

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.