

BMNG5330 – Industry Placement

MASc students spend a minimum of 4 weeks, while PhD students spend a minimum of 4 months at a local, national or international medical technology industry. Students will be exposed to many aspects of the medical device industry including: design and development, quality assurance for ISO13485, Health Canada and FDA regulatory processes and practices. The companies range from medical technology startups to established multinational firms. Companies and students must sign the **BMNG5330 industry placement expectations** form accompanying this document.

Arranging the industry placement

Industry placements will be identified by the student and supervisor and the placement and expectations are to be approved by the Supervisory Committee. The approved placement is to be submitted to the Program Coordinator at least one-month prior to beginning placement. If travel funding is requested a formal letter with a budget needs to be submitted to the Program Director at least one-month before travel. Receipts and normal travel policy for reimbursement or travel advances will apply.

Requirements of the industry placement.

Description: Students are expected to observe, practice and report on their activities that are relevant to medical technology industry processes. This can include writing a standard operating procedure (SOP) that meets ISO13485 requirements, or may include participation in other aspects including control of industry documents, such as design requirements documents, engineering change orders, risk analysis, etc.

Industry placement presentation. The students must prepare a 10 minute presentation that describes the nature of their work-placement and report what they contributed during the placement. This presentation should make reference to medical technology recommended or required ISO13485, FDA or health Canada requirements.

Presentations occur once per year and is mandatory for all students who have completed a work-placement in the past year, and is attended by all students of the BioMedic program.

The presentation is public and open to all faculty and students. Students must inform the industry at which they took their placement of the content of their presentation prior to the presentation day so that confidential material is not presented to the public.

Successful completion is based on a satisfactory presentation that includes the following:

1. Clear and understandable slides and speech
2. Content that describes one or more medical technology industry practices
3. Content that makes reference to regulatory standards (one or more of ISO13485, FDA, or health Canada).

Attending faculty of the BioMedic program will grade the presentations on a pass/fail basis. In unlikely case of failure, the scientific committee will determine if further work exposure is required or if the presentation must be reattempted or other appropriate remedial action is required.

BMNG5330 industry placement expectations form

We the company _____ will permit the student _____ access to our company, and the student will be able to observe and participate in some industry practices relevant to the development and commercialization of medical technology. Such industry practices can include helping formulate standard operating procedures, participating in risk analysis, or observing portions of the quality assurance ISO13485 or requirements for Health Canada or FDA.

The work term will also likely include engineering research and development work. It is the expectation of the BioMedic program that the industry will expose the student to proper medical technology industry practices.

The student will present a portion of the industry practice they learned to the BioMedic students and faculty in an open presentation held annually each year. The student will inform the company of the content of the presentation so that confidential information is not presented.

Confidentiality and Intellectual Property. The student and company will complete a confidentiality agreement, and if is required, an intellectual property agreement. The attached agreement is a template provided by NSERC, but the company can choose to use their customary agreement. The student

If there are any questions, please contact Dr Geoff Maksym, gmaksym@dal.ca, BioMedic program industry liaison Officer and Eleanor Seaman-Bolton, esb@da.ca

Template BioMedic non-disclosure agreement, based on NSERC templates.

(from http://www.nserc-crsng.gc.ca/NSERC-CRSNG/policies-politiques/Clauses_Clauses_eng.asp)

Confidential Information: The Company and the student may disclose confidential information one to the other to facilitate work under this Agreement. Such information shall be in written or other tangible form and shall be marked so as to identify it as confidential, or, if disclosed orally or visually, shall be stated to be confidential at the time of disclosure and summarized in writing and confirmed as confidential within thirty (30) days of disclosure. Confidential information shall be safeguarded and not disclosed to third parties by the receiving party.

Confidential information shall not include information that:

- a. Is already known to the party to which it is disclosed;
- b. Is or becomes part of the public domain without breach of this Agreement;
- c. Is obtained from third parties that have no obligations to keep confidential to the parties to this Agreement.

Academic Progression: Notwithstanding any other term or condition of this Agreement, no delay is permitted for the defence of a student researcher's thesis based in whole or in part on the Results.

Where a graduate student is employed in the performance of work under the Project, the graduate student will own the copyright to the thesis report developed in conjunction with this Project. The graduate student will not be delayed in any way by the requirements of this Agreement in writing, presenting, and defending his or her thesis to meet the usual academic requirements for graduation.