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ADAPTING THE INDUSTRIAL STAGE-GATE® PROCESS TO CREATE A NOVEL MASTER'S DEGREE INNOVATION CURRICULUM

Angelika Domschke[1] and John A. Blaho[2]

[1]Domschke Consulting, LLC, Duluth, GA, USA
[2]NYC Regional Innovation Node, New York, NY, USA

This article describes the creation of a novel product-driven master's degree curriculum in translational medicine based on the industrial Stage-Gate® process. Stage-Gate is an essential tool used by top industrial companies to successfully manage complex development processes for products like medical devices and drugs. Intimate knowledge of this tool is key in the translation of a brilliant concept to a successful product. Currently, Stage-Gate is predominantly taught to high-level executive leadership personnel or in business-related graduate programs. Unfortunately, this "top-down approach" does not leverage the full workforce that is involved in the process. A skilled workforce on all levels, including graduate-level technical experts, is desired by industry to reduce costly ramp-up resources and to boost the attrition rate of successful new products.

We adapted the Stage-Gate process to a new and exceptionally visionary master's degree program in translational medicine. A vertically integrated strategy was utilized to implement Stage-Gate. Industry expert lecturers were assigned to teach Stage-Gate in the context of small and large company environments. The Stage-Gate process itself was integrated into the curriculum schedule to allow continued hands-on practice from a company perspective. Courses were aligned and supplemented to adequately deepen key aspects of the Stage-Gate tool and seamlessly integrate the multidisciplinary curriculum that combines comprehensive core competency in medicine, engineering, and business. Finally, students were required to undergo a formal Stage-Gate review at the completion of each Stage-Gate step. The results illustrate the effectiveness of this adaptation to teach the Stage-Gate tool in a pilot cohort.

Key words: Novel master's degree program curriculum; Translational medicine; Stage-Gate® process; Entrepreneurship; Product–driven; Industry-driven

INTRODUCTION

When considering the application of the biomedical industrial Stage-Gate Process® (1) to a graduate-level educational situation, it is important to take a moment to reflect on a healthy trend that is emerging in new graduate programs, particularly those in the life sciences and biomedical engineering. This new movement promotes the close alignment of education and business in preparing students for seamless integration into business careers. In life science, this trend is in response to the critical need for increasing the rate of successful medical products, which falls significantly behind the considerably higher industrial and governmental research spending (2). A primary driver of this incongruity is believed to be the lack of a skilled workforce (3) in

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Address correspondence to John A. Blaho, Ph.D., NYC Regional Innovation Node, 555 West 57th Street, Suite 1407, New York, NY 10019, USA.
Tel: +1 (646) 664-3578. E-mail: jblaho@cuny.edu or Angelika Domschke, Ph.D., 3379 Ennfield Way, Duluth, GA 30096, USA.
E-mail: Angel.Domschke@yahoo.com

small university start-ups and large industrial companies alike.

University programs, particularly conventional master's degree programs in translational medicine or science, typically provide an excellent education in technologies. There remains, however, a gap between the acquired education of students and their true workplace readiness as it pertains to education in the practical knowledge of the multidisciplinary product development process, key skill sets, standards, and norms needed to manage complex processes while mastering translational hurdles. This gap often hampers the successful development of brilliant scientific discoveries that incubate within university start-up hubs.

A similar situation exists in industry, where a skilled workforce that is capable of mastering complex product development processes is key. Medical products are generally highly technically advanced; therefore, expert industrial engineers and scientists often carry much of the responsibility for the design and development of these products. In many cases, these technical experts are recruited at the graduate level to ensure a competitive edge in the rapid-growing technical environment. This leads to costly ramp-up periods and the high risk of incorrect decisions, which may impede the successful development of a bright idea through the complex hurdles to the final product.

A growing number of university programs are responding to this demand by offering multidisciplinary course materials that relate to the early stages of the product development process. This trend, however, comes with a unique challenge of its own: the efficient linkage and management of complex course materials and high-quality teaching standards. An example of such a multidisciplinary Master of Translational Medicine (MTM) program is the joint program between University of California, San Francisco, and University of California, Berkeley, which was funded by a gift from Andrew S. Grove (http://uctranslationalmedicine.org). Similarly, Grove approached the leadership of the City College of New York (CCNY) of the City University of New York (CUNY) to develop another innovative MTM training program focusing on industrial key skill sets and best practices as well as entrepreneurship. The CCNY executive team, under the lead of the dean of the Grove School of Engineering, Professor Gilda Barabino, recruited author Domschke as the CCNY MTM industrial consultant. Domschke served as the program's acting director to help with design and implementation, with a specific focus on industrial best practices and tools such as Stage-Gate. Author Blaho developed the program's entrepreneurship components. Together, the authors collaborated on the creation of the novel industrial Stage-Gate- and entrepreneurship-driven aspects of this new MTM program.

The new CCNY MTM separates itself from conventional programs in translational medicine or science through its far-reaching goal of seamlessly fusing contemporary translational medicine with core knowledge in all of the multiple disciplines that play key roles in the successful development of medical products. For example, the multidisciplinary CCNY MTM program comprises biomedical engineering capstone projects, business management with a particular focus on entrepreneurship, finance, regulations and standards, intellectual property, and quality assurance. This program aims to establish a new standard, one that facilitates the translation of brilliant ideas to successful medical products.

METHODS

The Stage-Gate Process

History

Stage-Gate is an important management tool that provides the roadmap for conceiving, developing, and launching new products. The general concept is believed to have its origin back in the 1940s (4). It has since been refined by many well-known pioneering institutions and companies, such as the National Aeronautics and Space Administration, ExxonMobil, DuPont, Royal Bank, and Procter & Gamble (5). According to an AC Nielsen study in 2010 (6), a rigorous stage-and-gate system increases company sales performance from new products by a factor of 6.5 times. By the year 2000, almost 75% of product developers in the U.S. were using this stage-and-gate system (6). In recent years, thought leaders such as Robert G. Cooper have taken on further refinements of this process to meet the needs of increasingly complex product processes (6). Particular emphasis is placed on the quality of the ideas that

enter the Stage-Gate system. Elements such as voice of the customer (VOC) research, spiral or iterative development, sharp definition of the value proposition, and open innovation or design thinking have been integrated into the modern Stage-Gate systems (7).

The Stage-Gate process is of great value in particular for the medical industry (8). The medical product development process has become progressively complex in recent years. The arrival of new technology concepts, stricter regulatory requirements, and the ever-increasing importance of reimbursement decisions for successful device commercialization require careful planning and strategy-setting, coordinated decisions, and consistent, rigorous business processes. Study results suggest that Stage-Gate processes are the predominant development model used in the medical device industry (8).

Application of the Stage-Gate Process

When applying Stage-Gate, complex medical product development is viewed as a process, which is separated into small well-defined and manageable steps called "stages." The process begins with a discovery stage and ends with the post-launch review. Typical stages in this process are as follows:

0) Discovery/ideation: Dedicated to the project initiation and idea screening
1) Scoping: Opportunity and risk analysis
2) Feasibility: Technical feasibility and business case
3) Full development: Design verification and validation
4) Scale-up and launch preparation: Final validation to product launch preparation
5) Launch: Product launch and post-launch assessment

Each stage is designed to gather information to reduce key project uncertainties and risks. Each stage typically costs more than the preceding one. The process is one of incremental commitments and a series of increasing investments. But, with each stage and step-increase in project cost, the unknowns and uncertainties are driven down so that risk is effectively managed (1). A cross-functional and multidisciplinary team is assigned to each stage, resulting in a highly co-operative process (Figure 1).

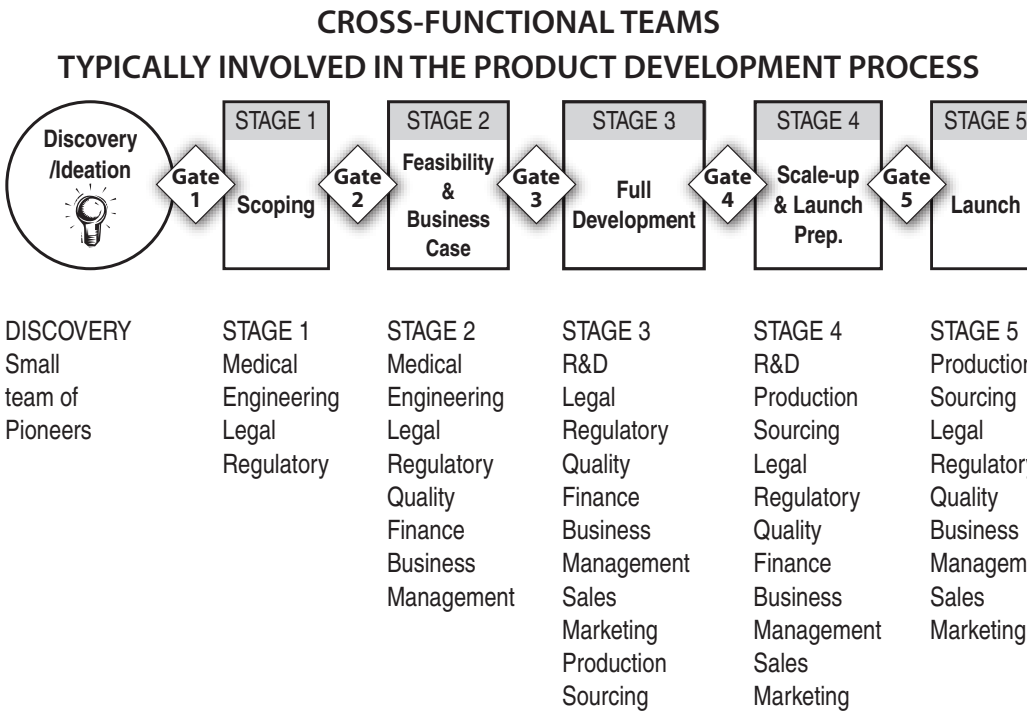

Figure 1. Schematic reprsentation of the Stage-Gate process.

In the Stage-Gate process, each stage is followed by a decision gate, at which point activities and information available at the time of the previous stage (such as the project progress, business case, risk analysis, etc.) are presented by the multidisciplinary team. The carefully compiled information (deliverable) is reviewed by the stakeholders and executive committee of the company (the gatekeepers) in specifically assigned board meetings (gate meetings). The gatekeepers may arrive at the decision to move the project forward and invest in the next defined stage (go decision). Alternatively, if the results of the previous stage are not favorable, the gatekeepers may decide to redo parts of the previous stage or stop the program completely (kill or no go decision).

Curriculum Adaptation of Stage-Gate

The Stage-Gate tool for the CCNY MTM program was designed to closely resemble the Stage-Gate process of a biomedical company, as it applies in the early product development stages of a medical device. It was implemented into the curriculum according to the following strategies: i) introduction to Stage-Gate, ii) integration of the Stage-Gate process into the curriculum schedule, and iii) alignment and supplementation of the course material.

i) ***Introduction to Stage-Gate:*** In preparation for the launch of the MTM program, student input sessions were held with the intention to round out the lecture content with topics that are of particular interest for the trainees. The feedback indicated a high interest in several topics related to industrial aspects. Students were most interested in learning the most up-to-date information about industry tools applied in the process of moving an idea toward a successful product and which processes are most relevant to start-ups and top companies alike. Students also wanted to gain an understanding of specific company needs related to their product development processes in the context of different sized company environments (small, midsize, large) and company life-cycles. Finally, students wanted insight into the work environments of different sized companies (e.g., the responsibilities of a chief technology officer (CTO) in a start-up company versus a top 500 company, etc.)

To address student needs, sector experts were recruited as lecturers and guest lecturers to provide effective introductions to and answer questions about these topics of high interest within the first semesters. A set of special lectures and individual student mentor sessions were created to build on the broad expertise of Domschke in bringing a product to market in different sized company environments. Preceding the Engineering Entrepreneurship course, Blaho created an introductory lecture with the purpose of familiarizing students with the terms of the business canvas model that would be the central aspect of their later course work. Finally, prior to the actual MTM program initiation, a kick-off event was held to introduce this new CCNY program and its unique product-driven approach to students and university faculty. The following brief summaries describe examples of the lecture topics and content covered in the first semesters of the curriculum schedule to introduce the Stage-Gate process.

- **Integrating Industry Tools and Expertise**: Part of the kickoff program included an introductory lecture from Domschke on her role as acting director and industry consultant. This lecture gave an overview of the program concept along with an introduction to Stage-Gate and its integration into the curriculum schedule. Finally, an overview of program curriculum was given.
- **Building the Stage-Gate Tool for MTM**: This second lecture by Domschke reviewed the typical stage activities and gates deliverables in the development of a medical product, including an overview of the simulated stages and gates as they pertain to the MTM Program, a review of required student assignments (i.e., deliverables) for the first gate meeting, and an overview of the flow of the first gate meeting and its required presentations.
- **Strategic Focus in Different Sized Company Environments**: This lecture, taught by Domschke, introduced prevalent company cultures, organizational life cycles, and the relationship between company size and strategic focus. Large, midsize, and small company environments, as well as particular dynamics of start-up environments, were investigated in case studies. The process of

company growth and the different needs in each growth phase, which create different work environments and career opportunities, were discussed. Additional topics included product life cycles and the creation of short-, mid-, and long-term product portfolios.

- **Individual Student Mentor Sessions**: Domschke's one-on-one student mentor sessions were held each month throughout the program to help students explore their own talents and true interests. In these sessions, students defined their preferred work environments and company fits so that they might take charge of their own career choices and plan the next steps toward the realization of their goals. Homework was assigned during each session, including the creation of a career canvas that adopted the principles of the career help book *What Color Is Your Parachute* by Richard Boles (9). The canvas categories included a mission statement, favorite knowledge, transferable skills, working conditions, responsibilities, people, and geography.
- **Getting to Market: It Takes People, Process, and the Promise of Profits**: Two lectures were given by Kip Creel on the Stage-Gate process. Creel is the founder and president of Stand Point, an Atlanta-based agency specializing in VOC studies that trains top-200 companies in the development of a successful Stage-Gate process. The "Getting to Market" lecture covered cognitive styles, innovation team interactions, sources of ideas, identification and validation of customer needs (techniques and methods), VOC in the Stage-Gate process, and the anatomy of a concept.
- **Navigating the Complex Product Development Process: The Stage-Gate Paradigm:** Creel's second lecture covered organizational considerations, investment decisions, the Stage-Gate process, the "front end" of innovation, and evolved Stage-Gate.

ii) ***Integration of the Stage Gate process into the curriculum schedule:*** The Stage-Gate process itself was integrated into the curriculum schedule with the objective of fostering a deeper understanding from a business or company perspective, offering hands-on working knowledge of the actual product development process, and providing ample training in industry-relevant multidisciplinary communication skills. An effective integration of stages and gates into the curriculum was achieved by having Stages 1 to 3 coincide with the three semesters of the program, with each semester ending with a gate meeting (Figure 2).

- **Creation of a Fictional Company**: As an educational paradigm, a fictional company was created as part of the Stage-Gate integration. The capstone engineering project served as core technology for the fictional company. The capstone project itself was conceived in close collaboration with biomedical sponsors. In the case of the first cohort, students were to develop a technically advanced device to measure joint movement. The fictional company for the first cohort

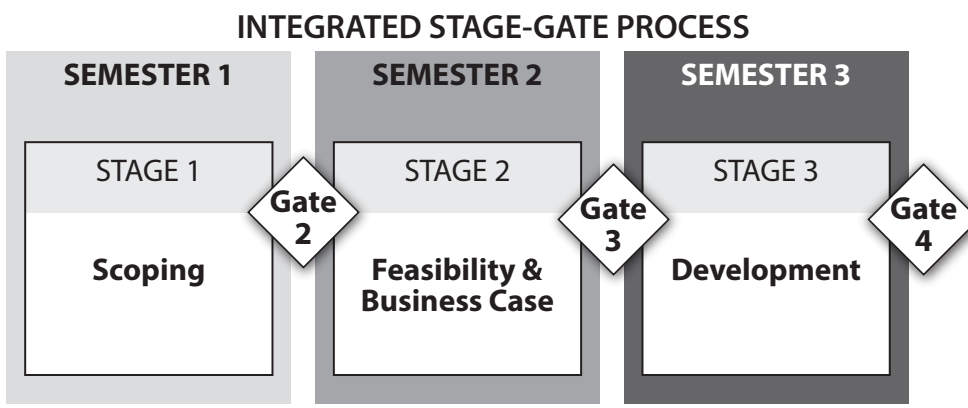

Figure 2. Schematic showing the integration of the Stage-Gate process into the curriculum schedule.

was named ELBONIX and was theoretically envisioned to rank amongst the top 200 biggest companies. This fictional company setting offered students the opportunity to work with the Stage-Gate tool in the role of junior leadership who presented at company board meetings (gate meetings). College faculty and industry partners assumed the roles of multidisciplinary stakeholders (gatekeepers) of the company. Students were encouraged to take ownership of and lead the gate meetings. They presented and discussed gate deliverables relevant to their fictional company. Emphasis was placed on the presentation of knowledge gained during their analyses from a business perspective and their ability to link together the multidisciplinary MTM course material from a business management viewpoint.

iii) ***Alignment and supplementation of courses:*** The objective of this final phase of the program was to create a transparent structure for the complex multidisciplinary course material in the context of a real-life, early-stage medical product development process. Stage-Gate provides a clear structure defined by the stage activities and gate deliverables assigned to each discipline, which form the basis for the communication and discussions in subsequent gate meetings. The typical disciplines in the early stages (1 and 2), stage activities, and gate deliverables of a medical device product are shown in Figure 3.

The main difference between Stages 1 and 2 is that in Stage 1, the deliverables are preliminary estimates, whereas, in Stage 2, those estimates are replaced with evidence-based final assessments. The disciplines of quality, business management, and finance are of particular interest in Stage 2. In recent years, quality and business management with an emphasis on entrepreneurship have been progressively moved into earlier stages in order to proactively comply with regulatory demands and improve risk management.

The alignment of the curriculum with the stages of the medical device development process was

THE MEDICAL DEVICE PRODUCT DEVELOPMENT PROCESS
TYPICAL STAGE 1 AND 2

DISCIPLINES	ACTIVITIES	DELIVERABLES
MEDICAL RESEARCH	Define strategic focus	Disease analysis Gap analysis Problem / need statement
BIOMEDICAL ENGINEERING	Assess technical feasibility	Product concept & Product success criteria
LEGAL (IP)	Assess IP strategy	IP / Patent strategy
REGULATORY	Assess regulatory strategy	Regulatory plan
QUALITY	Implement Quality plan	Quality management
Business Management / Entrepreneurship	Assess customer insights Create business model	Customer insights Business Case
FINANCE	Assess financial justifiability	Cost / Value analysis
Program Management	Cross-functional communication Pull it all together	Solid plan for the next stages

Figure 3. Table showing the activities and deliverables of Stages 1 and 2.

introduced in a lecture entitled "Building the Stage-Gate Tool for MTM Fictional Company: ELBONIX." This lecture included a review of the MTM stage activities and gate deliverables as well as the gate meeting process. In preparation for the first and second gate meetings, students received guidelines for the preparation of the gate deliverables as well as templates for the slide presentation.

Figure 4 depicts the alignment of these disciplines with the MTM program curriculum. Stage 3 of the medical device product development process relates to the full development. The following two key aspects of Stage 3 are part of the Semester 3 curriculum.

- **Prototype Development**: The goal in Stage 3 is prototype development and ultimately testing with patients following an institutional review board approved protocol. However, the successful design of a concept does not only depend on technical expertise. Other factors, such as knowledge of the patent landscape surrounding the technology, are equally important to assure intellectual property (IP) rights and financial success for the company. Thus, securing IP rights and patent filing were also goals. Technical experts, capable of exploring IP landscape and design and with smart patenting know-how, are a great asset. Expert guest lecturers were recruited to teach this important skill set.
- **Intellectual Property, Regulations, and Quality Assurance**: This course is of particular interest from an industry perspective because it teaches the knowledge to design and navigate the most effective path. It proactively addresses translational hurdles that make a significant difference in the development time (years) and determines if the process will become a success or failure. Domschke created and assisted in the execution of this course, leveraging her extensive and nationally recognized expertise in industry research leadership and medical product devel-

THE MEDICAL DEVICE PRODUCT DEVELOPMENT PROCESS
CCNY'S MTM CURRICULUM OVERVIEW

ALIGNED WITH THE TYPICAL STAGES 1 AND 2 OF A MEDICAL DEVICE DEVELOPMENT PROCESS

DISCIPLINES	COURSE CONTENT	DELIVERABLES
MEDICAL RESEARCH	• Translational Challenges in Medicine • Translational Challenges in Diagnostics, Devices, and Therapeutics • Biomed. Ethics • Transl. Research Design	Strategic focus: Disease analysis Gap analysis Problem / need statement
BIOMEDICAL ENGINEERING	Prototype engineering of medical device (in collaboration with med. Institutions)	Product concept & Product success criteria
LEGAL (IP)	• Intellectual property / Patenting basics • Smart patent search / Smart Patenting	IP / Patent strategy
REGULATORY	• Regulatory basics (FDA, international) • Device & drug regulations and filing	Regulatory plan
QUALITY	• Quality systems & regulations	Quality management
Business Management / Entrepreneurship	• Entrepreneurship & business leadership	Customer insights Business Case
FINANCE	• Cost analysis, the business of translation	Cost / Value analysis

Figure 4. Table showing the alignment of Stage-Gate disciplines with the MTM curriculum.

opment from conception to launch. The industry subject matter expert Dr. Abhishek Datta, who is employed as CTO at a medical device start-up company, was recruited as course director.

- Regulatory topics covered were the latest regulatory developments presented at the 2015 conference Food and Drug Administration (FDA) Small Business Regulatory Education for Industry (REdI). These topics included the FDA and its regulations, establishment registration, medical device listing, medical device tracking, drug establishment registration, drug listings, and an overview of basic regulatory requirements. Details of the FDA approval process were given, including device classification, predicate devices, the de novo classification process, humanitarian device exemption, product codes and regulation numbers, drug regulation, orange book, types of drug filings, drug product exclusivity, and Hatch-Waxman regulations. Regulatory pathways for medical devices were described, including 510(k), 513(g), and premarket approval filings. Regulatory pathways for drugs included new drug applications, abbreviated new drug applications, and 505(b)(2) filings. Students were assigned medical devices or licensed drugs for which they researched the regulatory pathway that led to its approval. Further topics included strategies for interactions with the FDA, clinical trial basics, and select international regulations (European Union, Canada, etc.).
- IP discussions began with an overview of patents. Topics included patent definition, content, terms, and acquisition. Students were walked through a patent example that included a description of all its aspects (methods, ranges, etc.). Other topics included requirements for patentability, freedom to operate, inventorship and proof of invention, trademarks and copyrights, provisional and non-provisional applications, U.S. filing, international patent coverage and filing, patent examination, notice of allowance, patent maintenance, licensing, the university IP process, nondisclosure agreements, patent enforcement basics, burden of proof, trials in the U.S., trials outside U.S., infringement, infringement opinions, validity opinions, and damages and injunctions. Students performed initial searches of the United States Patent and Trademark Office website for patents related to their planned projects. The goal was to enable them to integrate the IP sequencing timeline into the product development pathway.
- In addition to the comprehensive course material described above, the basics of smart patent searching and smart patenting were taught by University Research Commercialization Manager Neeti Mitra at the CUNY Technology Commercialization Office. This workshop enabled the students to find, understand, and evaluate patents related to their products as well as enabled communication with legal experts to create successful patents. Topics included novelty and prior art searches as well as understanding the background and purpose of the invention. Students were taught how to identify the key areas of invention, develop search strategies to identify similar patents, and find relevant key word, international patent classification, and structure data in relevant patent databases. Students were encouraged to create a final search set for analysis and to identify prior art. Smart patenting topics included IP management, patent commercialization, strategies of defensive and offensive patenting, cross-licensing, in-licensing, out-licensing, fields of use, territories, and time frames.
- Quality assurance (QA) is an essential part of Stage 3. The MTM program includes comprehensive quality assurance classes and an expert guest lecture. Classes in QA were taught in the first semester. Continued QA "refresher" lectures—to be placed throughout the whole curriculum—are envisioned for future cohorts. QA was covered in a series of guest lectures. Topics included FDA quality system regulation, quality policy, a quality manual, and subsystems of a quality system (i.e., management using six systems: design controls, material controls, record controls,

equipment and facility controls, production and process controls, corrective and preventive action (CAPA)). The topic of organizational structure and responsibilities included management control subsystems, quality policy, audits, reviews, training, inputs, outputs, verification, validation, transfer, change, risk management, and technical files. The topic of production and process control covered how manufactured products meet specifications, including process control, validation, monitoring, purchasing, acceptance, sampling, calibration, vendor assessment, identification, storage, labeling, installation, and servicing. The area of non-conformities and CAPA focused on quality policy that strives for continuous improvement. Topics included collecting and analyzing data; identifying and investigating product and quality problems; root cause analysis; identifying and implementing corrective and preventive actions; verifying and validating; providing information for management review; differences between correction, corrective action, and preventive action; and customer feedback. Finally, the topic of medical device reporting included reporting, recall and vigilance systems (European Union and Canada), customer complaints, risk management, internal audit, external audit, management review, International Organization for Standardization (ISO) 13485, and differences among U.S. FDA, good manufacturing practice, and ISO. Guest lectures given by Susan Littlefield, manager for Quality Systems & Regulatory Affairs at the Georgia Eye Bank, focused on the real-life company approach to quality: how to build quality into the process, separate the department for quality, and introduce quality systems.

- ISO standards, which are important standards related to medical devices and drugs, were an integral part of the MTM I6100 Intellectual Property, Regulation, and Quality Assurance course material. Relevant standards were discussed in great detail, including the history of the ISO standards and other norms.

Engineering Entrepreneurship Using the Lean LaunchPad Methodology

In 2011, the National Science Foundation (NSF) adopted the Lean LaunchPad methodology of entrepreneurial immersion, hypothesis-driven customer discovery, and business model validation (10,11) via the creation of the NSF Innovation Corps (NSF I-Corps™) program. The New York City Regional Innovation Node (NYCRIN), the third I-Corps node created through support from the NSF, is led by CUNY in partnership with Columbia University and New York University and includes a network of over 25 regional institutions (12). Previously, NYCRIN successfully adapted the NSF I-Corps program for undergraduate engineering entrepreneurship training (13).

The NSF I-Corps boot camp is seven weeks long and is taught by seasoned commercialization experts, including serial entrepreneurs, investors, and directors of innovation. Each cohort consists of 21 to 24 teams of three: an NSF-funded principal investigator, an entrepreneurial lead who is typically a graduate student or postdoc familiar with the technology, and an industry mentor. These three-person teams are required to develop business model hypotheses about their technology's value proposition and customer segments, which together create a product/market fit, along with the remainder of the Business Model Canvas (BMC). The team must test their hypotheses by "getting out of the building" and interviewing at least 100 potential customers during the seven-week course. Learning the customer pain points leads to insights that can either validate or invalidate the teams' hypotheses. The methodology favors experimentation over elaborate planning, customer feedback over intuition, and iterative design over traditional "big design up front" development (14). The course is a modified flipped classroom, in which the pedagogical learning is assigned through videos in the Udacity series *How to Build a Startup* to be watched outside of class time. Class sessions are used for the teams to present their weekly insights with feedback from the teaching team followed by a discussion of the video and corresponding assigned text, which covers one block of the BMC each week. After sufficient data is gathered, the team can pivot as a result of a pattern of invalidations and must continue their customer discovery process to reach a go

or no go conclusion by the end of the course. Simply put, the NSF I-Corps program enables academic researchers to quickly determine the technology's readiness in the marketplace.

The challenges we met in adapting this process to the new CCNY MTM program included the small number of students in the class and the fact that the program focused on a single technology solution. Accordingly, the Engineering Entrepreneurship course began with three weeks of introduction (how the course fits into the Stage-Gate process), ideation, and brainstorming. We "promoted" each student to the level of division head and charged them with identifying which indication their division would investigate by customer discovery for the semester. We then proceeded through the usual Lean Launch-Pad inverted classroom model for the remainder of the course. Students were expected to create a final lessons learned video and make a final lessons learned presentation. Results in Figure 5 indicate that the students learned a significant amount about aspects related to the creation of a business model. The left panel of Figure 5 shows the students' level of understanding prior to the course, and it is mixed. However, upon completion of the course (right panel), the students indicate that they understood a great deal about all of the aspects of a business model. These results suggest that incorporating the Lean Launch-Pad methodology into a Stage-Gate-driven program can successfully teach entrepreneurship concepts.

RESULTS

Whenever a new teaching paradigm is launched, it is imperative that an accurate assessment process is also developed alongside to determine the overall impact of the teaching process. For example, the Engineering Entrepreneurship course described above leveraged its already existing assessment procedure (13). Instructors successfully captured the key learning milestones that the students accomplished (Figure 5). A similar rigorous assessment plan was also developed for the CCNY MTM program, and the results were as follows.

Mentoring Sessions Provide Real-Time, Longitudinal Assessments

As described in the Methods section above, Domschke regularly met with the students in defined sessions to assist students in the pursuit of their career paths and to learn first-hand how their learning was progressing. Students were asked for feedback, which was shared in a timely manner with the program advisory board for review and possible program modification. It was concluded that these timely feedback sessions assisted in keeping the evolving program on track.

Stage-Gate Meetings Enable Group Faculty Assessments

At the end of each stage (semester), the students were required to give formal Stage-Gate presentations to their company executives (the faculty). Thus, all students presented the multidisciplinary course material they had learned in a coherent manner and from a business perspective in front of all faculty in one single session. During the immediate subsequent executive review session, the faculty were able to have an honest, data-driven discussion about the progress of the students through the program. It was concluded that these sessions functioned as an important, nonbiased quality control step for the program, as all faculty reviewed the students' progress through their colleagues' courses.

Semester 1 Student Feedback Empowered the Students

Following the first gate meeting, the students were asked to fill out a very short feedback survey with two questions: 1) How would you rate the efficacy of the MTM program to develop your professional skills? and 2) How would you rate the helpfulness of the mentor session to develop a more focused picture of your career aspiration and steps toward achieving it? Both of these open-ended questions were rated on a scale of 0 to 10 (0= not helpful at all, 10= extremely helpful), and the students were asked to support their rankings with a short written response. As expected, these surveys enabled the tracking of the professional progress of the students. An important conclusion from this activity was that it served as a method for reinforcing to the students that the faculty are interested in their development as professionals as well as their learning as students.

A Detailed, Final Survey Documented the Impact of the Program

After the completion of the second Stage-Gate meeting (during the third and final stage), the

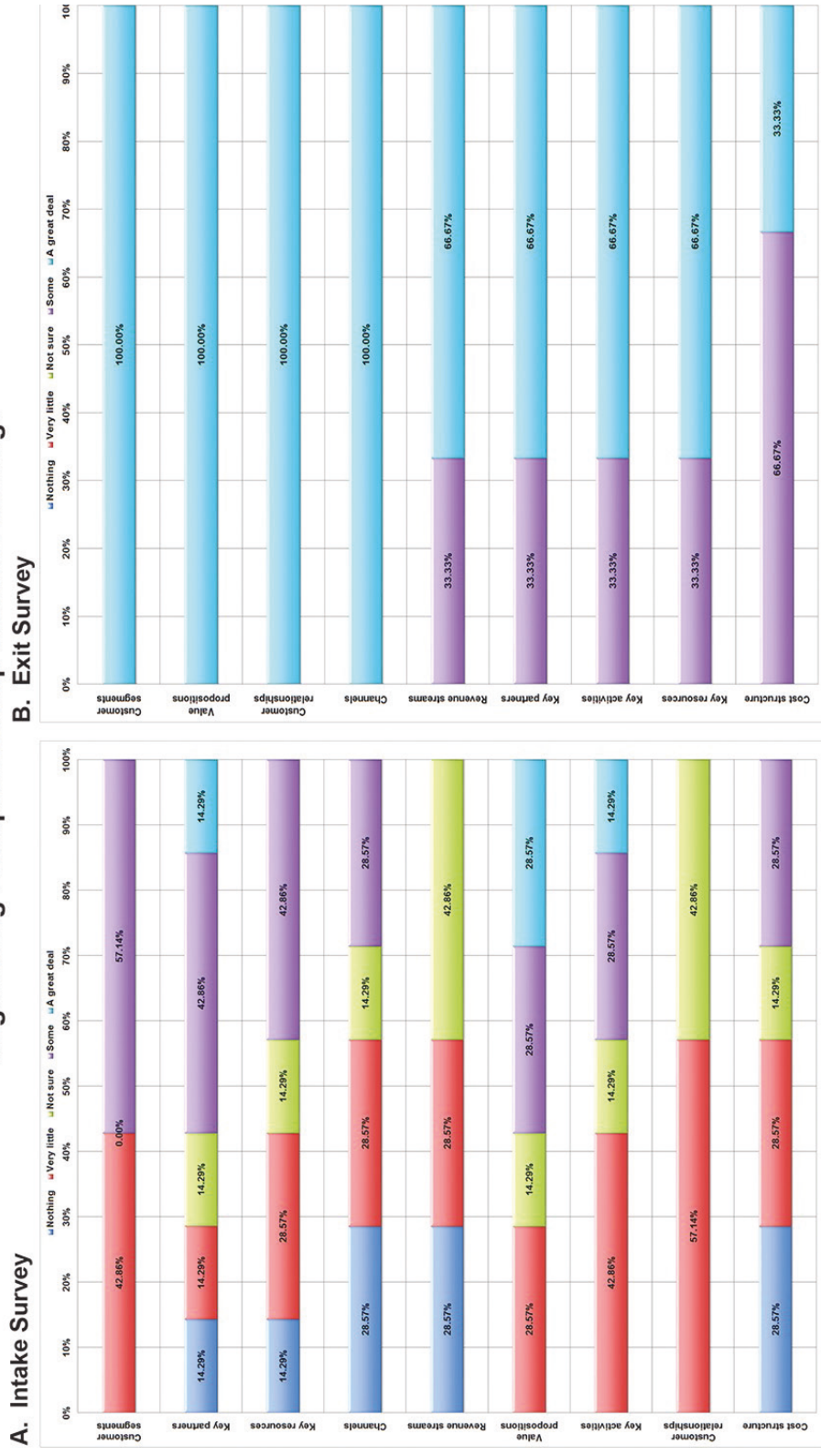

Figure 5. Results related to students' understanding of topics related to the development of a business model. The difference in the percentages reflects a difference in the number of students who completed the survey before and after completion of the Engineering Entrepreneurship course.

students were required to complete a detailed survey that covered topics extending back to the beginning of the program. Results from this survey may be summarized as follows.

- Students acquired knowledge related to the Stage-Gate process. Stage-Gate is a tool to manage complex medical product development. It views product development as a process with a series of stages, and it was integrated into the CCNY MTM program plan. After the students completed the early stages (Stages 1 and 2), they were asked to indicate how knowledgeable they were about the tool (Figure 6). For all students, there was a significant amount of learning about what the process is and what its stages are. Based on these findings, it was concluded that the Stage-Gate tool can, indeed, be adapted to graduate student training.
- Students acquired skills related to product development. Following the second gate meeting, three-quarters of the students felt that they had learned how to apply the Stage-Gate process (Figure 7). When reviewing how much they knew before MTM compared with after, the students gained a significant amount of knowledge in moving a project into the next developmental stage (go or no go) based on the gate deliverables. They also learned how to propose next steps and activities for the subsequent development stage as well as how to communicate well with the multidisciplinary teams within the gate meetings using appropriate technical terms.
- Students acquired skills related to applying the Stage-Gate tool. Following the second gate meeting, three-quarters of the students felt that they had learned the product development process (Figure 8). When comparing how much they knew before MTM with after, the students gained a significant amount of knowledge in defining key product activities and gate deliverables.
- Students felt that lectures provided relevant course content. Students were asked how they rated invited lectures, including "Introduction to Stage-Gate (Kickoff)," "Getting to Market: It Takes People, Process, & the Promise of Profits," and "Building the Stage-Gate Tool for ELBONIX Lectures." In all cases, the students felt to a

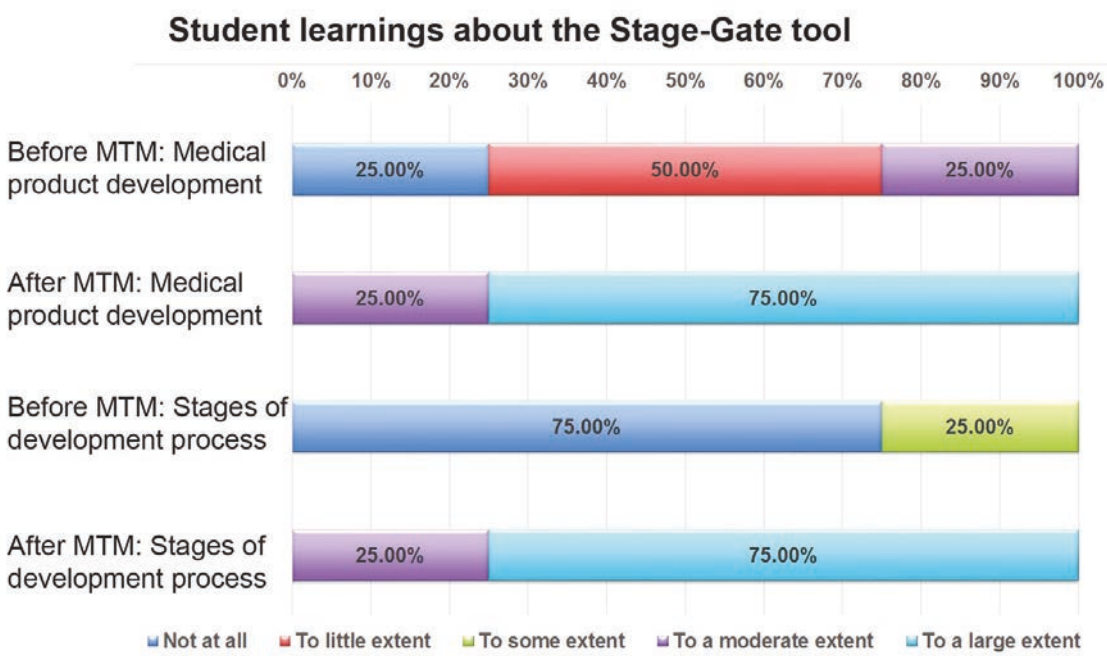

Figure 6. Representation of learning by students about the Stage-Gate process acquired after the MTM program.

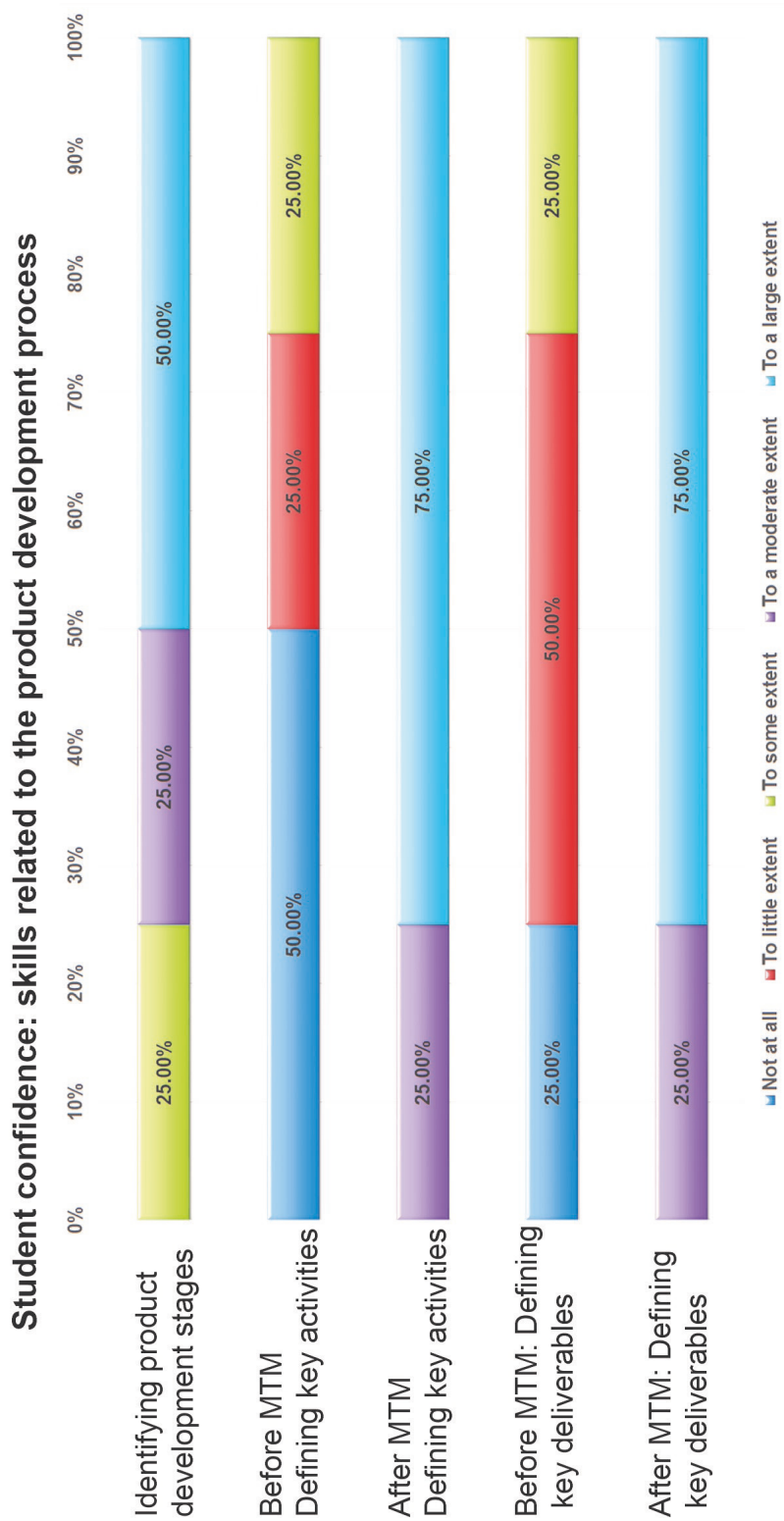

Figure 7. Comparison of skills related to product development by students acquired after the MTM program.

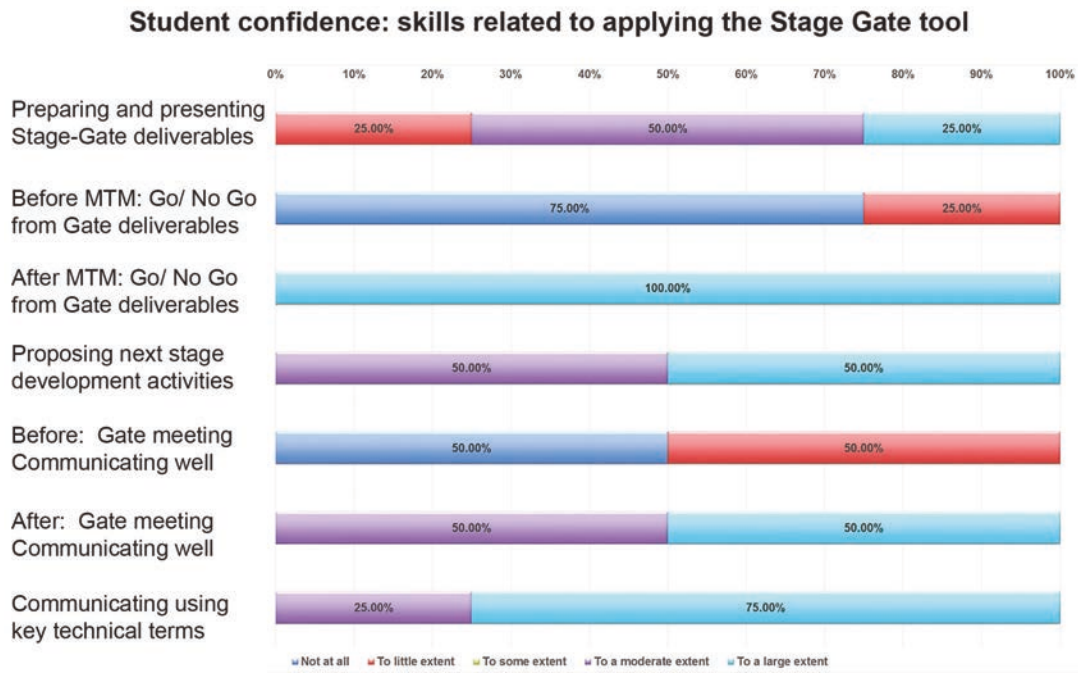

Figure 8. Comparison of skills related to applying the Stage-Gate process acquired after the MTM program.

large or moderate extent that these lectures were relevant to them. Based on these results, it was concluded that supplementary guest lectures are a valuable mechanism for providing additional course content.

- The multidisciplinary course material gave students confidence in their own skills. Students felt to a large extent that they had acquired skills in i) drafting a translational path (milestones and timelines) within a product development process, ii) drafting a translational path for regulatory, intellectual property, and quality, iii) conceiving translational hurdles in the multidisciplinary course material, iv) communicating these translational hurdles from a business relevant perspective, and v) comprehending and articulating how the disciplines of the MTM program work together in the early stages of the product development process.

- Students agreed that the fictional company and Stage-Gate process provided value. Students were asked directly if they felt that the introduction of a fictional company into the lesson plan helped them in practicing the Stage-Gate tool. They strongly agreed that the knowledge learned in connection with the fictional company inspired them to create ideas that could be developed into successful products. In addition, it allowed them to practice the Stage-Gate process and increase their confidence so that they could apply their knowledge to other product ideas. Similarly, the students felt that they had gained knowledge regarding i) the concept of a company life cycle, ii) the process of company growth and the different needs in each growth phase, which create different work environments and career opportunities, iii) the concept of product life-cycles and product portfolio management, iv) the idea that management of a short-, mid-, and long-term portfolio creates a need for different talent, v) the fact that organizations and companies have different cultures impacting the work environment, and vi) their preferred company environments.

- Mentor sessions empowered students to pursue career opportunities. Students strongly felt that the mentor sessions i) defined their talents and true interests, ii) better defined their preferred work environments, and iii) encouraged them to actively pursue the next steps toward their career

goals, explore their talents and true interests, take charge of their career choices, and address hurdles on the path toward their career objectives.

DISCUSSION AND CONCLUSIONS

The implementation of the industrial Stage-Gate process over a full 12-month graduate-level master's degree program is a novel teaching paradigm. Combining the Stage-Gate process with the Lean LaunchPad methodology enables students to gain industrial expertise that is relevant to career options in both start-up and mature companies. In addition to standard didactic teaching, the CCNY MTM program involves personal mentorship, experiential learning, and team building exercises so that the students become well-rounded and better positioned for their next career steps.

Based on our findings, we conclude the following:

- Adaptation of the industrial Stage-Gate process as a pedagogical tool is feasible in a graduate-level product-driven master's degree program.
- Coordination of the teaching of industrial concepts with canonical academic graduate courses provides necessary real-life context to the students. The unanticipated consequence of this pairing was that the students become fully aware of the risks and challenges involved in commercializing their prototype devices.
- Participation in the Stage-Gate review process at the end of each semester by all course faculty of record helped the development of an integrated prototype device, as input from all experts was shared and discussed as a team.

While the students who are fortunate enough to participate in this program benefit in many ways, delivering such an ambitious program is not easy. Recruitment of instructors is a particular challenge since most university faculty simply do not have the necessary industrial experience to deliver the needed content that a hybrid Stage-Gate/Lean LaunchPad program demands. It is very important that the course coordinators and directors for courses with industry-relevant content are the appropriate industry experts. Unfortunately, instructors with broad knowledge and industrial experience who can commit to a full 15-week course are a challenge to identify. While guest lecturers can suffice for specific defined topics, coordinating schedules with such speakers can be difficult, so course agendas need to be flexible to accommodate this.

Another area that can present challenges is the recruitment of appropriate students for such a multidisciplinary program. As it is anticipated that students with diverse educational backgrounds will apply for this program, the curriculum must be flexible enough to embrace all students equally. The success of the inaugural year was due in part to the fact that the original students completely bought into the process and were fully integrated into the program, even providing suggestions for industrial topic areas that they wanted covered in the course material. Looking ahead as the program scales, it will become more and more important to maintain such student input and integration so that the program content remains current and relevant.

In conclusion, while offering such an in-depth industry-based graduate student training program may be challenging, the rewards to the student are innumerable. It is hoped that this Stage-Gate-inspired program will help to better prepare students for long, fulfilling industrial careers.

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