REGULATORY FOCUS

Value of an RA qualification in continuous professional development and career progression

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Continuous professional development (CPD) is important for employee personal development and is of strategic value for organizations. Having qualified and knowledgeable personnel can help deploy strategy and yield competitive advantage in the marketplace. This article presents the results of a qualitative and quantitative study on the progression and experiences of industry-based graduates who completed a masters in regulatory affairs. The results demonstrate that regulatory knowledge and qualifications are an advantage and of value in both personal and professional development. From a human capital investments perspective, there are wider benefits to employers and sponsoring organizations in terms of return on investment and attainment of new skillsets and competencies.

Introduction and background

The medical technology (medtech) sector in Ireland is recognized as one of the five global emerging hubs. The sector employs more than 40,000 people in Ireland and is the second largest per capita employer of medical and technology

professionals in Europe. As many as 9 of the world's top 10 medical technology companies have a base in Ireland.[1]

Medical technology is also a major contributor to the EU economy, which has more than 27,000 medtech companies employing more than 675,000 people in high-quality jobs.[2] The market size was estimated at roughly €12.6 billion in 2020.[1] The success of the medtech industry in Ireland and indeed worldwide brings with it a shortage of suitably skilled professionals. According to a 2020 report by the World Economic Forum,[3] 66% of participants believed they could gain a return on investment on funding of upskilling and reskilling of employees within a year. Given the increased demand in employment opportunities and the shortage of skilled professionals in pharma and medtech companies, especially in light of the COVID-19 pandemic, those data are encouraging. Indeed, in many countries during the COVID-19 crisis in 2020, pharma and medtech companies were deemed "essential" and remained in operation throughout the pandemic, when other sectors were closed.

In 2014, the Irish MedTech Association (IMA), in response to a shortage in skilled regulatory professionals, approached third-level institutes and universities in Ireland (the third-level institutes would be similar to post-secondary education and university level within the US) to ascertain if they could design a postgraduate master's course in regulatory affairs. The shortage of skills, combined with "a perfect storm" of impending regulatory changes in Europe at the time, a growing marketplace, and impending revisions of the ISO 13485 and ISO 14971 meant increasing pressure for manufacturers.

A masters in regulatory affairs was designed and subsequently delivered in partnership by an Irish third-level institute of technology in partnership with an Irish university. The course was designed with input of Irish industry stakeholders and multinationals, including Boston Scientific, Medtronic, Allergan, Merit Medical, and Integer, to ensure the program content was aligned with industry needs.

Study aim and method

The present study was undertaken with industry-based professionals working in the medical device industry who completed a master's degree in regulatory affairs. The two-year master's course commenced in 2015 and at time of this study, in late 2020, there had been four graduating classes. From an anecdotal point of view and informal correspondence, graduates seemed to be progressing vertically within their organizations, rather than laterally, while completing the course and after graduation. The authors wanted to assess and quantify the impact, if any, that a regulatory qualification was having on the career progression of their industry-based students and graduates.

A qualitative study in the form of one-on-one interviews was first carried out with the program's first graduating class of 2017. A quantitative survey was developed and then circulated to 70 students who were either former graduates or pending graduation in 2020.

Interview results

Students from the first graduating class of 2017 were selected for one-on-one interviews because they had graduated 3 years before the study and, because there were only 17 in the graduating cohort, it was a manageable size for the short semistructured interviews. All interviewees were asked the same four questions, but they were encouraged to expand on their answers if they wanted to impart more information or elaborate further. This semistructured and informal interview format led to richer data in terms of reflection and commentary about the course and the interviewees personal career progression and development since completion. The interviews were held online and recorded for ease of analysis and collation of themes afterward.

The 2017 cohort had had the most time to reflect on the impact of a CPD regulatory qualification and education on their careers and personal development.

All the graduates interviewed (100%) stated that the course had had a positive effect on their career (Question: "Do you feel that the course has helped your career positively?").

Interviewee comments in response to the second question, "Why do you feel that this CPD course helped your career positively?" summarized in **Table 1**. Most respondents' comments ranged from several attributing their promotion to having completed the course and that the course "increased knowledge" and "opened doors."

Table 1. Selected responses[a] to the question, 'Why do you feel that this CPD course helped your career positively?'

I have never worked directly and never plan to work directly in Regulatory. My background is Quality and course content is very relevant to what we do every day.
Brought learnings into work, positive impact on company, share knowledge, wouldn't have progressed so quickly without masters' [degree].
Expansion of knowledge allowed more business involvement.
Opened doors.
I have changed jobs twice within my original company and have moved company since completing [the course].
I was promoted to a senior RA manager as the MSc was desired by my employer.
I was promoted.
Provided new opportunities, allowed company take on RA from parent site, provided competitive advantage for Irish site for NPD.
Yes, promoted and have since moved company.
Yes, promoted during course.
Transition from Ops to Regulatory Quality role.
I have been promoted. My qualification and new knowledge helped.

[a]Comments transcribed from interviews in response to the question.

A third question, "Were you promoted during the course or since completing it?" expanded on the second question on the course helping careers positively and provided more details. The resulting comments are summarized in Table 2. All the graduates were promoted, with one graduate undertaking a lateral move into another department. As is shown in **Table 2**, many of the graduates moved into management roles, more senior roles, or moved organizations for more senior roles.

Finally, the interviewees were asked if they would recommend the course to others, and 100% responded that they would and had already done so to colleagues who had registered for the course and had since either graduated since or were due to graduate. The researchers have noted that organizational peers and direct reports of many graduates have registered for the course over the last few years and that "personal recommendations" from previous graduates is a high source of recruitment of new students.

Survey results and analysis

While the qualitative study was valuable, a larger quantitative survey was also developed and then circulated to 70 individuals who had either graduated from the course or had completed the course and were pending graduation in November 2020. There was a 70% response rate. It is interesting to note that most students came from larger enterprises, which had more than 500 employees. In all, 65.3% of respondents came from the large enterprise category, and roughly a third, about 34.7%, came from small- and medium-sized

Table 2. Selected responses[a] to the question, 'Were you promoted during the course or since completion?'

Yes, promoted to manager.
Yes, transitioned from Quality to a Regulatory role and then moved to another company to a senior Regulatory role.
Yes, moved company to a senior management Regulatory role and was promoted to a Regulatory manager after 6 months.
Moved to QA and Regulatory manager role in another company.
Changed jobs twice within company and have moved company.
Yes – to manager.
Yes, promoted.
More responsibility – lateral move to Quality role for ISO 13485 deployment.
Moved to QA manager role in another company.
Promoted and moved company.
Promoted.
Yes, promoted to head of Quality.
Promoted to principal RA.

[a]Comments transcribed from interviews in response to the question.

enterprises with fewer than 500 employees (SMEs; **Table 3**). The larger-enterprise representation is easily explained as Europe is a hub for many multinational device manufacturers. Larger enterprises also have larger budgets for CPD and employee training and development. The smaller SME representation at nearly a third of the sample population is likely because these companies do not have a large regulatory department and resources. One person in an SME may be responsible for the entire regulatory affairs and quality function. Thus, knowledge of regulatory and quality in terms of regulations and systems is a priority for SMEs. Notably, of the 450 medtech companies in Ireland, four out of five are SMEs or startups, with 60% of these companies being homegrown.[1]

Participants were also asked about the length of experience they had in medical device industry. This data demonstrated there is an even spread between those with between those 1-5 years' experience and those with 20 or more years' experience (26% for both categories), with the remaining 48% having 6-19-years' experience.

Students were also asked in which regulatory functions they worked when they started the course and after they had completed it (**Figure 1**). Surprisingly, just over 35% of professionals were working in the regulatory function when they started the course, although a further 13% had a dual quality assurance and regulatory affairs (QA-RA) role. The students with the dual roles were mainly based in SMEs and their reasons for completing the course have been previously discussed in this article. That meant that just over 65% of participants were outside the regulatory function, and mainly from quality and support functions, such as manufacturing quality, quality systems, postmarket surveillance or medical device reporting, sterilization, design assurance, and research and development.

Those numbers did not change when the participants were asked the same question after completing the course. It would be natural to assume that graduates would move into regulatory roles after completing a regulatory master's degree, but that was not the case overall. Although the percentage of students in a regulatory function increased from 36% on commencing the course to 40% in a regulatory function after the course completion, that was not

Table 3. Size of organizations in which graduates worked

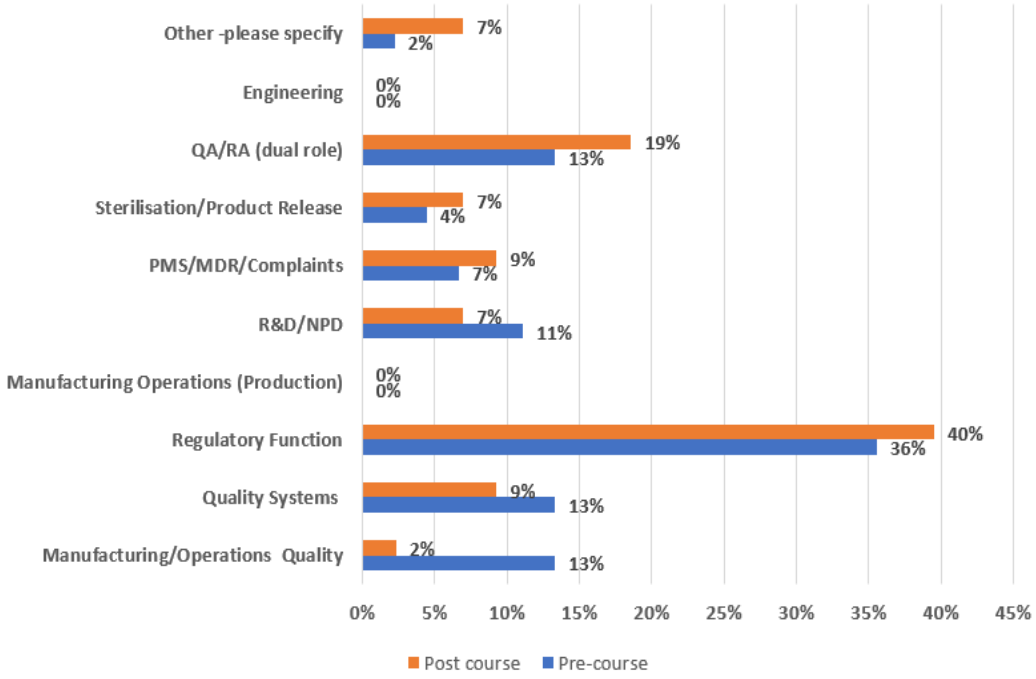
Company size (no. of employees)	% of graduates employed
<100	20.41
101-500	14.29
501-1,000	10.20
1,001-1,500	12.24
1,501-2,000	0.00
>2,000	42.86

a sizable increase. However, the percentage in dual QA-RA roles increased from 13% to 19%. That increase in the dual QA-RA role was attributed to the students who had come from SMEs being promoted from manufacturing quality and regulatory roles into QA-RA lead roles and some graduates had moved from larger enterprises to SMEs to gain experience in start-up SME companies. In Europe as many as 95% of medtech companies are SMEs.[1]

In all, 13% graduates were in operations/manufacturing quality roles before the course and that function had the biggest reduction or transfer to other sections because only 2% worked in the area after the course. Further analysis found that several factors could be attributed to the reduction in that the graduates were promoted into dual QA-RA site roles as mentioned previously. Many had also moved organizations because experienced operations quality professionals were in short supply within the wider industry. The "Other" category – graduates who did not fit into mainstream functions – increased from 2% to 7%. They were the graduates who joined notified bodies and became independent regulatory consultants after completing the course.

While there was not a huge change in the percentage of graduates moving into regulatory functions before and after the course or moving into other functional areas this ratified the importance of regulatory knowledge throughout the entire product lifecycle. The finding also demonstrated that the graduates and, by default, their organizations felt the qualification was of value in their existing functions and to their careers in those functions. From analysis of the data related to those graduates who stayed in functions outside of RA, many were

Figure 1. Comparison of functional areas in which graduates worked before and after course completion



promoted to senior manager, director, principal engineers, and global and site project management roles within their own organizations or in other new organizations.

Of interest is that the gender split in the graduate population was 71% women and 29% men, suggesting there are fewer men than women working in regulatory, quality, and quality-support functions, which are the main functions the graduates came from.
Graduates were next asked if they had changed roles since starting or completing the master's degree. Of those who had had changed roles, 78% indicated the role had been a promotion, with 22% indicating they had moved laterally within the organization. Of those who changed roles, more than half indicated that they had at least one role change since starting/competing the course, with just more than 27% stating they had changed roles twice (**Figure 2**).

This data positively correlates with student views and feedback that the course has had a positive impact on their careers and that their enhanced skillset is being applied within their roles and organizations.

Only 38% of respondents stated they had left their original company since starting or graduating from the course and this reflects a market for suitably qualified professionals within the medtech industry (**Figure 3**). This data can be interpreted in several ways, but the fact that 62% of graduates remained with their original organizations and the majority said they were promoted, is a positive indictment of the value their organization placed on their CPD qualification and on retention of human capital.

The aforementioned positive indictment of an organization's value on a master's degree was further corroborated by answers to the question "Does your organization value your pending/current master's qualification?"

Figure 2. Selected responses to question, 'If you have changed roles: how many role changes have you had since starting or completing the course?'

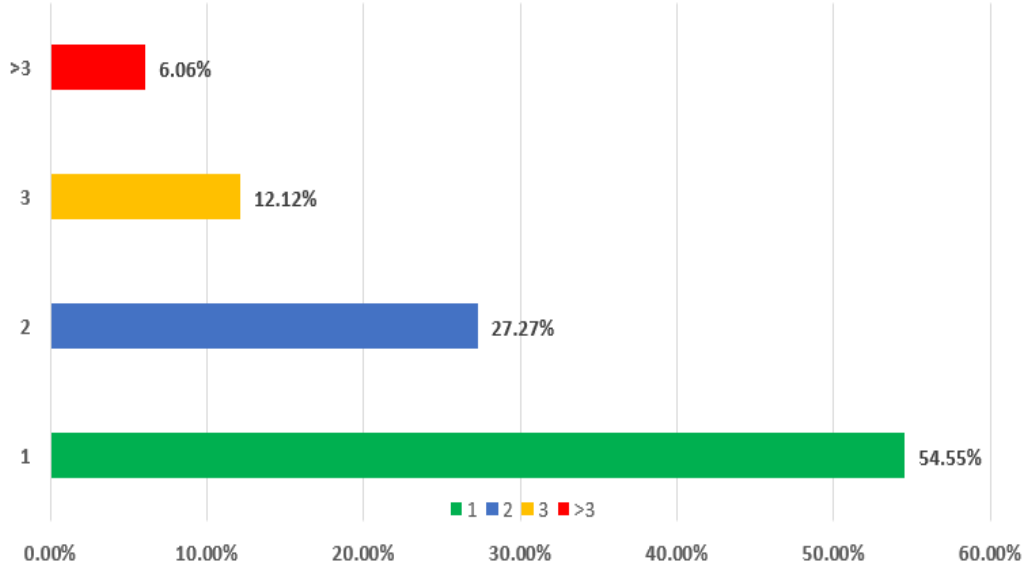
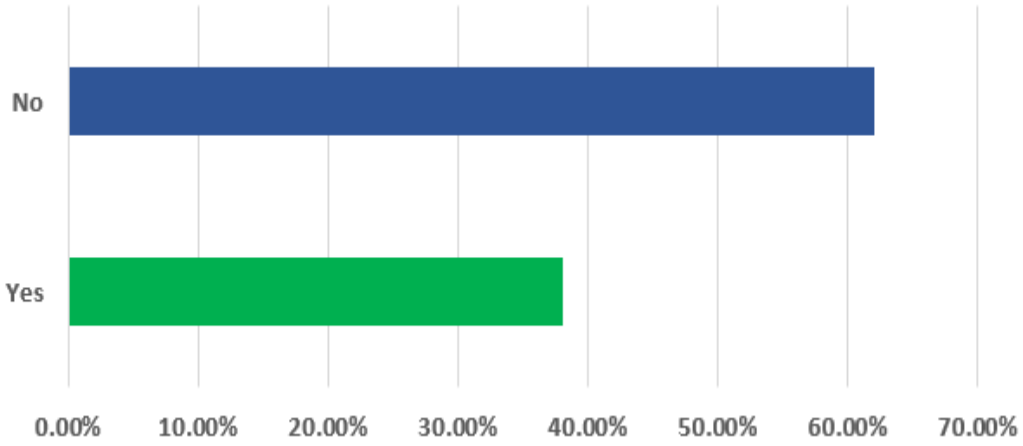


Figure 3. Responses to question, 'Have you moved organization since starting or completing the course?'



Just under 43% of respondents strongly agreed and just under 41% agreed their qualification was valued by their employer (**Figure 4**).

To expand on the value an organization places on a CPD qualification, graduates were further asked if having a master's qualification was instrumental and a contributor to their organizational move, promotion, or lateral moves since commencement or completion of the course. In response, 31% strongly agreed that the course contributed to the move, with 38% agreeing the course was instrumental in their progression (**Figure 5**). In summary just under 70% of the respondents agreed or strongly agreed that a CPD course was a positive attribute and had a positive correlation to their progression.

Figure 4. Responses to question, 'My organization values my pending/current MSc qualification'

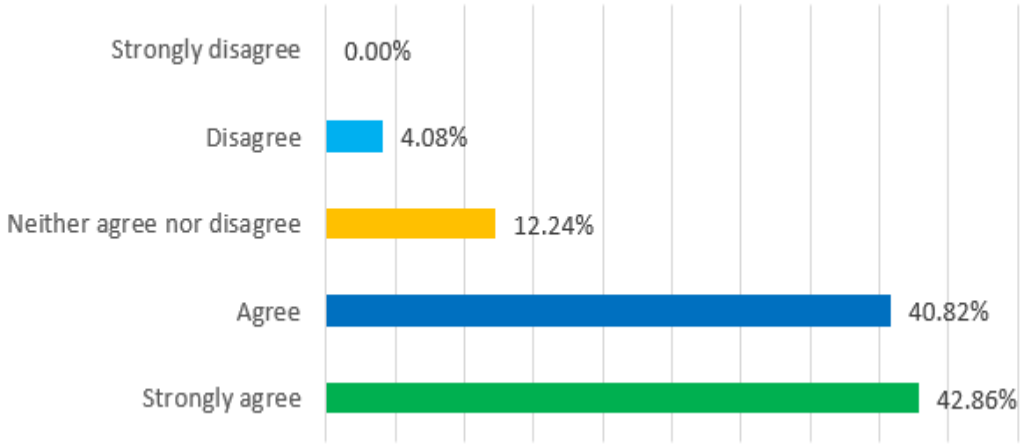
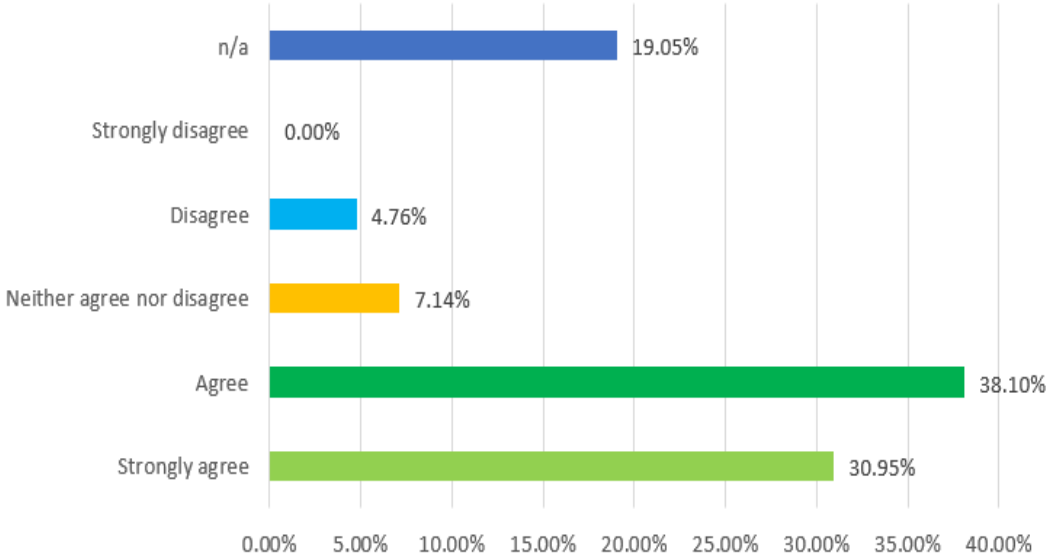


Figure 5. Responses to question 'Having a pending/current MSc qualification was instrumental and a contributor to my promotion/move'



When the students were asked if they would recommend the course to other people, a resounding 100% of graduates said they would recommend the course to peers and colleagues.

Finally, respondents were asked how they funded the course fees. This question was asked to further substantiate if graduates' organizations value their CPD paths and demonstrated this by funding their CPD progression. The course was initially designed for the Irish medtech industry, in conjunction with the Irish Medical Association Skillnet, to meet a growing demand for regulatory professionals and overcome a skills shortage. Thus, it was expected to have a high number of students (85%) receive partial or full funding from their employer organizations and/or the IMA. Just under 15% were self-funded. Most of the self-funded students have come from the UK, US, Australia, New Zealand, Saudi Arabia, and mainland Europe. The self-funded portion is increasing because of the internationalization of the course as it is online and accessible and there is increasing demand for skilled regulatory professionals. Increasing harmonization within the regulatory world and a broad global regulatory and quality curriculum means the educational provider's geographic location is no longer a barrier to enrolment.

Discussion and conclusion

Although there was a very high response rate (70%) to the authors' quantitative survey, it would have been insightful to gain an understanding of a higher percentage of the graduate population. The qualitative interview study, carried out with the first graduating class, had 100% participation. However, the authors would like to carry out the following:

- A survey in late 2021 to examine the current situation of the graduates who participated in the study and to expand the sample size to include the 2020 graduating class and current 2021 class;

- More qualitative interviews with a larger sample of graduate classes from recent years; and
- Interviews with the graduates' employers to assess their value of this CPD qualification on their employees' development and their organizations in general.

This study demonstrates there is an industry need for CPD courses and qualifications in regulatory affairs as demonstrated by the numbers of industry-based professionals investing 2 years in gaining a master's qualification while in full-time employment in this case study. Organizations place a value on CPD courses in regulatory as they have promoted and improved progression opportunities for employees upon completion of such CPD courses. A CPD course is a positive experience in terms of personal development and knowledge gain.

It is important for all personnel within an organization to understand a product realization lifecycle and the interconnectivity of different functions with each other as internal customers. Increasing knowledge of regulatory affairs (European, US, and global) and other functions and systems, such as quality management systems, sterilization, design assurance, manufacturing operations, postmarket surveillance, and risk management, can only be of added value to a company and deliver enhanced products in terms of safety and quality.

An organizational culture that supports continuous professional development in regulatory affairs is advantageous for both the organization, its employees, and its customers. Organizations should continue to advance the development of regulatory skills and knowledge and wider enterprise awareness through supporting continuous professional development. This will allow organizations to flourish through developing leadership skills and enhancing knowledge, which, in turn, supports the organization's efficiency, compliance, and competitiveness.

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