

FOR APPROVAL

PUBLIC

OPEN SESSION

то:	Academic Board
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DATE:	May 13, 2015 for June 1, 2015
AGENDA ITEM:	6

ITEM IDENTIFICATION:

Proposal for a new graduate program in Biomedical Engineering as an additional offering within the existing Master of Engineering degree, Faculty of Applied Science and Engineering

JURISDICTIONAL INFORMATION:

Section 5.3.1. of the Terms of Reference for the Academic Board states that academic program proposals coming from the Board's committees, including the new graduate programs and degrees, require Executive Committee confirmation.

GOVERNANCE PATH:

- 1. Committee on Academic Policy and Programs [for recommendation] (May 12, 2015)
- 2. Academic Board [for approval] (June 1, 2015)
- 3. Executive Committee [for confirmation] (June 15, 2015)

PREVIOUS ACTION TAKEN:

The proposal for the Biomedical Engineering graduate program within the existing Master of Engineering received approval from the Faculty of Applied Science and Engineering Council on April 17, 2015.

HIGHLIGHTS:

This is a proposal for a new graduate program in Biomedical Engineering, to be offered by the Institute of Biomaterials and Biomedical Engineering. Currently there are six programs in the Faculty of Applied Science and Engineering that confer the Master of Engineering; this new program will be the seventh. The proposed program will be a full-time, three-session, professional degree and will consist of coursework (3.5 FCE) and an internship (1.5 FCE) in the third session. Potential applicants to this program could be recent graduates from a broad range of undergraduate engineering programs such as chemical, material science, electrical and mechanical, and in particular those with a minor in biomedical engineering, bioengineering or the equivalent or seasoned professional who want to enter the medical device industry.

The curriculum will be delivered by the Institute of Biomaterials and Biomedical Engineering (EDU:A), a highly multidisciplinary unit associated with the following three Faculties: the Faculty of Applied Science and Engineering, the Faculty of Dentistry and the Faculty of Medicine. The curriculum will focus on the development and design of biomedical devices with a significant emphasis on biomedical sciences, biomedical engineering technology, commercialization and entrepreneurship. The proposed Biomedical Engineering program includes an internship in which students will apply the knowledge gained in the first two sessions to develop a prototype for a device to address an important problem in healthcare in the biomedical industry or in academic laboratories.

The proposed program was developed in consultation with the Faculty of Applied Science and Engineering, the Faculty of Medicine, the Faculty of Dentistry, and key faculty members and members of hospitals and research centres related to the M.H.Sc. in Clinical Engineering. Consultation also took place with hospital-based partners on establishing new opportunities for student placements and with industry on the curriculum content, as detailed in the proposal.

The program was subject to external appraisal on February 25, 2015 by Robert E. Kearney (McGill University), Heather Sheardown (McMaster University) and William Wagner (University of Pittsburgh). The external reviewers made a number of helpful suggestions, which resulted in small changes to the program as originally conceived as is reflected in the Dean's response to the review report. The final proposal received approval from the Council of the Faculty of Applied Science and Engineering on April 17, 2015.

FINANCIAL IMPLICATIONS:

Any new/additional financial obligations resulting from this program will be met at the Faculty/Divisional level.

RECOMMENDATION:

Be It Resolved

THAT, subject to confirmation by the Executive Committee

THAT the proposed Biomedical Engineering graduate program as an additional offering within the existing Master of Engineering degree, as described in the proposal from the Faculty of Applied Science and Engineering dated April 2015, be approved effective September 1, 2016.

DOCUMENTATION PROVIDED:

• Proposal for a new Biomedical Engineering program within the existing Master of Engineering degree, Faculty of Applied Science and Engineering



University of Toronto New Graduate Program Proposal

This proposal has been developed in line with the University of Toronto's Quality Assurance Process.

Name of Proposed Program:	Master of Engineering in Biomedical Engineering
Degree Name and Short Form:	Master of Engineering (M.Eng.)
Program Name:	Biomedical Engineering
Professional Program: (yes/no)	Yes
Unit offering the Program:	Institute of Biomaterials & Biomedical Engineering (IBBME)
Faculty / Academic Division:	Faculty of Applied Science & Engineering (FASE)
Faculty / Academic Division Contact:	Professor Markus Bussmann Vice-Dean, Graduate, FASE
Graduate Unit Contact:	Professor Julie Audet Associate Director and Graduate Coordinator, IBBME
Anticipated Start Date of New Program:	September 2016
Version Date:	April 8, 2015

New Graduate Program Proposal

Master of Engineering in Biomedical Engineering Institute of Biomaterials & Biomedical Engineering Faculty of Applied Science & Engineering

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1 Executive Summary

This proposal is for a new program in Biomedical Engineering within the Faculty of Applied Science & Engineering's (FASE) existing Master of Engineering (M.Eng.). The proposed program responds to the growing need for biomedical engineers in the job market, which is driven mainly by the increased demand for biomedical devices. The program also aims to provide a pathway for strong students interested in pursuing a professional career in biomedical engineering, as opposed to a career in research. There is marked enthusiasm for this degree among current undergraduate engineering students and from industry, as is evidenced by recent surveys and biomedical device market analyses revealing that graduates from the proposed program would be extremely competitive in the current job market.

The program will focus on the design and development of biomedical devices incorporating diverse components, from software to sensors to biomaterials, even stem cells. Choosing from a wide variety of courses and internship opportunities, students will gain in-depth knowledge in an area of biomedical engineering aligning with the Institute of Biomaterials & Biomedical Engineering's (IBBME) four established applied research fields (outlined in section 2.2).

Graduates of the Master of Engineering in Biomedical Engineering program will have gained the hands-on experience necessary to take on real-world design challenges with a keen ability to translate ideas into commercial realities. For instance, they will be able to play key roles in the commercialization of biomedical devices used for the early diagnosis of diseases, promote the regeneration or repair of damaged tissues and organs, rehabilitate injured patients, promote the independence of people with physical and cognitive disabilities, and support their caregivers.

The M.Eng. is the recognized professional degree in the discipline of engineering for applicants who want to expand upon their skills for professional practice. The Biomedical Engineering M.Eng. program will appeal to recent graduates who have a great interest in pursuing careers as professional engineers (rather than training as researchers), and feel that the M.A.Sc./Ph.D. research programs are not the most direct paths to achieve their goals. It will also appeal to seasoned professionals who want to enter the medical device industry. FASE currently offers six M.Eng. degree programs; the proposed Biomedical Engineering program will be the seventh¹.

As Canada's premier graduate biomedical engineering program and one of the leading BME programs in North America, IBBME is uniquely positioned² to address the growing demand for a skilled workforce in the biomedical device industry through the proposed Biomedical Engineering M.Eng. program.

¹ The recent Master of Engineering in Cities Engineering and Management confers a distinct degree, the M.Eng. C.E.M.

² Invest in Canada (2012). Medical Devices: Canada's competitive advantages

The growth of IBBME over the past decade provides a strong support base and multiple opportunities to facilitate this role, as discussed in section 2.2. Existing resources will support the design applications in the curriculum, and significant commercialization infrastructure centres – in which core IBBME faculty members play important leadership roles – are on or near the main University campus and can offer additional internship opportunities outside IBBME for students in the program. IBBME's annual operating budget is supported by U of T's Faculties of Applied Science and Engineering, Medicine, and Dentistry; these Faculties also directly support IBBME's graduate programs in terms of scholarships, graduate courses, leadership training, academic resources, research facilities and career support.

The proposed program is a full-time, three-term, non-thesis professional degree based on coursework concentrated in three pillars: biomedical engineering technology, entrepreneurship. biomedical sciences, and commercialization and Program requirements include two new core entrepreneurship courses (BME1800H and BME1801H) which will be taught in the context of biomedical device commercialization, and an internship in applied research (BME1899) in the biomedical industry or in academic laboratories where students will be expected to develop a prototype for a device to address an important problem in healthcare. Since students in the program will be required to reach a very high level of technological achievement, the "M.Eng." degree accurately captures the strong design and industrial foci of the proposed program.

The program will be housed within IBBME in the Faculty of Applied Science & Engineering. It is anticipated that enrolment in the program will grow by approximately ten students per year during the first five years, resulting in a total of nearly 50 students in the program by the fifth year. This is compatible with the Faculty's enrolment targets.

2 Program Rationale

2.1 Overview

A Biomedical Engineering program within the existing FASE M.Eng. degree is being proposed to address the increasing industry demand for engineers who can design and commercialize biomedical products to solve medically-relevant problems, or assist in the maintenance of health.

An aging population and growing expectations for health and quality of life in our society have resulted in an increasing need for cost-effective biomedical devices for rehabilitation, prevention, treatment, and diagnosis. These new technologies support healthier living, enhance resources for aging populations still living in their homes, and address broad-scale health care challenges such as diabetes, cancer and heart disease, among others.

As a result of this demand, the field of biomedical engineering – the application of engineering principles and design concepts to medicine and biology for healthcare

purposes – has grown substantially. Engineering principles are now being applied in hospitals, nursing homes, diagnostic laboratories, pharmacies, medical device manufacturing, rehabilitation services, research laboratories, and many other areas. The projected world market for medical devices is expected to grow 8 to 20% from 2010 to 2020, and Canada's share of world exports could potentially reach 15% by the end of that period¹.

In Canada, however, this growth is hindered by the lack of skills and training required to apply engineering design to address challenges in health and disease, conduct applied research, recognize business opportunities, and understand the challenges of moving technology forward in a regulated environment. This requires urgent attention to ensure the competitiveness of our medical device industry.

This shortage is mainly a result of the expansion of biomedical engineering from highly specialized research programs and technologies with limited access to common users, into mainstream, cost-effective technologies. Exacerbating this is the lack of applied research and business training provided at the undergraduate level, or in conventional M.A.Sc. and Ph.D. biomedical engineering programs.

The need is now critical¹ for a professional graduate program that can equip engineers with the skills necessary to seize the exciting opportunities offered by this growing and changing industry.

2.2 Context at the University of Toronto

Through IBBME, the University of Toronto currently offers three graduate-level entry points into biomedical engineering:

- 1. Master of Applied Science (M.A.Sc.) thesis-based degree, heavily focused on research
- 2. Doctor of Philosophy (Ph.D.) thesis-based degree, heavily focused on research
- 3. Master of Health Science (M.H.Sc.) in Clinical Engineering intense clinical theme with students doing rotations in surgical suites, rehab facilities, dialysis labs, etc. in preparation to manage clinical engineering resources, primarily within hospitals.

While the M.A.Sc. and Ph.D. programs prepare researchers to innovate solutions to the world's most pressing health care challenges, they do not enable engineers to gain the skills and training required to design, manufacture and commercialize biomedical devices.

The M.H.Sc. in Clinical Engineering relates most closely to the proposed degree: both are enhanced by connections with health-relevant activities, and are aided by

¹ Medical Devices: Challenges and Opportunities for Enhancing the Health and Wealth of Canadians (April 2011), prepared by Medical Devices Innovation Institute (MDI²) in Consultation with National Stakeholders.

relationships between IBBME and its partners.¹ However, unlike the M.H.Sc. in Clinical Engineering, the proposed program focuses on device fabrication and the entrepreneurial aspects of biomedical engineering, and prepares graduates to work in an industrial, rather than clinical, setting. Moreover, while the proposed M.Eng. includes an option of studying human physiology and human factors, it is mandatory for the M.H.Sc. program. Conversely, business courses are not part of the regular curriculum for M.H.Sc. students, while they are a requirement in the M.Eng. program.

The M.Eng. is further distinguished from the M.H.Sc. program as its students will conduct an internship in one of IBBME's four major intersecting research fields that span the breadth of the biomedical engineering continuum and reflect the distinct, demonstrable and collective strengths of the program's faculty members:

- 1. Neural/Sensory Systems Rehabilitation
- 2. Biomaterials, Tissue Engineering and Regenerative Medicine
- 3. Nanotechnology, Molecular Imaging and Systems Biology
- 4. Engineering in a Clinical Setting

This option, while already established for the M.A.Sc. and Ph.D. programs, is not available in the M.H.Sc. program.

Finally, students in the M.H.Sc. program graduate with the experience and exposure to the clinical environment that allows them to apply for accreditation as a Professional Clinical Engineer. The proposed Biomedical Engineering M.Eng. program will not offer that option.

Rationale for M.Eng. Degree

The extent of the differences between the existing graduate degrees offered in IBBME and the proposed Biomedical Engineering program are such the former cannot accommodate the requirements of the proposed program. Instead, as the recognized professional degree for engineers, the Master of Engineering will allow applicants to expand upon their skills for professional practice. Conferring an M.Eng., the program will build upon IBBME's existing multidisciplinary breadth of expertise in the bioengineering field, and train its graduates to design, manufacture and commercialize medical devices.

Comparison of IBBME's Graduate Programs

The following table compares the graduate programs currently offered at IBBME with the proposed Biomedical Engineering program.

Table 1: The Path of Graduate Biomedical Engineering at the University of Toronto				
ProgramM.A.Sc. /Ph.D. in Biomedical EngineeringM.H.Sc. in Clinical EngineeringM.Eng. in Biomedical Engineering (proposed)				

¹ The Institute for the Advancement of Technology for Health (Techna), the Intelligent Design for Adaptation, Participation and Technology (IDAPT) Centre at Toronto Rehabilitation Institute (TRI), and the Centre for Research in Advanced Neural Implant Applications (CRANIA), among others.

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Target Cohort	Engineering, Life or Physical Sciences undergraduate students	Engineering undergraduate students	Engineering undergraduate students Engineers with industrial experience
Courses	2.0 FCE/3.0FCE One core course on bioengineering science: BME1450 At least one 0.5 FCE in a life sciences course for a student with an engineering background and one 0.5 FCE in an engineering course for a student with a background in life sciences Wide selection of science and engineering courses inside or outside BME	4.0 FCE Defined curricular path	Course requirements total 3.5 FCE Two core courses on biomedical device development: BME1800 and BME1801. At least 1.0 FCE in each of the three lists of selected courses (see Appendix A). a) Engineering BME technology b) Commercialization and Entrepreneurship c) Biomedical Sciences
Curriculum	Research thesis-based	Course, clinical internships, and thesis- based	Course and project- based (internship worth 1.5 FCE)
Program Fields	Four fields (defined in section 2.2) plus a 5th field in clinical engineering for the Ph.D. program only	No distinct fields	Four fields (defined in section 2.2)
Career Pathway	Academic and other	Hospital- and clinical- based	Industry and consulting

Positioning of IBBME

As an interdisciplinary unit integrated within three Faculties at the University of Toronto, (Applied Science & Engineering, Medicine, and Dentistry), IBBME is uniquely positioned to offer the M.Eng. in Biomedical Engineering program. These Faculties directly support IBBME's graduate programs in terms of scholarships, graduate courses, leadership training, academic resources, research facilities and career development.

IBBME's vision is to be established among the top world-leading biomedical engineering research institutes/departments, and to be recognized as having one of the most innovative pedagogical programs combined with high-impact research within a unique trans-disciplinary environment. Its primary mission is to provide the University and its Toronto-area clinical partner institutions with excellent and comprehensive education for its trainees, and to perform internationally-ranked research in biomedical engineering,

with an emphasis on establishing impact in healthcare and innovation in the biomedical field.

The growth of the Institute over the past decade provides a strong support base and multiple opportunities to facilitate this role. Core IBBME faculty members play important leadership roles in significant infrastructure initiatives such as CRANIA, the Centre for Commercialization in Regenerative Medicine (CCRM), the Donnelly Centre (DC), Techna, and the new Ted Rogers Centre for Heart Research; these organizations on or near the main University campus can offer additional internship opportunities outside IBBME for its M.Eng. students.

The proposed program builds upon resources already established in IBBME. Its teaching laboratory, formalized research program generating \$12-14M/year in research activity, 17 active spin-off companies, three commercialization infrastructure centres (see above), and extensive hospital affiliations can support the design applications in the curriculum, while the newly-established FASE programs in global engineering, business and mechatronics have been relatively untapped by the current Biomedical Engineering programs.

The program is also well positioned to take advantage of IBBME's long-standing academic, industrial and hospital partnerships and teaching resources. In addition to offering its own graduate courses within the Institute, IBBME's core faculty have developed a large number of 500- and 1000-level graduate courses within the Faculty's departments of Chemical Engineering & Applied Chemistry, Materials Science & Engineering, Electrical & Computer Engineering, and Mechanical & Industrial Engineering.

2.3 Consistency with Academic Plans

During the preparation of its 2010-2015 academic plan, IBBME concluded it should engage further in professional biomedical engineering education at the graduate level in order to complement the training of an established undergraduate engineering cohort.

The proposed Biomedical Engineering program within the existing M.Eng. degree aligns with a key priority in the resulting academic plan, namely to "expand the graduate curriculum in order to provide a greater innovative/biodesign/entrepreneurship training experience, within the framework of IBBME's greater Toronto area (GTA) network and with international collaborators." This is also well-aligned with the Faculty's research academic plan, which recognizes that:

"The challenges facing our healthcare system place financial strain on government resources and are pushing the frontiers of biomolecular science and patient-specific therapies and diagnostics. Integration of engineering practices with medical sciences, as well as the existing collaboration between Engineering, the Faculty of Medicine, and the University affiliated hospitals, helps us identify and study more efficient diagnostic strategies and better disease-monitoring leading to an enhanced quality of life."

Establishing the Biomedical Engineering program is also in line with the core values of

the Faculty of Medicine's current and on-going strategic planning, which emphasizes "integration, collaboration and partnerships" as well as knowledge translation and social responsibility. This proposal speaks to all of these themes, given that the program benefits from IBBME's partnerships with Toronto hospitals, and its focus on translational research with an emphasis on active patient involvement integrates technology with society.

The proposed M.Eng. is also well aligned with the Faculty of Dentistry's current academic plan, which is focused on using its interdisciplinary strength to capitalize on strategic alliances to establish new partnerships and build an environment of growth that will lead to the translation of knowledge into the clinic. Towards these goals, Dentistry has established a Clinical Studies Centre, and has retained several of IBBME's faculty to teach their graduate courses.

2.4 Degree Nomenclature

The proposed program will be one of a number within the established Master of Engineering degree offered by the Faculty of Applied Science & Engineering. These include M.Eng. programs in:

- Aerospace Science and Engineering
- Chemical Engineering and Applied Chemistry
- Civil Engineering
- Electrical and Computer Engineering
- Materials Science and Engineering
- Mechanical and Industrial Engineering

The new program will be similar to the established M.Eng. programs in terms of duration, entrepreneurship content and learning outcomes (see section 9). In addition, like M.Eng. degrees offered elsewhere in North America, the proposed focuses on the development and application of leading edge engineering technologies.

As with the other FASE M.Eng. programs, the proposed program will not prepare students for licensure as Professional Engineers (P.Eng) under the *Ontario Professional Engineers Act R.S.O. 1990*, administered by Professional Engineers Ontario (PEO). Licensure as a P.Eng. typically requires that applicants hold an undergraduate engineering degree from a Canadian Engineering Accreditation Board-accredited program, fulfil the engineering work experience requirements, and successfully complete PEO's professional practice examination.

2.5 Distinctiveness

Just as there are currently no programs at the University of Toronto similar to the proposed Biomedical Engineering M.Eng., there are no programs elsewhere in Canada that focus on the design and commercialization aspects of biomedical device development, or require a similar level of technological achievement of students.

While other Canadian programs similarly focus on biomedical discovery and combine entrepreneurship and science, the proposed M.Eng. is distinguished by its much stronger emphasis on engineering design and technology, which is typical of an M.Eng.

degree. In the proposed program, students are required to design a medical device: this is optional in the other programs where students can focus on other business or scientific aspects.

Moreover, students in the proposed program will take courses and conduct an internship in one of the four previously-defined fields that represent applied research strengths at IBBME; these fields are not formally defined in any other external program.

Comparison with Ontario Programs

Graduate programs in Ontario that focus on biomedical discovery include:

- M.H.Sc. in Translational Research (MHSc in TR) at the Institute of Medical Science, Faculty of Medicine (U of T). Approved by the Ministry of Training, Colleges and Universities, this program is scheduled to commence in September 2015. Situated in the Health Sciences degree program, it aims at bridging the gap between laboratory research and clinical practice, and has a strong emphasis on generating ideas and the development of multidisciplinary communication skills. While graduates of this M.H.Sc. and the proposed program develop quite different skill-sets, the programs are complementary in that both present an opportunity for the development of synergistic interactions between students and instructors, facilitated by being offered at U of T. (http://www.ims.utoronto.ca/programs/professional/trp_home.htm)
- Master of Biotechnology (M.Biotech) at the University of Toronto Mississauga (UTM). Combining science and business courses with an internship, this program is much broader in scope than the proposed Biomedical Engineering M.Eng., as it exposes students to many other aspects of biotechnology and biomolecular sciences, such as those related to the pharmaceutical, environmental and agricultural industries. (<u>http://www.utm.utoronto.ca/mbiotech/</u>)
- Combined Bachelor-Master Program in Biomedical Discovery and Commercialization at McMaster University. This program was inaugurated in January 2015, and includes a strong emphasis on drug discovery and development. (<u>http://bdcprogram-mcmaster.ca/</u>)
- Master of Medical Biotechnology at the University of Windsor. Located in the Department of Chemistry and Biochemistry, this program focuses on drug discovery and the pharmaceutical industry. (http://www1.uwindsor.ca/professional/master-of-medical-biotechnology-0)
- M.Eng. Program in Engineering in Medicine at Western University. With the exception of two entrepreneurship courses, this program is almost exclusively comprised of engineering courses and does not include an internship opportunity. (http://www.eng.uwo.ca/gradstudies/MEng_Medicine.htm)

With the exception of Western's M.Eng. program, the differences between these programs and the proposed are also reflected in the admission requirements. The requirements for these programs are defined primarily for students with a minimum of a bachelor's degree in life sciences, chemistry or related fields, while in the proposed

program, the students must have a minimum of a bachelor's in engineering. These admission requirements are in alignment with the program requirements, as it is felt that a strong engineering design background will maximize the chances of a student's success in the program, and ensure that he or she can progress sufficiently to meet the internships requirements of device prototyping.

Comparison with International Programs

Some international universities have developed innovative programs similar to the proposed M.Eng., demonstrating a global need for this type of education. Examples of similar international programs include:

- Duke University offers an innovative program combining biomedical engineering with entrepreneurship training and internships.
- University of Cincinnati's M.Eng. in Biomedical Engineering/Medical Device Innovation program (inaugurated in the fall of 2015) specializes in biomedical devices and includes both business courses and a capstone project.
- Stanford University's renowned Biodesign Innovation Program offers graduate courses and various activities related to the design of medical devices.
- Northwestern University's NUvention Medical Innovation course is aimed at graduate and undergraduate students.
- Johns Hopkins University's M.A.Sc. in Bioengineering Innovation & Design focuses on medical device design and commercialization.
- UC Berkeley's M.Eng. in Bioengineering combines courses in engineering and entrepreneurship with a capstone project.
- The U.K.'s University of Strathclyde offers an M.Eng. in Biomedical Engineering.
- Berkeley and the University of California in San Francisco offer a joint Master of Translational Medicine (MTM) degree, which is similar to the University of Toronto's M.H.Sc. in Translational Medicine described earlier.

IBBME and FASE will capture best practices emerging from its global peers in the proposed M.Eng. program.

3 Need and Demand

There has been a significant increase – both on the job and in education markets – for engineers trained in the field of biomedical engineering. The U.S. Bureau of Labor Statistics forecasts a 72% growth rate for jobs in the U.S. alone during the period 2008 to 2018, and identifies biomedical engineers as one of the fastest-growing occupations. At IBBME, the number of graduate students in the biomedical engineering programs (M.A.Sc./Ph.D. and M.H.Sc.) has almost quadrupled over the past decade to nearly 300 graduate students, a growth rate of 15% per year over the past five years.

IBBME's current graduate programs do not address this well-documented shortage of workers with expertise in medical devices (nor do other programs in Canada); this is the major factor preventing Canada from occupying an important position in this industry. In 2008, 60% of the medical device companies in Canada were based in Ontario and more than a third of them had unfilled positions, with more than half reporting a shortage of skilled workers³. MEDEC (the national association for the Canadian medical technology industry) writes that "a shortage of highly educated and skilled workers will limit the growth of Canada's medical devices industry."¹

This is the right time for the proposed program. The University of Toronto is also the right place to develop it, as host of the premier graduate biomedical engineering research program in Canada and one of the leading programs in North America. Toronto is poised to become a vital centre of commercialization if it can generate the skilled applied workforce: IBBME alone has 17 active start-up companies in this area, each with 2-25 employees, and its faculty have research collaborations with close to 50 different companies in this sector. Many other local, national, and international companies are affiliated with researchers and investigators across the city's hospital network, greatly facilitating the availability of internship positions for students registered in the proposed program.

Through exit surveys of M.A.Sc./Ph.D. students, we know that IBBME's graduates have found employment in a diverse and wide-ranging spectrum of careers spanning the health care continuum. The program will prepare students particularly well for the biomedical device industry, since they will graduate with an increased understanding of the regulatory requirements, the commercialization process and how to conduct applied research in specific areas. Moreover, students will have acquired significant hands-on experience and the ability to translate ideas into commercial realities.

Given the exposure to cutting edge biosciences or engineering, some students may decide to pursue a Ph.D. Although IBBME already provides a direct entry path for highly accomplished undergraduates and would do the same for professional Master's students, the M.Eng. would not be considered a conventional entry point for the Ph.D. program.

³ Segmenting the Data-Regional labour market information on biotechnology in Canada. 2008 (<u>www.biotalent.ca</u>)

¹ Medical Devices: Challenges and Opportunities for Enhancing the Health and Wealth of Canadians (April 2011), prepared by Medical Devices Innovation Institute (MDI²) in Consultation with National Stakeholders.

4 Enrolment

The proposed program is projected to reach a steady state of 50 students by 2020-2021, after four years of increasing enrolment of ten students a year. It is anticipated that most of the students will be domestic (around 70%) and all will be full-time. The increased enrolment in FASE is included in the Faculty's enrolment projections for M.Eng. degree programs during the academic years 2015-2016 to 2018-2019 (FASE Enrolment Report 2013-14), as it includes an average increase in head counts of ten students per year during that period (mostly an increase associate with domestic students enrolment).

Year in program	Academic year						
	2016-17	2017-18	2018-19	2019-20	2020-21*	2021-22	2022-23
1	10	20	30	40	50	50	50
Total	10	20	30	40	50	50	50

Table 2: Graduate Enrolment Projections

5 Admission Requirements

The proposed Biomedical Engineering program within the existing M.Eng. is designed primarily for recent graduates from a broad range of undergraduate engineering programs such as chemical, material science, electrical and mechanical, and in particular those with a minor in biomedical engineering, bioengineering or the equivalent. It will be well suited for recent graduates who want to enhance their current skills, and appropriate for seasoned professionals who want to enter the medical device industry. Admission of students from other science programs will be approved on a case-by-case basis by the program director. The program is expected to be particularly attractive to students who have completed FASE's undergraduate minor in biomedical engineering.

Students will require at least an A– (80%) average in the last two years of their undergraduate engineering degree, and some preliminary exposure to biomedical engineering-related curriculum in their undergraduate training in at least one of the following areas:

- engineering biology
- physiological control systems
- bio-instrumentation

- innovation, research and development applied to design
- biomechanics

It is possible that some meritorious applicants may not have had sufficient exposure to life sciences and human biology. In that case, they will be required to take a physiology course (such as JBP1022H) during their first term in the program, as part of their course credits.

Through their internships, graduates from the proposed program will be expected to display expertise in at least one of the four biomedical engineering research fields represented at IBBME:

- 1. Neural/Sensory Systems and Rehabilitation
- 2. Biomaterials, Tissue Engineering and Regenerative Medicine
- 3. Nanotechnology, Molecular Imaging and Systems Biology
- 4. Engineering in a Clinical Setting

These admission requirements will help ensure that students entering the program have prior engineering and science backgrounds sufficient to attain this level of expertise upon graduation, and the pre-requisite skills and knowledge to achieve meaningful advances in their project internship.

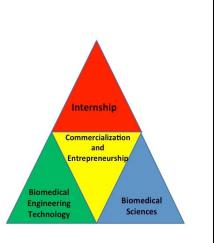
M.Eng. students must enrol in the full-time program from the fall session in September. They must register continuously, including the summer session, until completion of the applied research project (internship) and required course credits.

There will be a BIU assignment to this program per the current fulltime M.Eng. program in FASE. The M.Eng. will require successful completion of ten half-course equivalents, of which seven must include formal half-courses and an M.Eng. internship (equivalent of 1.5 FCE).

6 Program Requirements

6.1 Overview

The proposed Biomedical Engineering program within the existing M.Eng. degree is aimed at individuals with an undergraduate degree in engineering who plan to move directly into industry to work in biomedical device development, specifically to design and commercialize biomedical devices. The program is a three-session, non-thesis degree based on coursework in engineering, biomedical sciences and entrepreneurship. The program requirements also include an internship in applied research in the industry or in an academic research laboratory.



The proposed M.Eng. spans the entire discipline of biomedical engineering. Through their research internship, students will be exposed to at least one of the four previouslymentioned applied research fields in IBBME, but will not specialize in any particular domain.

Students will build their curriculum from a menu of courses drawn from three core pillars: (1) biomedical engineering technology; (2) commercialization and entrepreneurship; and (3) biomedical sciences. The different courses available in pillars (1) and (3) align with IBBME's applied research fields (see Appendix A), which reflect the Institute's multidisciplinary nature and its world-renowned graduate programs and faculty.

The program is made up of a total of 5.0 full-course equivalent (FCE) credits composed of seven half-credit courses, or 3.5 FCE (30 hours each), followed by a three half-credit equivalent internship (1.5 FCE) that will put into practice the knowledge base in engineering, biomedical sciences and commercialization acquired from the three base pillars. Courses in engineering are half-courses. Throughout this proposal, a course will refer to a 0.5-weight course. Of the seven courses, a minimum of 1.0 FCE must come from each of the three pillars (with the one additional half-course from any one of the three pillars).

Session	Course/activities	
	Submit "Curriculum Plan" to the program director by August	
Session 1 Fall (2.0 FCE)	 BME1800: Biomedical Product Development I (0.5 FCE) Choose one half-course from the BME Engineering Technology pillar and one from the Biomedical Sciences pillar. Choose one additional half-course in any of the three pillars (BME Engineering Technology, Biomedical Sciences, Commercialization and Entrepreneurship) Submit outline of internship proposal to the program director (end of session 1) 	
Session 2 Winter (1.5 FCE)	 BME1801: Biomedical Product Development II (0.5 FCE) Choose one half-course from the BME Engineering Technology pillar and one in the Biomedical Sciences pillar Submit detailed internship proposal and Gantt chart to the program director (mid-session 2) 	
Session 3 Summer	BME1899: Internship in Applied Research (1.5 FCE) in one of four research fields:	
(1.5 FCE)	 Neural/Sensory Systems Rehabilitation Biomaterials, Tissue Engineering and Regenerative Medicine Nanotechnology, Molecular Imaging and Systems Biology Engineering in a Clinical Setting 	

The internship will normally be scheduled during the third term, or summer session. Students will be made aware that courses are not commonly offered during the summer session, and that any change to the program order may risk affecting time to completion.

6.2 Course Requirements

Because the courses offered in the engineering and bioscience pillars are drawn from IBBME's four research fields, students will have proactively select courses that best align with their internship plans (section 7.2). Samples of appropriate curriculum pathways have been prepared for each of the four research fields (Appendix A).

Of the seven courses, four (2.0 FCE) must be BME (or joint BME i.e. JxB) courses. The remaining three courses (1.5 FCE) can be taken from any other department associated with the program (this does not consider the 1.5 FCE associated with the internship, BME1899). If students wish to enrol in other U of T courses, they must obtain permission from the program director. All courses must be graduate-level, which includes 500- and 1000- courses. Students can take a maximum of one 500-level course. Two course failures will result in a recommendation to the School of Graduate Studies to terminate a student's registration in the program.

A list of courses relevant to the proposed program in presented in Appendix A.

6.3 Internship Requirements

The knowledge gained by students in the first two terms will be applied in a real-life context as they face the challenges of medical device development through a required internship in applied research.

The internship is typically undertaken during the summer, and students must be registered in the program. By the end of session one (December), students will have identified an internship supervisor and will submit an outline of their project proposal to the program director for approval. The program director will determine if the project is compatible with the objectives and duration of the program and aligns well with one of IBBME's four applied research fields. In some cases, this may require the program director to visit the sites of the internships and meet with potential internship supervisors. At the end of the first half of session two (end of February), students will submit a detailed internship proposal and a Gantt chart to the program director who will determine if the project is compatible with the program timeline and can be completed within four months.

Students may undertake a work term exchange program with another institution; define an independent project; undertake a project within the IBBME consortium of partners and access resources within that cohort; carry out a project in industry, private consulting firm or government institution; or work as part of an interdisciplinary team to address a pressing issue brought forward to the institute.

It is expected that students will cover four important aspects of biomedical device development during their internship:

- 1. Clinical, medical or health needs assessment (need of healthcare providers and patients). For this project component, the students will apply concepts manly related to their Biomedical Science courses.
- 2. Concept development (literature and patent searches, input from experts). For this project component, the students will apply concepts related to their Engineering, Entrepreneurship, Biomedical Science courses.
- 3. Design and prototyping. For this project component, the students will apply concepts mostly related to their Engineering and Biomedical Sciences courses.
- 4. Development of business models. For this project component, the students will apply concepts mostly related to their Entrepreneurship courses.

The internship will be evaluated by both the internship supervisor at the host organization and the program director. Upon completion of their project, students will submit a technical project report to the internship supervisor and the program director, who will evaluate the report. Students must submit their final report before a degree recommendation can be forwarded to School of Graduate Studies. Students will receive a pass/fail mark for their Internship (BME1899) based on the four aspects defined above, as well as the five criteria defined in section 7.2. The program director will be responsible for the final decision regarding the mark the student will receive for the internship.

See Appendix A for a full list of the course numbers and titles, indicating whether they are new or existing, as well as samples of curriculum pathways.

See Appendix B for the proposed graduate calendar copy.

7 Program Description

7.1 Distinctive Elements of the Proposed Program

The professional Biomedical Engineering program will include the following features:

- Two new core biomedical engineering entrepreneurship courses (BME1800 and BME1801) which will include modules on "Regulatory Requirements" and "Biomedical Engineering Ethics".
- The requirement for students to demonstrate a very high level of technological achievement during their internship in applied research in biodesign (BME1899)
- The ability of students to obtain an M.Eng. with a broad selection of biomedical engineering-specific courses (see section 2.2)

- Capitalization on the most extensive and comprehensive biomedical engineering unit in Canada, and one of the top in North America. IBBME has the ability to leverage a significant number of resources both at the University and in the hospitals
- Clear branding of a professional industrial biomedical engineering program because of its focus on biomedical device development, enhanced by connections with clinically relevant activity (aided by links to Techna, IDAPT at TRI, CRANIA and other partnerships in IBBME)
- Relevance to current market situations that allow students to tap into Ontario's manufacturing base

Whereas the province of Ontario's Quality Assurance Framework requires that students complete a minimum of 2/3 of their courses at the graduate level, the University of Toronto requires graduate students to complete all of their course requirements at the graduate level. The proposed program complies with this requirement.

The program length relative to the number of credits is similar to other FASE M.Eng. programs, however, unlike other M.Eng programs, the Biomedical Engineering program will be offered only on a full-time basis due to the research-intensive requirements of the internship.

7.2 Internship Administration

IBBME already has significant experience with the administration of internships since they are important components of the M.H.Sc. program in Clinical Engineering. The graduate office will actively seek internship positions throughout the year for all students in the Biomedical Engineering M.Eng. program. Students will also be encouraged to find internship positions on their own relating to one of the Institute's four research fields; however, the program will be responsible for assigning internships, so no student will be without one.

Students will be required to submit a "Curriculum Plan" before the beginning of their first session in the program (i.e. by the beginning August). In this form, they will select their field of interest (one of the four IBBME fields) and identify courses for each session of the program. The program director will review and approve each Curriculum Plan (in parallel with the information included in the student's file in terms of previous studies and experiences) and suggest alternatives, if necessary. This process will offer opportunities for students to obtain guidance from the program director early in the program. At the end of the first session in the program (December), the program director will organize a mandatory workshop to inform students about the preparation, requirements related to the internships, and the expectations of the different stakeholders (including intellectual property issues).

As mentioned, a research proposal for the internship must be approved by the program director during the terms preceding the commencement of the internship. Both the internship supervisor and student must provide signatures to indicate agreement on the

specifics of the internship and its learning objectives. The form also specifies the responsibilities of the students, internship supervisors, and the M.Eng. program office. Currently in the M.H.Sc. in Clinical Engineering, students are required to submit a biweekly report to the program director during their internship, and the same approach will be implemented in the M.Eng program. Every two weeks, each student will be required to submit brief updates on their project which will be signed by the internship supervisor and forwarded to the program director. The program director will use this documentation to ensure that the internship activities remain aligned with the objectives of the program and that the progress is satisfactory and the expected timeline for the internship (four months) is realistic.

Upon completion of the internship, students are required to write a report covering the four main aspects of biomedical device development (section 6.3), and their final results. The report should be approximately 30 pages (double-spaced) and should be submitted to the internship supervisor and program director within two weeks of finishing the internship. Internship supervisors will be asked to complete an evaluation of the student's work at the completion of the internship. The assessment of a student's work may take into account the following performance indicators:

- 1. The student has displayed expertise in at least one of the fours fields of biomedical engineering represented at IBBME
- 2. The student can reflect upon overall design strategy and has identified areas where alternative or better approaches could have been used (if applicable)
- 3. The student has considered the cost-effectiveness of his/her approach
- 4. The student has considered the validity of his/her assumptions.
- 5. The student has appreciated potentially conflicting interests or points of view (patients, physicians and business persons)

8 Fields/Concentrations

Students in the M.Eng. program will choose one of four fields in biomedical engineering in which to conduct their internship and take courses. IBBME's M.A.Sc. and Ph.D. programs already include these fields, which represent well-established areas of research strength in the Institute:

- 1. Neural/Sensory Systems Rehabilitation
- 2. Biomaterials, Tissue Engineering and Regenerative Medicine
- 3. Nanotechnology, Molecular Imaging and Systems Biology
- 4. Engineering in a Clinical Setting

These fields were formally approved for the M.A.Sc. and Ph.D. programs by the FASE Council in December 2013.

9 Degree Level Expectations, Program Learning Outcomes and Program Structure

The proposed program addresses the following FASE M.Eng. degree level expectations (DLEs) and learning objectives. The DLEs are common across all M.Eng. degrees offered at the University of Toronto, although they may be defined differently and/or be satisfied in different activities depending on the discipline. In the proposed program, DLEs are satisfied via a combination of courses and an internship.

Table 3: Master of Engineering DLEs

This Master of Engineering in Biomedical Engineering is awarded to Master of Engineering students who have demonstrated:

1. Depth and Breadth of Knowledge A systematic understanding of engineering and applied science knowledge including, where appropriate, relevant knowledge outside the field and engineering discipline, and a critical awareness of current problems and/or new insights, much of which is at, or informed by, the forefront of their engineering or applied science discipline.	 Depth and breadth of knowledge is defined in the Biomedical Engineering program as expertise in at least one field of biomedical engineering and an understanding of the challenges of moving technology forward in a regulated environment. This is reflected in students who are able to: Apply mathematics, life sciences, physical sciences, and engineering to biomedical device development (e.g. to develop a concept for a device and a design a prototype). Appreciate potentially conflicting interests or points of view (patients, physicians and business persons). 	 The program design and requirement elements that ensure these student outcomes for depth and breadth of knowledge are: Coursework in engineering, biomedical sciences and entrepreneurship. A core entrepreneurship course which will be a survey course that will cover a variety of technologies and applications. Captured in the internship where students will cover four important aspects of biomedical device development (need assessment, concept development, design and prototype, business models).
 2. Knowledge of Methodologies A conceptual understanding and methodological competence that: (a) Enables a working 	Knowledge of Methodologies is defined in the Biomedical Engineering program. as a conceptual understanding and methodological competence that:	 The program design and requirements that ensure these student outcomes for knowledge of methodologies are: Outstanding instructors whose

FASE MASTER OF ENGINEERING (M.Eng.) DEGREE LEVEL EXPECTATIONS (Based on the DLEs approved by the Faculty of Applied Science & Engineering in 2011)	FASE MASTER OF ENGINEERING (M.Eng.) PROGRAM LEARNING OBJECTIVES AND OUTCOMES Specific to the proposed M. Eng. in Biomedical Engineering	HOW THE PROGRAM DESIGN AND REQUIRED ELEMENTS SUPPORT THE ATTAINMENT OF STUDENT LEARNING OUTCOMES Specific to the proposed Biomedical Engineering	
 comprehension of how established techniques of inquiry are used to interpret knowledge in the discipline. (b) Enables a critical evaluation of current developments in the discipline. (c) Enables a treatment of technical issues and judgments based on established principles and techniques. 	 Enables a working comprehension of how experimental methods and data analysis methods can be used to assist the design of biomedical devices and optimize them. Enables a critical evaluation of current developments in the at least one field of study at IBBME and familiarity with viewpoints of experts in other disciplines (e.g. medicine and business). Enables a treatment of technical issues and judgments based on principles of engineering designs and method of data analysis. This is reflected in students who are able to: Develop a concept for a medical device based on literature and patent searches, input from experts. Consider and evaluate the validity of the assumptions on which the device concept is based. Critically and comprehensively assess a complex problem from the viewpoints of stakeholders. Distinguish between what is known and what is unknown and subsequently elaborate a research plan that will shed light on the unknown. Evaluate a biomedical device design strategy and identify areas where alternative or better approaches could be used, to consider and evaluate 	 expertise will bring both theory and practice to the classroom. Course papers and case studies for the Engineering, Commercialization and Entrepreneurship, and Biomedical Sciences, where students will have the opportunity to explore in-depth topics. Captured in the internship where students will cover four important aspects of biomedical device development (need assessment, concept development, design and prototype, business models). 	

FASE MASTER OF ENGINEERING (M.Eng.) DEGREE LEVEL EXPECTATIONS (Based on the DLEs approved by the Faculty of Applied Science & Engineering in 2011)	FASE MASTER OF ENGINEERING (M.Eng.) PROGRAM LEARNING OBJECTIVES AND OUTCOMES Specific to the proposed M. Eng. in Biomedical Engineering	HOW THE PROGRAM DESIGN AND REQUIRED ELEMENTS SUPPORT THE ATTAINMENT OF STUDENT LEARNING OUTCOMES Specific to the proposed Biomedical Engineering
3. Level of Application of Knowledge	Application of Knowledge is defined in the Biomedical Engineering	The program design and requirements that ensure these
Competence in the application of an existing body of data in the critical analysis of advanced problems or issues. Here, advanced indicates a difficulty level beyond that encountered at the undergraduate level.	 program. as ability to identify areas where engineering can be used to innovate and solve problems in medicine and develop a plan to achieve this goal. This is reflected in students who are able to: Proficiently identify, formulate, and solve advanced biomedical engineering problems. Use advance techniques, skills, and modern engineering tools necessary for to develop a design and prototype for a new biomedical device. Distinguish between what is known and what is unknown and elaborate a research plan that will shed light on the unknown. Proficiently design and validate experiments, systems, components or processes to meet desired needs. Develop a concept for a biomedical device based on literature and patent searches, input from experts. Critically assess a complex 	 student outcomes for level and application of knowledge are: Exams and projects in the Biomedical Engineering Technology, Commercialization and Entrepreneurship, and Biomedical Sciences pillar courses. Captured in the internship where students will cover four important aspects of biomedical device development (need assessment, concept development, design and prototype, business models). Captured in the internship where students are expected to achieve significant advances in biomedical device prototyping.
	problem with opposite and conflicting perspectives.	
 4. Professional Capacity/Autonomy (a) The qualities and transferable skills necessary for employment requiring: 	Professional Capacity/Autonomy is defined in the Biomedical Engineering program as the ability to translate ideas into commercial realities.	 The program design and requirements that ensure these student outcomes for professional capacity/autonomy are: Individual exams in the
		 Individual exams in the Engineering Technology,

FASE MASTER OF ENGINEERING (M.Eng.) DEGREE LEVEL EXPECTATIONS (Based on the DLEs approved by the Faculty of Applied Science & Engineering in 2011)	FASE MASTER OF ENGINEERING (M.Eng.) PROGRAM LEARNING OBJECTIVES AND OUTCOMES Specific to the proposed M. Eng. in Biomedical Engineering	HOW THE PROGRAM DESIGN AND REQUIRED ELEMENTS SUPPORT THE ATTAINMENT OF STUDENT LEARNING OUTCOMES Specific to the proposed Biomedical Engineering
 i. The exercise of initiative and of personal responsibility and accountability. ii. Decision-making in complex situations. (b) The intellectual independence required for continuing professional development. (c) The ethical behaviour consistent with academic integrity and the use of appropriate guidelines and procedures for responsible conduct in a professional context. (d) The ability to participate meaningfully as leaders in society. 	 This is reflected in students who are able to: Prepare research papers and practicum reports. Integrate professional, social, ethical and environmental considerations in to their decision analysis. Display proficient contemporary technical and scientific comprehension and lifelong learning. Complete the degree requirements in a timely manner. Demonstrate project management skills. Revise plans and adapt to the unexpected. 	 Commercialization and Entrepreneurship, and Biosciences pillar courses. Evaluation of internship report (quality of research proposal, research design and innovation and conclusions). Course papers and case studies for the core Commercialization and Entrepreneurship courses where students will have the opportunity to explore in-depth topics (specifically in the Regulatory Requirements Module and the Biomedical Engineering Ethics Module). Independent work in the internship.
5. Level of Communications Skills The ability to communicate ideas, issues, and conclusions clearly in oral and written form. This includes being capable of constructing a credible argument and presenting it in appropriate formats.	 Communications Skills is defined in the Biomedical Engineering program as an ability for proficient technical and scientific communication. This is reflected in students who are able to: Construct a credible argument and present it in appropriate formats. Generate research and position papers. Make professional presentations. Condense complex topics and analyses into simple and easily communicated messages for a diverse set of stakeholders. 	 The program design and requirements that ensure these student outcomes for level of communication skills are: Course papers and case studies for the Biomedical Technology, Commercialization and Entrepreneurship, and Medical Sciences, where students will have the opportunity to explore in-depth topics. Internship report.

FASE MASTER OF ENGINEERING (M.Eng.) DEGREE LEVEL EXPECTATIONS (Based on the DLEs approved by the Faculty of Applied Science & Engineering in 2011)	FASE MASTER OF ENGINEERING (M.Eng.) PROGRAM LEARNING OBJECTIVES AND OUTCOMES Specific to the proposed M. Eng. in Biomedical Engineering	HOW THE PROGRAM DESIGN AND REQUIRED ELEMENTS SUPPORT THE ATTAINMENT OF STUDENT LEARNING OUTCOMES Specific to the proposed Biomedical Engineering
6. Awareness of Limits of Knowledge Cognizance of the complexity of knowledge, its underlying assumptions, and the potential contributions of other interpretations, methods, and disciplines.	 Limits of Knowledge is defined in the Biomedical Engineering program. as cognizance of the complexity of knowledge, its underlying assumptions, and the potential contributions of other interpretations, methods, and disciplines. This is reflected in students who are able to: Critically assess a complex problem with opposite and conflicting perspectives (patients, physicians and business persons). Prepare a research proposal (practicum) and develop a research plan. Judge when it is necessary to consult experts in specific areas. Recognize limitations of methods used (in medicine, engineering and business). Envision areas for future work/research, or next steps in research and development. 	 The program design and requirements that ensure these student outcomes for level of awareness of limits of knowledge are: Evaluation of internship report (quality of research proposal, research design and innovation and conclusions). For the internship report, one of the performance indicators used will be that the student has the ability to reflect on overall design strategy and has identified areas where alternative or better approaches could have been used, if applicable and the student has considered the validity of his/her assumptions.

10 Assessment of Learning

For the graduate courses in the proposed Biomedical Engineering program, evaluations are based on midterms, final exams, assignments and group projects. Best practices in IBBME encourage graduate course instructors to provide feedback such as marked assignments or tests before the middle (fifth week) of the term to allow for adjustments or remediation on the part of the students or instructors. All graduate courses are subject to student evaluation at the end of the session. The director of IBBME reviews all of the course evaluations so that necessary adjustments in course contents and delivery can be made.

The internship in applied research is a critical part of the program, intended to provide an opportunity for students to apply the concepts learned in their courses to a complex biomedical problem related to the field. During their practicum, students will be expected to complete the following tasks:

- apply concepts mainly related to their Biomedical Science courses to perform a healthcare needs assessment (need of healthcare providers and patients)
- develop a concept for a new biomedical device to address those needs that will require applying concepts related to their Engineering, Entrepreneurship, Biomedical Science courses
- apply concepts mostly related to their Engineering and Biomedical Sciences courses to design a prototype
- apply concepts mostly related to their Entrepreneurship courses to develop a business model for the device

Successful completion of the internship will therefore require that students have learned the relevant materials from their courses and attained the level of performance expected and defined in the program's objectives.

For the internship, students will prepare an interim and final report that will be evaluated by their practicum supervisor and by the program director. After the interim report, a written assessment of the student's progress along with recommended considerations or changes (as appropriate), will be provided.

The final internship report will be submitted to the internship supervisor and program director within two weeks of completing the internship. Internship supervisors will be asked to complete an evaluation of the student's work at the completion of the internship. The assessment of the student will be based on a rubric that takes into account how successfully their work was completed, or whether the student had made significant advances in the four phases of biomedical device development listed above (need assessment, concept development, prototype development and business model), as well as the following performance indicators.

- 1. The student has displayed expertise in at least one area of biomedical engineering
- 2. The student has the ability to reflect on overall design strategy and has

identified areas where alternative or better approaches could have been used, if applicable

- 3. The student has considered the cost-effectiveness of his/her approach
- 4. The student has considered the validity of his/her assumptions
- 5. The student has appreciated potentially conflicting interests or points of view (patients, physicians and business persons)

During the first five years of the program, IBBME will assess the success of the program by following students closely after graduation, and recording employment data. After working a year in industry, graduates will be invited to provide feedback about the program. In addition, employers will be invited to provide feedback about the graduates. If necessary, feedback will be used to adjust the program curriculum to better address the needs of the students and medical device industry.

11 Consultation

This proposal follows the recommendation of a steering committee report commissioned by IBBME and presented to the Dean of FASE in 2012. The report described a strategy for ensuring that the University of Toronto retains active positioning in the area of undergraduate and graduate biomedical engineering training.

The following units contributed to the steering committee report, and will assist in developing and delivering the proposed program's curriculum content:

- Chemical Engineering & Applied Chemistry
- Materials Science & Engineering
- Electrical & Computer Engineering
- Mechanical & Industrial Engineering
- FASE Graduate Office
- FASE Cross-Disciplinary Programs Office
- Institute of Medical Science, Faculty of Medicine

The proposed Biomedical Engineering program was discussed with core IBBME faculty in September 2014, although they had discussed the premise of building an M.Eng. from a minor in biomedical engineering earlier. IBBME has presented this M.Eng proposal to the Faculty of Dentistry, and to the Faculty of Medicine, in particular to the Office of the Vice-Dean Graduate and Life Sciences Education and to the Institute of Medical Science since it will soon offer the new M.H.Sc. in Translational Research. Overall, the feedback was enthusiastic and several suggestions were incorporated in this proposal. Undergraduate students and industry have also been consulted regarding the description of the curriculum content.

In addition, core and cross-appointed faculty located in the following hospitals and research centres are already participating in IBBME's M.H.Sc. in Clinical Engineering (e.g. classroom teaching, placements for internships and research theses). They will be involved in the development of the courses and project practicum components of the

M.Eng. curriculum:

- Toronto Rehabilitation Institute (IDAPT program)
- Sunnybrook Health Sciences Centre
- Holland Bloorview Kids Rehabilitation Hospital
- University Hospital Network-Toronto Western (Techna program)
- Mount Sinai Hospital
- Donnelly Centre for Cellular and Biomolecular Research
- MaRS (Medical and Related Science) technology incubator (Entrepreneurship program)
- Hospital for Sick Children (Centre for Image Guided Innovation & Therapeutic Intervention (CIGITI) and the Hammers and Nails program (to be launched).
- Faculty of Dentistry (Department of Biomaterials)

During the development of this proposal, new opportunities for student placements emerged from discussions with hospital-based partners. Scientists at the Sunnybrook Health Science Centre and the Centre for Imaging Technology Commercialization discussed with IBBME's director, the launch of BioDesign North in collaboration with Stanford University (see section 2.5) and a plan to exploit potential synergies with the proposed M.Eng. program. The Hospital for Sick Children (HSC) and IBBME developed a plan for the Hammers and Nails program, which will be based on a partnership between HSC's surgeons and students in IBBME's master's programs where surgeons will present clinical problems and engineers will develop innovative solutions. The BioDesign North and the Hammers and Nails programs are compatible with shorterterm projects such as those that meet the requirements for the M.Eng. program.

12 Resources

12.1 Faculty Complement¹

The program will initially operate using the current graduate office resources. During the first years of the program, when the total enrolment is expected to be 10-20, the M.Eng. will be added onto the portfolio of the program staff managing the M.H.Sc. in Clinical Engineering; this will greatly facilitates the M.Eng. launch since the internships in the two programs will be administered in a similar manner. As the program grows beyond 20 students, a program director will be recruited specifically for this program. Ideally, this program director should be a professor with strong industrial ties and/or experience in the medical device industry.

While there is an opportunity to capitalize on existing faculty (as instructors or program administrators), we anticipate the additional recruitment of two to three new faculty members. This activity is already written into IBBME's 2010-2015 strategic plan, and partnerships with the industry and hospitals are already in play.

¹ Electronic copies of faculty CVs are available.

Table 4: Faculty Complement

CI: course instructor; TS: thesis supervisor; C/PS: clinical or practice supervisor

Name	Home Department / Unit	Rank	Graduate Faculty Membership Status (e.g., Associate/ Full privileges)	Commitment to other programs	Nature of contribution to this program (CI, TS, C/PS)
Tenured					
Julie Audet	IBBME	Associate	Full		CI, TS
Berj Bardakjian	Electrical and Computer Engineering (51%)	Full	Full	IBBME (49%)	CI, TS
Warren Chan	IBBME	Full	Full		CI, TS
John Davies	Dentistry (51%)	Full	Full	IBBME (49%)	CI, TS
Ofer Levi	IBBME (51%)	Associate	Full	Electrical and Computer Engineering (49%)	CI, TS
Alex Mihailidis	Occupational Science & Occupational Therapy	Full	Full	IBBME	TS
Milica Radisic	IBBME (51%)	Full	Full	Chemical Engineering (49%)	CI, TS
Jonathan Rocheleau	IBBME	Associate	Full		CI, TS
Paul Santerre	Dentistry (50%)	Full	Full	IBBME (50%)	CI, TS
Molly Shoichet	Chemical Engineering	Full	Full	IBBME	TS
Craig Simmons	Mechanical and Industrial Engineering (66%)	Full	Full	IBBME (34%)	CI, TS
Eli Sone	IBBME (51%)	Associate	Full	Materials Science (49%)	CI,TS
David Steinman	Mechanical and Industrial Engineering	Full	Full	IBBME	TS
Kevin Truong	Electrical and Computer Engineering (51%)	Associate	Full	IBBME (49%)	TS, CI

Name	Home Department / Unit	Rank	Graduate Faculty Membership Status (e.g., Associate/ Full privileges)	Commitment to other programs	Nature of contribution to this program (CI, TS, C/PS)
Aaron Wheeler	Chemistry	Full	Full	IBBME	TS
Willy Wong	Electrical and Computer Engineering	Associate	Full	IBBME	CI, TS
Chris Yip	Chemical Engineering (51%)	Full	Full	IBBME (49%)	CI, TS
Lidan You	Mechanical and Industrial Engineering (72%)	Associate	Full	IBBME (25%)	CI, TS
Peter Zandstra	IBBME	Full	Full		CI, TS
Tenure Stream					
Rodrigo Fernandez Gonzalez	IBBME	Assistant	Full		CI, TS
Penny Gilbert	IBBME	Assistant	Full		CI, TS
Alison McGuigan	Chemical Engineering	Assistant	Full	IBBME	TS
Paul Yoo	IBBME (51%)	Assistant	Full	Electrical and Computer Engineering (49%)	CI, TS
Margaret Cheng	IBBME	Assistant	Full		CI,TS
Non-Tenure Stream (i.e., CLTA)					
Jan Andrysek	Holland Bloorview	Assistant	Full	IBBME	CI, TS
Elaine Biddis	Holland Bloorview	Assistant	Full	IBBME	CI, TS
Tom Chau	Holland Bloorview	Full	Full	IBBME	TS
Tony Easty	UHN, Toronto General Hospital	Associate	Full	IBBME	TS

Name	Home Department / Unit	Rank	Graduate Faculty Membership Status (e.g., Associate/ Full privileges)	Commitment to other programs	Nature of contribution to this program (CI, TS, C/PS)
Moshe Eizenman	Ophthalmology	Full	Full	IBBME	CI, TS
Geoff Fernie	Toronto Rehabilitation Institute	Full	Full	IBBME	TS
Marc Grynpas	Mount Sinai	Full	Full	IBBME	TS
Rita Kandel	Mount Sinai	Full	Full	IBBME	TS
Kei Masani	Toronto Rehabilitation Institute	Assistant	Full	IBBME	CI,TS
Milos Popovic	IBBME	Full	Full	IBBME	TS
Patricia Trbovich	UHN, Toronto General Hospital	Assistant	Full	IBBME	CI, TS
Jose Zariffa	Toronto Rehabilitation Institute	Assistant	Full	IBBME	CI, TS
Teaching Stream					
Dawn Kilkenny	IBBME		Associate		CI
Sessional Lecturer					
Others (e.g., adjunct, status only, clinical faculty, visiting or other)					

12.2 Learning Resources

Please see the following Appendices:

Appendix C: Library statement confirming the adequacy of library holdings and support

for student learning

Appendix D: Standard statement concerning student support services

12.3 Financial Support for Graduate Students

Financial support is not anticipated other than scholarships normally available to graduate students enrolled in professional programs. IBBME has a number of meritbased awards that will be available to the M.Eng. students. Professional engineering master's programs are not funded. However, emergency funding and loans are available from the School of Graduate Studies.

12.4 Space/Infrastructure

M.Eng. students will be accommodated in existing courses and classrooms associated with the current core biomedical engineering programs, including a newly-renovated classroom (RS412).

The main laboratory space (MB325; 208.5 NASM) provides dedicated space for activities such as molecular biology, bacterial manipulation, chemical analysis, cell engineering and manufacturing, and has been designed with proper safety-level attributes. Continued support from the engineering students' temporary special levy fund has allowed for the addition of state-of-the-art equipment (i.e., qPCR cyclers, spectrometers, industry-standard 3D printer workstations, etc.), with a suite of research-grade fluorescent imaging microscopes added in late 2014.

In addition to MB325, IBBME recently renovated its undergraduate teaching laboratory with the program in mind, with capacity for 77 students simultaneously (55 in the dry lab and 22 in the wet lab areas). The renovated lab opened in September 2011 and expanded with the addition of a satellite Design Studio in January 2015.

The Design Studio (MB64) is ideal for the new M.Eng. program since it was created to provide students with dedicated workspace to develop and prototype design components/projects as well as participate in simultaneous physiological data collection (i.e., gait analysis, EEG, ECG, respiration, etc., as relevant for the healthcare and rehabilitation industries). Equipment upgrades continue to improve the learning experience for our students, and allow instructors greater opportunity to develop their curriculum. The teaching lab manager has a Ph.D. in biological science and 19 years of laboratory/teaching experience. Specific technical support is also available for both cell/tissue culture as well as IT/design.

IBBME will continue to invest as the program matures to accommodate the required human and physical resources. When the program expands to 50 students, teaching lab times for the graduate courses that require wet or dry labs will need to be accommodated in different locations. Classroom accommodation in other engineering buildings can obtained via the Office of Space Management (Academic and Campus

13 Quality and Other Indicators

IBBME now has nearly 40 core faculty, 65+ cross-appointed faculty, and a wellestablished network of activity across eight teaching hospitals, 14 departments and five Faculties. Core faculty members hold leadership positions in CRANIA, Centre for Commercialization in Regenerative Medicine (CCRM), Donnelly Centre (DC), Techna and the new Ted Rogers Centre for Heart Research.

IBBME's core faculty has a formalized research program that generates \$12-14M/year in research activity, 17 active spin-off companies, and three commercialization infrastructure centres (mentioned above). Its extensive hospital affiliations provide support to introduce biomedical device design applications in the curriculum and internships.

Courses will be delivered by outstanding faculty and/or part-time lecturers whose research programs are at the leading edge of the of the four fields of research strengths at IBBME, and whose biomedical engineering experience is recognized in the medical industry field. Guest lectures by high profile industry, consulting and regulatory leaders and other researchers will further enhance the learning experience by bringing real examples and current issues to the classroom that might not otherwise be captured.

14 Governance Process

Levels of Approval Required	
Consultation with Provost	February 2015
Decanal and Provostial Sign-Off	February 2015
Graduate Unit Approval	February 2015
Faculty Governance Approval	April 2015
Submission to Provost's Office	April 2015
AP&P	May 2015
Academic Board	June 2015
Executive Committee of Governing Council	June 2015

The program may begin advertising as long as any material includes the clear statement that "No offer of admissions will be made to the program pending final approval by the Quality Council and the Ministry of Colleges Training and University (where the latter is required)."

Ontario Quality Council	
Submitted to MTCU (in case of new graduate degrees and programs, new diplomas)	



Appendix A: Curriculum Pathways and Courses

* Indicates that the course is currently under development (proposal under review)

Suggested Curriculum Pathways for each Field: Sample #1

Field #1: Neural/Sensory Systems Rehabilitation Neural/Sensory Systems Rehabilitation; Field #2: Biomaterials, Tissue Engineering and

	Pillars	Field #1	Field #2	Field #3	Field #4
Fall	BME Technology	BME1471: Rehabilitation Engineering BME1473: Acquisition and Processing of Bioelectric Signals	BME1480: Experimental Design and Multivariate Analysis	ECE1475: Bio-Photonics	BME1405: CE Instrumentation I
	Commercialization	BME1800* (core)	BME1800* (core)	BME1800* (core)	BME1800* (core)
	Biomedical Science	REH1120: Research Methods for Rehab Science	MSC7000Y: Regenerative Medicine	BME1459: Protein Engineering	JNS1000Y: Fundamentals of Neuroscience: Systems and Behavior
Winter	BME Technology	JEB1444: Neural Engineering	JMB1050: Biological and Bio-Inspired Materials	BME1462: Biological Image Analysis JEB1433: Medical Imaging	BME1439: CE Instrumentation II JEB1433: Medical Imaging
	Commercialization	BME1801* (core)	BME1801* (core)	BME1801* (core)	BME1801* (core)
	Biomedical Science	REH1510: Disordered and Restorative Motor Control	MSC7000Y: Regenerative Medicine BME1460: Quantitative Fluorescence Microscopy	BME1460: Quantitative Fluorescence Microscopy	JNS1000Y: Fundamentals of Neuroscience: Systems and Behavior
Summer	BME1899: Internship	BME1899: Internship	BME1899: Internship	BME1899: Internship	BME1899: Internship

Regenerative Medicine; Field #3: Nanotechnology, Molecular Imaging and Systems Biology; Field #4: Engineering in a Clinical Setting

Suggested Curriculum Pathways for each Field: Sample #2

Field #1: Neural/Sensory Systems Rehabilitation Neural/Sensory Systems Rehabilitation; Field #2: Biomaterials, Tissue Engineering and

	Pillars	Field #1	Field #2	Field #3	Field #4
Fall	BME Technology	BME1471: Rehabilitation Engineering	JTC1331: Biomaterials Science	BME1457: Biomedical Nanotechnology	BME1452: Signal Processing
	Commercialization	BME1800* (core)	BME1800* (core)	BME1800* (core)	BME1800* (core)
	Biomedical Science	MSC3001: The Foundations in Musculoskeletal Science	BME1454: Regenerative Medicine: Fundamentals and Applications	BME1459: Protein Engineering	JNS1000Y: Fundamentals of Neuroscience: Systems and Behavior
Winter	BME Technology	BME1472: Fundamentals of Neuromodulation Tech and Clinical App. JEB1444: Neural Engineering	JMB1050: Biological and Bio-Inspired Materials	BME1462: Biological Image Analysis	JEB1365: Ultrasound: Theory and Application JEB1433: Medical Imaging
	Commercialization	BME1801* (core)	BME1801* (core)	BME1801* (core)	BME1801* (core)
	Biomedical Science	REH1510: Disordered and Restorative Motor Control	BME1460: Quantitative Fluorescence Microscopy PSL1462: Molecular Aspects of Cardiovascular Function	JCB1349: Molecular Assemblies, Structure/Function/Prop. BME1460: Quantitative Fluorescence Microscopy	JNS1000Y: Fundamentals of Neuroscience: Systems and Behavior
Summer	BME1899: Internship	BME1899: Internship	BME1899: Internship	BME1899: Internship	BME1899: Internship

Regenerative Medicine; Field #3: Nanotechnology, Molecular Imaging and Systems Biology; Field #4: Engineering in a Clinical Setting



Biomedical Engineering (BME) Technology Courses

In this list, the following superscripts indicate which of the IBBME field(s) of research is most relevant to the course:

- 1. Neural/Sensory Systems Rehabilitation Neural/Sensory Systems Rehabilitation
- 2. Biomaterials, Tissue Engineering and Regenerative Medicine
- 3. Nanotechnology, Molecular Imaging and Systems Biology
- 4. Engineering in a Clinical Setting
- 5. All fields

IBBME courses:

BME 1452H	Signal Processing for Bioengineering ^{1,4}
BME 1405H	Clinical Engineering Instrumentation I ⁴
BME 1439H	Clinical Engineering Instrumentation II ⁴
BME 1436H	Clinical Engineering Surgery ⁴
BME 1458H	Pattern Discovery Methods for Biomedical Engineering ⁵
BME 1457H	Biomedical Nanotechnology ³
JEB 1444H	Neural Engineering ¹
JEB 1447H	Sensory Communications ¹
JEB 1451H	Neural Bioelectricity ¹
JEB 1365H	Ultrasound: Theory and Applications in Biology and Medicine ⁴
JEB 1433H	Medical Imaging ^{3,4}
JMB 1050H	Biological and Bio-inspired Materials ²
BME 1480H	Experimental Design and Multivariate Analysis in Bioengineering ⁵
BME 1464H	Orthopaedic Biomechanics and Mechanics of Biomaterials ²
BME 1472H	Fundamentals of Neuromodulation Technology and Clinical Applications ^{1,4}
BME 1473H	Acquisition and Processing of Bioelectric Signals ¹
BME 1471HF	Rehabilitation Engineering ^{1,4}
BME 1462H	Biological image analysis ³

Partner department courses:

DEN 1070H	Advances in Dental Materials Science ²
DEN 1081H	Bone Interfacing Implants ²
JTC 1331H	Biomaterials Science ²
ECE 1475H	Bio Photonics ^{3,4}
CHE 562H	Chemical Properties of Polymers ²
ECE 557H	Systems Control ^{1,4}
MIE 520H	Biotransport Phenomena ⁵
MSE 550H	Advanced Physical Properties of Structural Nanomaterials ^{2,3}
ECE1774H	Sensory Cybernetics ¹

Commercialization and Entrepreneurship Courses

IBBME courses:

*BME1800H	Biomedical Product Development I (New course, under review)
*BME1801H	14.1.2 Biomedical Product Development II (New course, under review)

Partner department courses:

APS 1001H	Project Management
APS 1005H	Operations Research for Engineering Management
APS 1010H	Cognitive and Psychological Foundations of Effective Leadership
APS 1012H	Management of Innovation in Engineering
APS 1015H	Social Entrepreneurship
APS 1016H	Financial Management for Engineers
APS 1017H	Supply Chain Management and Logistics
APS 1088H	Entrepreneurship and Business for Engineers
APS 1201H	Topics in Engineering and Public Policy
APS 1202H	Engineering and Sustainable Development
CHE 1435H	Fundamentals of Aerosol Physics and Chemistry

CIV 1307H	Life Cycle Assessment of Engineering Activities
MIE 561H	Healthcare Systems
MIE 506H	MEMS Design and Microfabrication Product Design
MIE 1501H	Knowledge Modelling and Management
MIE 1402H	Experimental Methods in Human Factors Research
HAD 5010H	Canada's Health System and Health Policy- Part 1
HAD 5020H	Canada Health Systems and Health Policy: Part II
MIE 1407H	Engineering Psychology and Human Performance
MGT 2015H	Special Topics in Strategic Management
MGT 2141H	Special Topics: Business Economics
LAW 524H	Patent Law for the Life sciences

Biomedical Science Courses

In this list, the following superscripts indicate which of the IBBME field(s) of research is most relevant to the course:

- 1. Neural/Sensory Systems Rehabilitation Neural/Sensory Systems Rehabilitation
- 2. Biomaterials, Tissue Engineering and Regenerative Medicine
- 3. Nanotechnology, Molecular Imaging and Systems Biology
- 4. Engineering in a Clinical Setting
- 5. All fields

IBBME courses:

BME 1453H:	Cell and Tissue Engineering ²
BME 1454H:	Regenerative Medicine: Fundamentals and Applications ²
BME 1459H:	Protein Engineering ³
BME 1460H:	Quantitative Fluorescence Microscopy: Theory and Application-to Live Cell Imaging ² , ³
BME/JBP 1022H:	Human Physiology as Related to Bioengineering II ⁵
JCB1349H:	Molecular Assemblies: Structure/Function/Properties

Partner department courses:

Fundamentals of Neuroscience: Cellular and Molecular ^{1,2}
Advanced Topics: Systems Biology in Physiology ^{2,3}
Biology of Connective Tissues ²
The Foundations in Musculoskeletal Science ^{1,2,4}
Systems Level Neuroplasticity ^{1,2}
Mechanistic Molecular & Cellular Neuroscience ²
Fundamentals of Ion Channel Function ²
Molecular Aspects of Cardiovascular Function ²
Advanced Topics: Cell and Molecular Neurobiology ²
Developmental Cardiovascular Physiology ²
Advanced Topics in Cardiovascular Science: Molecular Biology and Heart Signal Transduction ²
Advanced Topics in Cardiovascular Science: Heart Function ²
Advanced Topics in Cardiovascular Science: Vascular ²
Fundamentals of Neuroscience: Systems and Behaviour ^{1,2}
Applied Bioinformatics ^{2,3}
Proteomics and Functional Genomics ^{2,3}
Research Methods for Rehabilitation Science ^{1,4}
Disordered and Restorative Motor Control ¹
Cognitive Rehabilitation ^{1,4}
Advanced Topics in Behavioural Neuroscience I ¹

Appendix B: Graduate Calendar Copy

BIOMEDICAL ENGINEERING

Faculty Affiliation

Applied Science and Engineering

Degree Programs Offered

Biomedical Engineering—M.A.Sc., Ph.D., M.Eng., Fields: Neural/Sensory Systems and Rehabilitation Biomaterials, Tissue Engineering and Regenerative Medicine Nanotechnology, Molecular Imaging and Systems Biology Engineering in a Clinical Setting Clinical Engineering (Ph.D. only)

Clinical Engineering—M.H.Sc.

Collaborative Programs

The following collaborative programs are available to students in participating degree programs as listed below:

- 1. Addiction Studies Biomedical Engineering, M.A.Sc., Ph.D.
- 2. Cardiovascular Sciences Biomedical Engineering, M.A.Sc., Ph.D.
- **3. Genome Biology and Bioinformatics** Biomedical Engineering, Ph.D.
- **4. Health Care, Technology, and Place** Biomedical Engineering, Ph.D.
- 5. Musculoskeletal Sciences Biomedical Engineering, M.A.Sc., Ph.D.

6. Neuroscience

Biomedical Engineering, M.A.Sc., MSc, Ph.D.

7. Resuscitation Sciences

Biomedical Engineering, Ph.D. Clinical Engineering, M.H.Sc.

Overview

The Institute of Biomaterials and Biomedical Engineering (IBBME) offers facilities for research in biomedical engineering and for three educational programs leading to master's and doctoral degrees. Students may be registered in the M.A.Sc., M.Eng., M.H.Sc. or Ph.D. programs through the institute. Students interested in the Collaborative Program in Biomedical Engineering may register through one of the collaborating graduate units.

Biomedical engineering is a multidisciplinary field that integrates engineering and biology/medicine. It uses methods, principles, and tools of engineering, physical sciences, and mathematics to solve problems in the medical and life sciences for the study of living systems; the enhancement and replacement of those systems; the design and construction of systems to measure basic physiological parameters; the development of instruments, materials, and techniques for biological and medical practice; and the development of artificial organs and other medical devices. By its nature, the majority of the institute's work is interdisciplinary.

See list above for research fields in the Biomedical Engineering program (M.Eng., M.A.Sc. and Ph.D.).

IBBME also offers a M.H.Sc. in Clinical Engineering which is described in the section below.

Contact and Address

Web: www.ibbme.utoronto.ca

Institute of Biomaterials and Biomedical Engineering (IBBME) Graduate Office:

Email: admissions.ibbme@utoronto.ca Telephone: (416) 978-4841 Fax: (416) 978-4317

Institute of Biomaterials and Biomedical Engineering University of Toronto Room 407, Rosebrugh Building 164 College Street Toronto, Ontario M5S 3G9 Canada

IBBME Clinical Engineering Office:

Email: clinicaleng.ibbme@utoronto.ca Telephone: (416) 978-6102 Fax: (416) 978-4317 Institute of Biomaterials and Biomedical Engineering University of Toronto Room 407, Rosebrugh Building 164 College Street Toronto, Ontario M5S 3G9 Canada

Degree Programs

Biomedical Engineering

Master of Applied Science

The M.A.Sc. program is offered in the fields of 1) Neural/Sensory Systems and Rehabilitation; 2) Biomaterials, Tissue Engineering and Regenerative Medicine; 3) Nanotechnology, Molecular Imaging and Systems Biology; and 4) Engineering in a Clinical Setting.

Admission Requirements

Applicants are admitted under the General Regulations of the School of Graduate Studies. Applicants must also satisfy IBBME's additional admission requirements stated below.

A bachelor's degree in dentistry, engineering, medicine, or one of the physical or biological sciences from a recognized university with a minimum academic standing of A- in the final two years of study.

Program Requirements

The program normally comprises at least 2.0 full-course equivalents (FCEs), one of which must be BME 1450H *Bioengineering Science*. and an appropriate life science or engineering course. Engineering and physical science students must take a life sciences course, such as JPB 1022H (or an equivalent); life science students must take an engineering or physical science course, such as JPB 1055H (or an equivalent).

Students participate in two seminar courses: either BME 1010H or BME 1011H *Graduate Seminar* series, and JDE 1000H *Ethics in Research*.

Health and safety training workshops.

Successful completion of a research thesis in at least one of the biomedical engineering research fields: 1) Neural/Sensory Systems and Rehabilitation; 2) Biomaterials, Tissue Engineering and Regenerative Medicine; 3) Nanotechnology, Molecular Imaging and Systems Biology; or 4) Engineering in a Clinical Setting.

Program Length: 5 sessions full-time

Time Limit: 3 years full-time

Doctor of Philosophy

The Ph.D. program is offered in the fields of 1) Neural/Sensory Systems and Rehabilitation; 2) Biomaterials, Tissue Engineering and Regenerative Medicine; 3) Nanotechnology, Molecular Imaging and Systems Biology; 4) Engineering in a Clinical Setting and 5) Clinical Engineering.

Admission Requirements

Applicants are admitted under the General Regulations of the School of Graduate Studies. Applicants must also satisfy IBBME's additional admission requirements stated below.

A master's degree in dentistry, engineering, medicine, or one of the physical or biological sciences. Applicants to the Ph.D. in the field of Clinical Engineering must have an undergraduate degree in engineering.

Highly qualified master's students (M.H.Sc. students in Clinical Engineering or M.A.Sc. students in any field) may be considered for transfer into the Ph.D. program in any of the five fields. Clinical Engineering M.H.Sc. students must complete 3.0 full-course equivalents (FCEs) within the M.H.Sc. curriculum.

Direct admission with a bachelor's degree may be considered in exceptional cases.

Program Requirements

All fields:

Normally, at least 1.0 full-course equivalent (FCE) and successful completion of a thesis, representing an original investigation in biomedical engineering. Students who transfer without completing a master's degree in biomedical engineering must complete the total course requirements for both degrees (2.0 FCEs for the master's level plus 1.0 FCE for the Ph.D. level, for a total of 3.0 FCEs). Engineering and physical science students are required to take a life sciences course, such as JPB 1022H (or an equivalent); life science students are required to take a physical science course, such as JPB 1055H (or an equivalent).

Within 12 months of registration, students must pass a qualifying examination covering the broad field of biomedical engineering appropriate to their background.

Students will continue to meet with their supervisory committee at least once every 12 months until recommendation for the departmental oral examination is made. On the recommendation of the supervisory committee and special approval from their department Graduate Chair or Coordinator, candidates have the opportunity to waive the departmental oral examination and proceed directly to the Doctoral Final Oral Examination.

Two seminar courses: either BME 1010H or BME 1011H *Graduate Seminar* series, and JDE 1000H *Ethics in Research*.

Health and safety training workshops.

Students are also expected to take BME 1450H *Bioengineering Science* and pursue a thesis topic relevant to at least one of the following biomedical engineering research fields: 1) Neural/Sensory Systems and Rehabilitation; 2) Biomaterials, Tissue Engineering and Regenerative Medicine; 3) Nanotechnology, Molecular Imaging and Systems Biology; 4) Engineering in a Clinical Setting or 5) Clinical Engineering.

Clinical Engineering field:

*Complete the following requirements in addition to those listed above:

If a student does not have a formal degree in clinical engineering, 0.5 FCE from one of the IBBME clinical engineering courses (BME 1405H, BME 1439H, BME 1436H, or BME4444H) is required. A student who possesses protracted professional engineering experience (five or more years) will be exempt from this requirement.

Students in the Clinical Engineering field must (1) conduct their research in a clinical environment, and; (2) be co-supervised by both engineering and health science faculty. The primary supervisor must be IBBME-appointed; however, the co-supervisor could be from a clinical unit other than IBBME but must be appointed to SGS.

Program Length: 4 years full-time; 5 years direct-entry

Time Limit: 6 years full-time; 7 years direct-entry

Master of Engineering

Admission Requirements

Applicants are admitted under the General Regulations of the School of Graduate Studies. Applicants must also satisfy IBBME's additional admission requirements stated below.

A bachelor's degree in engineering or equivalent from a recognized university with a minimum academic standing of A- in the final two years of study.

Program Requirements

The program comprises at least 5.0 full-course equivalents (FCEs). At least 1.0 FCE must be taken from courses in Biomedical Engineering Technology. At least 1.0 FCE must be taken from two core courses in Commercialization and Entrepreneurship, specifically BME1800H and BME1801H. At least 1.0 FCE must be taken from courses in Biomedical Sciences.

In addition, students must successfully complete a 1.5 FCE internship (BME1899), usually over the summer term, in biomedical device development, in academic research laboratories, government institutions, health care facilities, in the industry, or in health care consulting firms.

The internship must be in at least one of the biomedical engineering research fields: 1) Neural/Sensory Systems and Rehabilitation; 2) Biomaterials, Tissue Engineering and Regenerative Medicine; 3) Nanotechnology, Molecular Imaging and Systems Biology; or 4) Engineering in a Clinical Setting.

The remaining 0.5 FCE can be a half-course in either Biomedical Engineering Technology, Commercialization and Entrepreneurship or Biomedical Sciences.

For the 5 FCEs, 2.5 must be BME (or joint BME i.e. JxB) courses (this includes the internship project BME1899). The remaining three courses (1.5 FCE) can be taken from any other department associated with the program. All courses must be graduate-level, which includes both 500- and 1000-level. Only one 500-level courses may be taken.

A curriculum plan must be submitted to the program director prior to the commencement of the program.

A written report submitted to the program director is required for degree completion

Students must also participate in health and safety training workshops that applies to their internship.

Program Length: 3 sessions full-time

Time Limit: 2 years full-time

Clinical Engineering

Master of Health Science

Minimum Admission Requirements

Applicants are admitted under the General Regulations of the School of Graduate Studies. Applicants must also satisfy IBBME's additional admission requirements stated below.

Selected students who hold a bachelor of applied science degree in engineering.

Program Requirements

Normally 4.0 full-course equivalents (FCEs), including BME 1405H, BME 1436H, BME 1439H, and one elective, relevant to a student's area of research. All students are required to take BME 1450H, a life sciences course, such as JPB 1022H (or an equivalent), and 1.0 FCE of internships (completed over two or three separate internships) in health care facilities, the medical device industry, or health care consulting firms.

Students participate in two seminar courses: one of BME 1010H or BME 1011H *Graduate Seminar* series, and JDE 1000H *Ethics in Research*.

Successful completion of a thesis.

Program Length: 6 sessions full-time

Time Limit: 3 years full-time

Course List

Not all courses are offered every year. Students should contact the IBBME office for information about course availability. Outlines of these and other closely related courses may be obtained from the IBBME office.

Appendix C: Library Statement

University of Toronto Libraries Report For

A Proposed New Graduate Professional Master's Program In

Biomedical Engineering (M.Eng. BME), 2014

Context: The University of Toronto Library (UTL) system is the largest academic library in Canada and is currently ranked third among academic research libraries in North America, behind Harvard and Yale.¹ The research and special collections, together with the campus and college libraries comprise almost 12 million print volumes, nearly 5.5 million microform volumes, more than 17,000 journal subscriptions, in addition to a rich collection of manuscripts, films, and cartographic materials. The system provides access to more than 1.5 million electronic books, journals, and primary source materials and increasingly supports access via personal handheld devices.² There are numerous collection strengths in a wide range of disciplines reflecting the breadth of research and instructional programs at the University. The University of Toronto Library system has an annual acquisition budget of \$28 million. The strong collections, facilities and staff expertise attract unique donations of books and manuscripts from around the world, which in turn draw scholars for research and graduate work.

	Major North American Research Libraries ³					
	2008-09	2009-10	2010-11	2011-12	2012-2013	
ARL RANK	UNIVERSITY	UNIVERSITY	UNIVERSITY	UNIVERSITY	UNIVERSITY	
1	Harvard	Harvard	Harvard	Harvard	Harvard	
2	Yale	Yale	Yale	Yale	Yale	
3	Columbia	Toronto (3rd)	Toronto (3rd)	Toronto (3 rd)	Toronto (3 rd)	
4	Toronto (4th)	Columbia	Michigan	Columbia	Columbia	
5	Michigan	Michigan	Columbia	Michigan	Michigan	

¹ Chronicle of Higher Education, "Library Investment Index at University Research Libraries, 2012 – 2013." In the Almanac of Higher Education, 2014.

² Figures as of 2013 taken from UTL's 2012-2013 Annual Report.

http://onesearch.library.utoronto.ca/sites/default/files/UTL%20Annual%20Report%202012-2013_FINAL_reduced%20size_0.pdf

³ Association of Research Libraries Statistics, 2013

2008-09	2009-10	2010-11	2011-12	2012-2013
RANK/ UNIVERSITY	RANK/ UNIVERSITY	RANK/ UNIVERSITY	RANK/UNIVERSITY	RANK/UNIVERSITY
4/Toronto	3/Toronto	3/Toronto	3/Toronto	3/Toronto
16/Alberta	11/Alberta	11/Alberta	10/UBC	18/Alberta
26/British Columbia	24/British Columbia	16/British Columbia	15/Alberta	24/UBC
34/Montreal	31/Montreal	32/Montreal	18/McGill	30/McGill
40/McGill	37/McGill	38/McGill	32/Montreal	35/Montreal

Space and Access Services: The Library system provides a variety of individual and group study spaces for both undergraduates and graduates in the 10 central and 23 divisional libraries on the St. George, Mississauga, Scarborough and Downsview campuses. The Engineering and Computer Science Library is open 78.5 hours per week from September to May and 59.50 hours per week from May to August. 36 networked public computer terminals are available within the Engineering and Computer Science Library and these provide access to the Library catalogue and online resources. The Library provides 267 seats for study and research. An additional 1400 study spaces are available in the nearby Gerstein Science Information Centre. Study space and computer facilities are available twenty four hours, five days per week at one location, Robarts Library. Web-based services and electronic materials are accessible at all times from campus or remote locations, through the U of T based Scholars Portal and other leading edge digital services.

Instruction & Research Support: The Library plays an important role in the linking of teaching and research in the University. To this end, information literacy instruction is offered to assist in meeting degree level expectations in the ability to gather, evaluate and interpret information. These services are aligned with the Association of College and Research Libraries (ACRL) Information Literacy Competency Standards for Higher Education.¹

Program Specific Instruction: Instruction occurs at a variety of levels for biomedical engineering students and is provided by the faculty liaison librarian for biomaterials and biomedical engineering. The Engineering & Computer Science Library facilitates formal instruction and offers course specific instruction to students enrolled at the graduate level in IBBME. Both Engineering & Computer Science Library and Gerstein Science Information Centre offer one-on-one consultations by appointment. The Library, through its <u>liaison librarians</u>, customizes feeds of library resources. These appear prominently in Portal/Blackboard course pages. The Library maintains an online guide for Biomaterials & Biomedical Engineering.

Collections: A number of college and campus libraries collect materials in support of biomedical engineering. The largest collections of materials are centrally located in Engineering & Computer Science Library and in Gerstein Science Information Centre. Collections are purchased in all formats to meet the variety of preferences and styles of our current students and faculty. The University of Toronto Library is committed to collecting both print and electronic materials in support of the biomedical engineering program at the University of Toronto.

¹ Association of College & Research Libraries. *Information Literacy Standards*. ACRL, 2006.

Journals: The Library subscribes to 25¹ of the top 25 journals listed in Journal Citation Reports (JCR)² in subject area 'Engineering biomedical'. Of these titles, all are available electronically to staff and students of the University.

Monographs: The University of Toronto Library maintains comprehensive book approval plans with 53 book dealers and vendors worldwide. These plans ensure that the Library receives academic monographs from publishers all over the world in an efficient manner. For biomedical engineering, monographs are purchased in electronic form where possible. The Library currently receives all current e-books directly from the following publishers: Springer, Elsevier, IEEE, Wiley and Oxford University Press, and subscribes to the Knovel engineering e-books multi-publisher collection.

Preservation, Digitization, and Open Access: The University of Toronto Library supports open access to scholarly communication through its institutional research repository (known as T-Space), its open journal and open conference services, and subscriptions to open access publications. In addition to acquiring materials in support of biomedical engineering, the Library is also, in cooperation with the Internet Archive, digitizing its monograph holdings published before 1923. These books are available without charge to anyone with access to the Internet through the Scholar's Portal e-Book platform.

Key Databases: The two major comprehensive discipline-specific online indexes supporting biomedical engineering are *Compendex* and *MEDLINE (OVID)* and the Library maintains subscriptions to both. Additional indexing of the relevant literature is provided by *BIOSIS Previews, EMBASE, IEEE Xplore, Scopus* and *Web of Science* databases. Additional access to the relevant medical literature is provided via the publicly available *PubMed* database. Access to literature in allied fields relevant to the proposed program such as business is available to biomedical engineering students through Library subscriptions to a number of databases including *Business Source Premier* and *Factiva*.

Prepared by: Cristina Sewerin, Acting Head, Engineering & Computer Science Library, University of Toronto, November 28, 2014

¹ One title, *Regenerative Medicine*, is available with a one year publisher embargo on the most current issues. Another title, *Organogenesis*, is available after a 6-month publisher embargo on the most current issues, and **s**ome articles may be available sooner.

² 2013 Journal Citation Reports[®] (Thomson Reuters, 2014)

Appendix D: Student Support Services

All University of Toronto undergraduate and graduate students have access to student services on all three campuses, Mississauga, St. George (downtown Toronto), and Scarborough, regardless of their "home campus". The services and co-curricular educational opportunities provide a complement to the formal curriculum by engaging and challenging students to reach their full potential as learners, leaders and citizens. At the University of Toronto (St. George Campus) these services are organized by Student Life Programs and Services, the academic division registrar offices, and the School of Graduate Studies, and support the success of our students from the time they are admitted through degree completion and beyond.

Students have access to comprehensive physical and mental health care on campus including a medical clinic, travel medicine services, immunization, contraception and sexual health education. Counselling and treatment options for psychological and emotional concerns include psychotherapy, group therapy and pharmacotherapy, as well as specialized assault counseling services.

Housing needs, including off-campus housing listings and resources for students living independently, are met through the Student Housing Service.

Coaching and education in the development of key learning skills – from time management to overcoming exam anxiety – is provided through the Academic Success Centre. The ASC also partners with faculty to integrate success strategies and support into the curriculum.

Students' career exploration and employment services are provided through a Career Centre offering resume and interview coaching, workshops, career resources, on and off-campus employment and volunteer listings, job shadowing, and career counseling.

Specialized services are provided for international students (orientation, advising, crosscultural counselling), students with disabilities (academic accommodations, advising), students with children or other family responsibilities (advising, resources, subsidized child care), aboriginal students (academic support, financial counselling) and lesbian, gay, bisexual and transgender students (counselling, referrals).

Participation in campus life and experiential learning are facilitated through Hart House (clubs, committees, events), the Centre for Community Partnerships (service learning), the Multifaith Centre (interfaith dialogue, events), and the Office of Student Life (leadership development, orientation, recognition and support for student groups, activities.) Sport and recreational facilities and programs are provided to all students through both Hart House and the Faculty of Kinesiology and Physical Education.

School of Graduate Studies, Student Services [all campuses]

All graduate students at the University of Toronto have access to registrarial services and cocurricular programs at the School of Graduate Studies that assist students in meeting their academic goals. Administrative staff at the School of Graduate Studies (SGS) provide registrarial services to graduate students including but not limited to recruitment, admission, orientation, registration, fees, program progress, awards/financial assistance and graduation.

The Grad Room is an accessible space on the St. George campus which provides University of Toronto graduate students with a lounge area and a multi-purpose space for academic, social and professional graduate student programming.

Grad Room is home to the Graduate Professional Skills Program (GPS). GPS is a nonacademic program presented by SGS consisting of a variety of offerings that provide doctoral stream students a range of opportunities for professional skills development. The program focuses on skills beyond those conventionally learned within a disciplinary program, skills that may be critical to success in the wide range of careers that graduates enter, both within and outside academe. GPS aims to help students communicate effectively, plan and manage their time, be entrepreneurial, understand and apply ethical practices, and work effectively in teams and as leaders.

The Office of English Language and Writing Support (ELWS) provides graduate students with advanced training in academic writing and speaking. By emphasizing professional development rather than remediation, ELWS helps students cultivate the ability to diagnose and address the weaknesses in their oral and written work. ELWS offers four types of instruction designed to target the needs of both native and non-native speakers of English: non-credit courses, single-session workshops, individual writing consultations, and website resources.

Appendix E: Cited References

Medical Devices: Challenges and Opportunities for Enhancing the Health and Wealth of Canadians (April 2011), prepared by Medical Devices Innovation Institute (MDI²) in Consultation with National Stakeholders.

Invest in Canada (2012). Medical Devices: Canada's competitive advantages.

Segmenting the Data-Regional labour market information on biotechnology in Canada. 2008 (www.biotalent.ca)

Appendix F: External Appraisal Report

Master of Engineering in Biomedical Engineering

Institute of Biomaterials & Biomedical Engineering Faculty of Applied Science & Engineering University of Toronto

Appraisal Report

March 11, 2015

This template was developed by the Office of the Vice-Provost, Academic Programs (February 2013) in compliance with the University of Toronto Quality Assurance Process. Reviewers are asked to provide an appraisal report evaluating the standards and quality of the proposed program using the evaluation criteria identified below. Please adapt this template as necessary.

Report Summary

On February 25, 2015, an appraisal of a proposed Master of Engineering in Biomedical Engineering was conducted at the University of Toronto, by a committee consisting of:

Robert E. Kearney, PhD Professor and Chair, Biomedical Engineering Department, Faculty of Engineering McGill University

Heather Sheardown, PhD Professor, Chemical Engineering Department, School of Biomedical Engineering McMaster University Scientific Director, 20/20 NSERC Ophthalmic Materials Network

William R. Wagner, PhD Professor, Surgery, Bioengineering and Chemical Engineering UPMC/University of Pittsburgh Schools of the Health Sciences, University of Pittsburgh Director, McGowan Institute for Regenerative Medicine

The committee was given the following information prior to the appraisal visit:

- MEng in Biomedical Engineering proposal
- Visit Terms of Reference
- Itinerary
- IBBME Annual Report, 2012-2013

- FASE Council Report Approval of IBBME Fields (December 2013)
- FASE Annual Report, 2014
- FASE Academic Plan, 2011-2016
- FASE Academic Plan, 2011-2016: Year Three Progress Report (November 2014)
- University of Toronto Quality Assurance Program (UTQAP)
- CVs of core IBBME instructors

On February 25, the committee met with representatives from:

- FASE leadership: Profs. Brenda McCabe (Acting Dean) and Markus Bussmann (Vice-Dean, Graduate)
- IBBME leadership: Profs. Christopher Yip (Director), Julie Audet (Associate Director, Graduate), Alex Mihailidis (former Associate Director, Clinical Engineering), and Craig Simmons (Associate Director, Research), and Sr. Lecturer Dawn Kilkenny (Associate Director, Undergraduate)
- University of Toronto leadership: Prof. Locke Rowe (Dean, School of Graduate Studies and Vice-Provost, Graduate Research & Education
- IBBME faculty
- IBBME students
- Cognate units, within and outside FASE, including: Chemical Engineering & Applied Chemistry, Engineering Science, Electrical & Computer Engineering, Material Science & Engineering, and Civil Engineering; Graduate and Life Sciences Education at the Faculty of Medicine, and the Faculty of Medicine's Translational Research Program in Health Science; and the Master of Biotechnology / Biology Med Program at the University of Toronto-Mississauga

Program Evaluation Criteria

1 Objectives

- Consistency of the program with the institution's mission¹ and unit's academic plans
- Clarity and appropriateness of the program's requirements and associated learning outcomes in addressing the academic division's graduate Degree Level Expectations
- Appropriateness of the degree nomenclature

The proposed MEng degree program builds off historical strengths at University of Toronto in biomedical engineering and also complements existing degree options of an MASc in Biomedical Engineering and an MHSc in Clinical Engineering.

With the projected growth in the health care sector of the global and Canadian economies, providing Master's level graduates trained in the design and regulatory challenges unique to the development of biomedical devices will be of benefit to the country's efforts in this area.

¹ University of Toronto mission statement: "The University of Toronto is committed to being an internationally significant research university, with undergraduate, graduate and professional programs of excellent quality." See http://www.utoronto.ca/about-uoft/mission-and-purpose.

Program requirements are clear and the desired outcomes are well stated in the proposal. The degree falls within a group of MEng degrees offered in the FASE and has similar educational objectives to these degree programs, even if the specifics of the educational program varies in some respects.

2 Admission Requirements

- Appropriateness of the program's admission requirements for the learning outcomes established for completion of the program
- Appropriateness of any alternative requirements for admission into the program such as minimum grade point average or additional languages or portfolios, along with how the program recognizes prior work or learning experience

The targeted population for the program is appropriate and it is expected that most applicants will be prepared to succeed in the program.

It would be helpful to define better the alternative requirements for admission for students who do not have a traditional background in biomedical engineering. Specifically, is a physiology course required? If a student does not have some minimal level of background in engineering or the life sciences (to be defined), what remedial action would be prescribed? Could a student enter and leave the program with no coursework in biology/physiology? Would this be acceptable?

3 Structure

- Appropriateness of the program's structure and regulations to meet specified program learning outcomes and Degree Level Expectations
- Rationale for program length in order to ensure that the program requirements can be reasonably completed within the proposed time period

Generally the program structure is attractive in how it draws from a pillar system to ensure coverage of the key skill sets desired. The new course to be introduced (BME 1800H, Biomedical Product Development) is targeted to provide much of the critical background in the product design process and regulatory considerations. The committee was concerned that such important topics may not be adequately served in a one semester course and recommend considering expanding this course to two semesters.

The coverage of ethics instruction was not addressed well in the proposal. For "Degree Level Expectations", one expectation is *"The ethical behavior consistent with academic integrity and the use of appropriate guidelines and procedures for responsible conduct in a professional context."* The intersection of healthcare and engineering is an area where too commonly ethical considerations have not been considered, resulting in significant public harm. Given the objective of placing graduates in the medical device design process, where ethical challenges will be routinely faced, it seems important to develop a course specifically addressing biomedical engineering (or medical drug and device) ethics. There are numerous such courses currently being offered internationally that

might serve as models. The currently available undergraduate engineering ethics course and the biomedical sciences course on ethics do not appear to address this need as the former does not address the unique concerns in the healthcare industry, and the latter is focused more on academic research ethics.

There was concern that the capstone internship course might be too short to ensure that all of the students would achieve the learning objectives set for this experience. Management would have to be very diligent with each student/mentor and there would be little time to move students if the planned project failed to develop. It is suggested to consider extending this Internship course to 6-8 months. While this would serve to increase the degree program to 14-16 months, it would help to ensure that the internship experience was beneficial to a greater number of students. Along these lines there was some student feedback that a slightly longer internship would be desirable in that it would better allow the student to demonstrate value to an industrial host and to perhaps increase the chance of converting the internship into a permanent position.

4 Program Content

- Ways in which the curriculum address the current state of the discipline or area of study
- Identification of any unique curriculum or program innovations or creative components and their appropriateness
- Evidence that each graduate student in the program is required to take all of the course requirements from among graduate level courses

The curriculum is clearly defined to address the needs of the students in the program. The committee was favourably impressed with the insight into the need for this type of degree in comparison to research based Masters and felt that there was a real opportunity for the program to succeed.

The committee was also quite impressed with the content of the "1800" course that is proposed. However there was some concern about the level of depth with which the course material could be covered in a single half year course and the committee felt that, particularly given that this represents one of the most innovative and unique aspects of the program, the course should be extended to two courses over two terms.

The internship was also viewed as a strong aspect of this program with the reservation that 4 months may not be sufficient time to gain the experience desired. An 6-8 month internship is recommended as noted above.

5 Mode of Delivery

• Appropriateness of the proposed mode(s) of delivery (full-time, part-time, compressed part-time, distance learning, online, mixed-mode or non-standard forms of delivery, flex-time options) to meet the intended program learning outcomes and Degree Level Expectations

The mode of delivery seems appropriate (specifically full time over a 1 year to 16 month period). The committee felt that there may potentially be an opportunity in the future to further develop this into a part time degree program suitable for students who are employed in relevant industry.

6 Assessment of Teaching and Learning

- Appropriateness of the proposed methods for the assessment of student achievement of the intended program learning outcomes and Degree Level Expectations
- Completeness of plans for documenting and demonstrating the level of performance of students, consistent with the academic division's statement of its Degree Level Expectations

In the graduate course component of the program, the committee was comfortable with the methods of assessment. In the internship component, there was concern that there may be some bias in grading by supervisors in the workplace. The program has evidence in place from a similar program that this is not a problem.

7 Resources

- Adequacy of the administrative unit's planned utilization of existing human, physical and financial resources, and any institutional commitment to supplement those resources to support the program
- Participation of a sufficient number and quality of faculty who are competent to teach and/or supervise in the program
- Adequacy of resources to sustain the quality of scholarship and research activities of graduate students, including library support, information technology support, and laboratory access
- Faculty have recent research or professional/clinical expertise needed to sustain the program, promote innovation and foster an appropriate intellectual climate
- Where appropriate to the program, financial assistance for students will be sufficient to ensure adequate quality and numbers of students
- Supervisory load distribution and the qualifications and appointment status of supervisors

The academic staff involved in the program are extremely well qualified, have the appropriate research interests and facilities to support the programme. Moreover, many of the staff have direct experience with issues related to medical device development and commercialization and so are well suited to support the new program.

However, in view of the flexibility of the program and the importance of the internship in achieving the learning objectives we believe there are two areas of concern with respect to resources.

The first area is related to the internship program which we believe will require substantial management effort if it is to meet its educational objectives. Significant tasks should include:

• Finding, developing and documenting internship options to ensure that: the internships are appropriate for the program; potential internship supervisors are aware of what is expected

and capable of providing the appropriate level of mentorship; salary expectations are clear; appropriate agreements are in place with respect to the management of Intellectual Property.

- Informing students about potential internship sites as early as possible (perhaps through a "boot camp" prior to the start of term) so that they can select the appropriate courses.
- Provision of individual counselling to students w.r.t. course selection to ensure their course work provides the training appropriate to the internship and fulfills the programme's objectives.
- Ensuring that all students are placed in appropriate internships.
- Preparing students for their internships and communicating clearly the expectations in terms of performance and reporting.
- Monitoring internships closely to identify mismatches at an early stage, evaluate the performance of both the student and supervisor, and corrective action, if needed, is taken promptly.
- Evaluation of internship reports and supervise students in their preparation.

It is our understanding that the current intention is that all of these function would be performed by the program director. It is our opinion that these tasks are well beyond what can be reasonably be expected from the Program Director; will certainly become unmanageable as the program grows to the expected 50 students/year. In consequence, we recommend the recruitment of a Programme Coordinator to assist the program director with particular responsibility for managing the internship program. Ideally this would be a professional engineer with previous experience in the development of medical devices. This could be a part-time position initially but will likely need to expand as the registration grows.

The second area of concern is related to the academic supervision of the students who, unlike research students, will not have a close relation to any member of the academic staff. Ideally, each student should have an academic mentor, with expertise aligned with the students preferred research area, to provide advice with respect to selection of courses and internships, and supervise the preparation of the interim and final reports. This will require the involvement of additional academic staff whose activities must be recognized as part of their teaching duties.

8 Quality and Other Indicators

- Quality of the faculty (e.g., qualifications, research, innovation and scholarly record; appropriateness of collective faculty expertise to contribute substantively to the proposed program)
- Program structure and faculty research that will ensure the intellectual quality of the student experience

The IBBME academic staff are extremely well qualified to deliver the courses needed in this program. Overall the program is well structured and has the potential to provide high quality professional training. However, we believe that there are three areas where the program structure should be modified. First, the course <u>BME 1800 Biomedical Product Development</u> is the core of the new program; the topics covered are entirely appropriate. However we believe the scope of the course work is too broad to be accommodated within a single half-course. Consequently, we recommend that:

- The course should be transformed into two mandatory half courses to be given in successive terms.
- The topics covered outline should be expanded to incorporate a section dealing explicitly with the ethical issues associated with the development of medical devices.

Secondly, there are numerous courses available to the students with little guidance as to which selections are appropriate. We recommend that:

- The definition of a limited number of "pathways" indicating which courses are appropriate for a student in each of the 4 areas of research focus.
- Methods be introduced to ensure that each student has personalized guidance as to which courses to take.

Third, the internship is an integral part of the training that is intended to meet many of the learning objectives in the program. We believe that considerably more structure is required if these objectives are to be met systematically. In particular we suggest that:

- The time currently allocated to the internship is not adequate to achieve the stated objectives which are appropriate but ambitious. The length of the internship should be expanded to a total length of 6 months.
- A structured method should be developed to prepare students for their internships either as part of the expanded Biomedical Product Development course, or a seminar activity.
- There is a need for much closer supervision of the internship environment than is currently envisioned. In particular we suggest that:
 - An "early warning system" is needed to identify internships which are not working at an early stage
 - A site visit where the university supervisor meets with the student and industrial supervisor at the internship location should be incorporated into the visit.
 - Feedback from the student and guidance from the University supervisor should be more frequent. One possibility would be through the use of an on-line journal to follow student's progress throughout the internship.
- The evaluation criteria of the internship must be modified to make it clear whether it is competency based (pass/fail) or evaluative. In addition the roles of the Program director and internship supervisor must be clarified to ensure that the final decision remains with the University and that students from different internship environments are evaluated equably. These need to clearly communicated to the student prior to the internships.

Recommendations

Essential

- Recruit a program coordinator to develop and manage the internship program.
- Expand <u>BME 1800 Biomedical Product Development</u> into two half term courses given in sequential terms.
- Add instruction material related explicitly to ethical issues associated with medical device development.
- Develop and deploy a more systematic system to follow students throughout the course of the internship to ensure that the nature of the work and guidance aligns with the pedagogical objectives.
- Provide guidance to the students in course selection through the development of "pathways" with suggested course for each the four research areas and the provision of individual student guidance.
- Consider the possibility of having "bootcamp" for students prior to start of the year to help guide students in choosing courses and internships.
- Consider increasing the duration of the internship to 8 months from 4 to better capitalize on the opportunities arising from the experience.
- Better define the internship management approach and define carefully how interim assessments will be performed for internship students. Scenarios need to be considered where the internship student is not making progress and how this will be corrected in a timely and effective manner. Further, given the need for more extensive management in this area, additional resources may be required to support the Internship program.
- Address the need for ethics education in the context of medical device design.
- Define potential remedial pathways for students entering the program without a biomedical engineering background, specifically considering students lacking any significant life sciences and physiology coursework in their background.

Appendix G: Dean, Faculty of Applied Science and Engineering, Administrative Response to External Appraisal Report



April 9, 2015

Prof. Sioban Nelson Vice-Provost, Academic Programs University of Toronto 27 King's College Circle, Room 224 Toronto, ON M5S 1A1

Dear Prof. Nelson

Re: Master of Engineering in Biomedical Engineering – Administrative Response

The proposed Master of Engineering in Biomedical Engineering, to be offered through the Institute of Biomaterials & Biomedical Engineering, underwent an external appraisal visit on February 25, 2015 under UTQAP. This appraisal has allowed us to critically reflect on the proposed program's strengths and opportunities.

The appraisers note in the report that the program will build on the University of Toronto's historical strengths in biomedical engineering, and benefit the health-care sector of the Canadian and global economies by providing master's level training in the design and development of biomedical devices. We were also pleased to see positive feedback from the appraisers on the program's structure, curriculum, mode of delivery and academic staff.

I write in response to the appraisers' comments and recommendations outlined in three areas.

Recommendation 1: Expand BME 1800 Biomedical Product Development Course

The course <u>BME 1800 Biomedical Product Development</u> is the core of the new program; the topics covered are entirely appropriate. However we believe the scope of the course work is too broad to be accommodated within a single half course. Consequently, we recommend that:

- The course should be transformed into two mandatory half courses to be given in successive terms.
- The topics should be expanded to incorporate a section dealing explicitly with the ethical issues associated with the development of medical devices.

Administrative Response

The Biomedical Product Development course will be covered in two half courses, BME1800 and BME1801, offered in the fall and winter, respectively. BME1801 will contain a module on Biomedical Engineering Ethics in which case studies relevant to the four IBBME research fields will be presented. Both BME1800 and BME1801 will have modules on Regulatory Requirements. This change is reflected in section 6 of the proposal (Program Requirements) and section 9 (Learning Outcomes), as well as in samples of suggested curriculum pathways (now provided in Appendix A).

Recommendation 2: Provide Additional Opportunities for Student Guidance

Potential remedial pathways should be defined for students entering the program without a biomedical engineering background, specifically considering students lacking any significant life sciences and physiology coursework in their background. Additionally, there are numerous courses available to the students with little guidance as to which selections are appropriate. We recommend that:

- Guidance be provided to students in course selection through the development of a limited number of "pathways" indicating which courses are appropriate for a student in each of the four areas of research focus.
- *Methods be introduced to ensure that each student has personalized guidance as to which courses to take.*
- *A* "boot camp" be considered for students prior to the start of year to help guide them in choosing courses and internships.

Administrative Response

In section 5 (Admission Requirements), the following was added:

"It is possible that some meritorious applicants may not have had sufficient exposure to life sciences and human biology. In that case, they will be required to take a physiology course (such as JBP1022H) during their first term in the program as part of their course credits."

Section 6 (Program Requirements) was modified as follows, and samples of curriculum pathways are now provided in Appendix A:

"Because the courses offered in the engineering and bioscience pillars are drawn from IBBME's four research fields, students will have proactively selected courses that best align with their internship plans (section 7.2). Samples of appropriate curriculum pathways have been prepared for each of the four research fields (Appendix A)."

The following modifications were made to section 7.2 (Internship Administration):

"Students will be required to submit a 'Curriculum Plan' before the beginning of their first session in the program (i.e. by the beginning of August). In this form, they will select their field of interest (one of the four IBBME fields) and identify courses for each session of the program. The program director will review and approve each Curriculum Plan (in parallel with the information included in the student's file in terms of previous studies and experiences) and suggest alternatives if necessary. This process will offer opportunities for students to obtain guidance from the program director early in the program. At the end of the first session in the program (December), the program director will organize a mandatory workshop to inform students about the preparation and requirements related to the internships, and the expectations of the different stakeholders (including intellectual property issues)."

"As mentioned, a research proposal for the internship must be approved by the program director during the term preceding the commencement of the internship. Both the internship supervisor and student must provide signatures to indicate agreement on the specifics of the internship and its learning objectives. The form also specifies the responsibilities of the students, internship supervisors, and the M.Eng. program office. Currently in the M.H.Sc. in Clinical Engineering, students are required to submit a biweekly report to the program director during their internship, and the same approach will be implemented in the M.Eng. program. Every two weeks, each student will be required to submit brief updates on their project, which will be signed by the internship supervisor and forwarded to the program director. The program director will use this documentation to ensure that the internship activities remain aligned with the objectives of the program and that the progress is satisfactory and the expected timeline for the internship (four months) is realistic."

The following modifications were also made to section 6.3 (Internship Requirements):

"The internship is typically undertaken during the summer, and students must be registered in the program. By the end of session one (December), students will have identified an internship supervisor and will submit an outline of their project proposal to the program director for approval. The program director will determine if the project is compatible with the objectives and duration of the program and aligns well with one of IBBME's four applied research fields. In some cases, this may require the program director to visit the sites of the internships and meet with potential internship supervisors. At the end of the first half of session two (end of February), students will submit a detailed internship proposal and a Gantt chart to the program director who will determine if the project is compatible with the program timeline and can be completed in four months."

Recommendation 3: Improve Structure of Internship

The internship is an integral part of the training that is intended to meet many of the learning objectives in the program. We believe that considerably more structure is required if these objectives are to be met systematically. In particular we suggest that:

- Given the need for more extensive management in the internship program, additional resources, such as the recruitment of a program coordinator, are required.
- The time currently allocated to the internship is not adequate to achieve the stated objectives which are appropriate but ambitious. The length of the internship should be expanded from 4 to a total length of 6 months.
- A structured method should be developed to prepare students for their internships, either as part of the expanded Biomedical Product Development course, or a seminar activity.
- A more systematic process should be developed and deployed to follow students throughout the course of the internship to ensure that the nature of the work and guidance aligns with the pedagogical objectives.
- There is a need for much closer supervision of the internship environment than is currently envisioned. In particular we suggest that:
 - An "early warning system" is needed to identify internships which are not working at an early stage
 - A site visit where the university supervisor meets with the student and industrial supervisor at the internship location should be incorporated into the visit.

- Feedback from the student and guidance from the University supervisor should be more frequent. One possibility would be through the use of an on-line journal to follow students' progress throughout the internship.
- The evaluation criteria of the internship must be modified to make it clear whether it is competency based (pass/fail) or evaluative. In addition, the roles of the program director and internship supervisor must be clarified to ensure that the final decision remains with the University and that students from different internship environments are evaluated equably. These need to clearly communicated to the student prior to the internships.

Administrative Response

Section 12.1 (Faculty Complement) of the proposal has been modified to address the appraisers' concerns regarding the human resources available for the management of the internships.

"The program will initially operate using the current graduate office resources. During the first two years of the program, when the total enrolment is expected to be 10-20, the M.Eng. will be added to the portfolio of the program staff managing the M.H.Sc. in Clinical Engineering; this will greatly facilitate the M.Eng. launch since the internships in the two programs will be administered in a similar manner. As the program grows beyond 20 students, a program director will be recruited specifically for this program. Ideally, the program director should be a faculty member with strong industrial ties and/or experience in the medical device industry.

While there is an opportunity to capitalize on existing faculty (as instructors or program administrators), we anticipate the additional recruitment of two to three new faculty members. This activity is already written into IBBME's 2010-2015 strategic plan, and partnerships with the industry and hospitals are already in play."

In the revised version of the M.Eng. proposal, students start planning their internship during session one instead of session two. During session two, students must now submit a detailed internship proposal that will include a Gantt chart so that the program director can verify that the students' plans are realistic and compatible with the program. By starting to plan the details of their internship early in the program (during the fall and winter sessions), students will receive frequent and useful feedback from the program director and internship supervisor, ultimately helping them achieve the learning objectives of the internship efficiently and effectively. See changes to section 6 (Program Requirements), in particular section 6.1 (Overview) and 6.3 (Internship Requirements).

"The internship will normally be scheduled during the third term, or summer session. Students will be made aware that courses are not commonly offered during the summer session, and that any change to the program order may risk affecting time to completion."

The proposal was modified in section 7.2 (Internship Administration) and section 6.3 (Internship Requirements) to address the concerns raised by the appraisers about student guidance (described above). Additional changes have also been made to section 6.3 (Internship Requirements):

"The internship will be evaluated by both the internship supervisor at the host organization and the program director. Upon completion of their project, students will submit a technical project report to the internship supervisor and the program director, who will evaluate the report. Students must submit their final report before a degree recommendation can be forwarded to School of Graduate Studies. Students will receive a pass/fail mark for their Internship (BME1899) based on the four aspects defined above, as well as the five criteria defined in section 7.2. The program director will be responsible for the final decision regarding the mark the student will receive for the internship."

Thank you for your participation in the appraisal process. We look forward to implementing this new program in the Institute of Biomaterials & Biomedical Engineering

Sincerely

Custina > Puss

Cristina Amon Dean

Enclosures

cc: Professor Christopher Yip Director, Institute of Biomaterials & Biomedical Engineering

Daniella Mallinick, Acting Director, Academic Programs, Planning and Quality Assurance, Office of the Vice-Provost, Academic Programs

Jennifer Francisco, Coordinator Academic Change, Office of the Vice-Provost, Academic Programs

Appendix H: Vice-Provost, Academic Programs' Response



April 27, 2015

Professor Cristina Amon Dean Faculty of Applied Science and Engineering University of Toronto

Re: Appraisal Report, Proposed new Biomedical Engineering program (M.Eng.)

Dear Cristina,

I am very pleased to receive the appraisal of the proposed new program in Biomedical Engineering within the existing Master of Engineering degree. Your administrative response to the appraisal nicely summarizes the report and highlights the specific suggestions made by the reviewers for consideration. In response to the reviewer's suggestions, you have made a number of significant changes to the proposal including extending the Biomedical Product Development course and adding additional content on medical ethics and regulation to this offering. You have added more supports and guidance for students, especially in terms of the summer internship; now students will begin planning the internship project in the first session and will receive feedback from the Program Director and Internship supervisors prior to starting their project. I note that you are confident that these additional activities will support students' timely completion of the program within 3 sessions.

The reviewers recognized the very strong biomedical engineering focus and felt that this program will be an excellent complement to the existing degree programs in Biomedical Engineering and Clinical Engineering. I will be very pleased to recommend this new professional master's program to governance for approval, following approval at the Divisional level.

Sincerely,

Sioban Nelson Vice-Provost, Academic Programs

cc.

Markus Bussman, Vice Dean, Graduate Studies, Faculty of Applied Science and Engineering Caroline Ziegler, Faculty Governance and Programs Officer, Faculty of Applied Science and Engineering Christopher Yip, Director, Institute of Biomaterial and Biomedical Engineering

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Jennifer Francisco, Coordinator, Academic Change, Office of the Vice-Provost, Academic Programs

Locke Rowe, Dean, Graduate Studies and Vice-Provost, Graduate Research and Education, SGS

Elizabeth Smyth, Decanal Advisor on Graduate Policies, SGS