software life cycle processes and usability engineering are covered, but without direct considerations of IEC 62304 and IEC 62366-1 standards; (2) traceability analyses along with handling of software changes and bugs are partially covered but configuration management is not part of the curricula; (3) although created, technical documentation is not aligned with requirements for regulatory submissions of medical device products; (4) secure coding practice is not used; (4) testing is covered in theory, but courses only partially cover its practical aspects; (5) cryptography is not part of the curricula; (6) data protection and privacy are only mentioned; (7) information security and penetration testing are not part of the curricula.

However, some topics relevant to medical device industry are addressed by these courses to a large degree: (1) software development life cycle models are discussed in general, including traditional and modern ones; (2) requirements engineering is taught and demonstrated as one of the essential parts of software development process (e.g., IEEE Software Requirements Specification template is used); (3) design activity resulting in software design specifications using UML and other techniques is extensively covered and applied; (4) handling of software changes and bugs is presented through the use of modern platforms for software versioning (such as Git and GitHub); (5) applying coding styles is encouraged by demonstrating good and established coding practices, as well as bad ones resulting in code smells; (6) writing unit tests is covered during discussion on testing in general, test-driven development and regression testing; (7) benefits of code reviews and similar agile practices in terms of software quality, productivity and knowledge sharing are discussed; (8) classical waterfall

model as well as agile frameworks such as Scrum and Kanban are presented and practiced as a means of organizing project activities and efforts in an agile team and software development process; (9) software architectural and structural design are performed on both undergraduate and graduate levels. Other topics related to software engineering in general are also covered, such as software product lines, functional and reactive programming principles, user interfaces and user experience design, etc.

The Information Systems Security course focuses on the area of organizational and technical aspects of information security and covers the majority of medical device industry needs. To fully cover the industry needs, the course would have to integrate security risk management process according to AAMI TIR57.

4 Conclusion

In this paper we have presented the case study results of the bidirectional software engineering knowledge transfer channels between university and industry, along with the gap analysis between the medical industry requirements and academic curricula for the three identified and relevant courses: Software Engineering, Software Analysis and Design, and Information Systems Security.

The analysis of knowledge transfer channels showed the variety of means for bidirectional knowledge transfer. These channels are used on different levels of FOI's structure, from management and administrative, through laboratories and centers to teachers and students at courses and projects. The overall infrastructure for knowledge transfer could be described as good.

However, the gap in undergraduate and graduate students' knowledge, if compared to industry needs, points out some weak aspects, particularly in the curricula itself. As the university study programs are, due to heavy regulations, hard to change, the curricula of observed courses hardly meets industry needs. The general conclusion is that restructuring, in both thematic and time manner, is necessary in order to include the topics that were identified as missing. The identified gap could be narrowed by restructuring and enhancing the current courses to better address the industry needs or by introducing a new course that would cover the topics specific for medical device industry needs. In our future research we plan to propose such curricula for currently relevant and necessary new courses in the field of information science.

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