

## **Graduate course 1 – Biomedical Product Development (ME760):**

### **Case Study 2 – An engineer in development of a medical product**

An engineer with a small company started working with an orthopaedic surgeon (who is also the engineer's supervisor) on a new knee implant design. The surgeon is the sole inventor of the design and would have financial gain if the device were developed into a clinically available product. The engineer has told the surgeon that, because of the novel nature of this device and its difference in function in comparison to current designs, further testing on potential failure modes of the design must be done before the concept can be translated to a clinical setting. The potential failure mode not yet addressed would not be immediately life-threatening, but could cause significant pain and suffering to the patient, as well as a second surgery. A short time later, the MD asks the engineer to participate in a meeting with a group of engineers from a large corporation, Company X. Company X has expressed interest in buying the novel device design to develop into a clinically available product. In this meeting, Company X engineers and the surgeon begin planning the development path for the device, including testing requirements and regulatory concerns. During this discussion, Company X engineers state that the design must be changed in a specific way just so that it can pass current FDA testing requirements. The research institute engineer points out that the current FDA testing requirements were developed for the old design failure modes, and brings up the need for additional testing to the group. This discussion is immediately shut down by Company X engineers who indicate that passing the regulatory tests is their only concern. The surgeon does not back his engineer colleague in this discussion, but instead pushes forward with the Company X engineering plan so that the technology transfer can proceed without interruption. What should the engineer do?

Are there any ethical issues presented in this example? If so, what are they?  
Does the ethical situation change if the engineer is an employee of Company X?