## TRANSLATIONAL LIFE SCIENCES

Upon completion of the Translational Life Sciences Concentration, the student will be able to:

- identify risks and design process controls to reduce risk to product quality.
- determine the correct classification of medical devices in order to design an appropriate development strategy.
- identify primary and secondary clinical trial targets to demonstrate product safety and efficacy.
- describe the medical device and pharmaceutical Quality Systems, and how those systems enable organizations to consistently produce products that are of the purported quality and safety, and meet user needs
- describe what needs to be studied and demonstrated during medical device and drug product development.
- determine effective ways to monitor and predict product process performance.
- · demonstrate practical use of risk management tool.

## First Year

Term 1		Hours
Fall		
BIOM 611	Vaccines and Immune Therapies	4
BIOM 605	Global Regulatory Requirements of Quality	3
	Hours	7
Term 2		
Spring		
BIOM 617	Business for the Sciences	3
BIOM 629	Product Development and Validation	3
BIOM 640	Life Science Innovation I	3
	Hours	9
Term 3		
Summer		
BIOM 635	Risk and Failure Analysis	3
BIOM 642	Life Science Innovation II	2
BIOM 643	Bioinformatics	3
	Hours	8
	Total Hours	24