Pre-IRB Evaluation Of Non-Certified Devices To Manage Safety Risk

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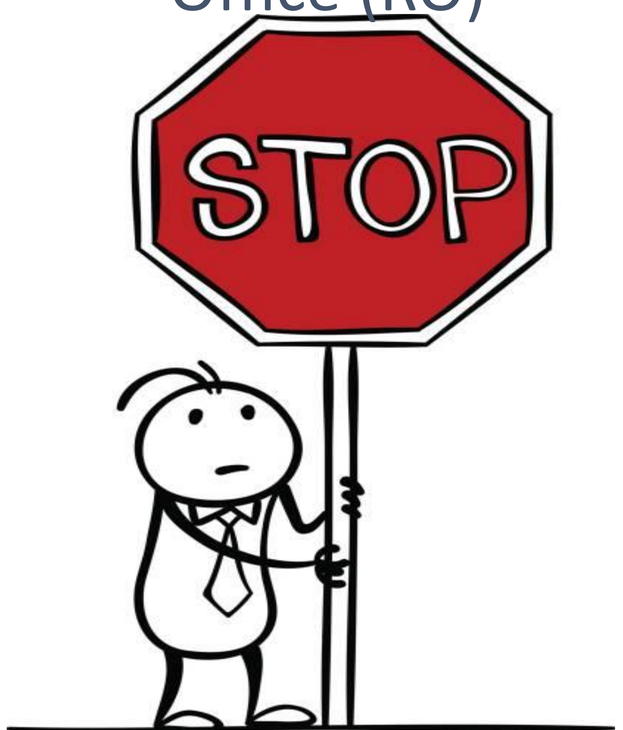
Introduction

Project Team

- Medical device design and development concluded
- Bench verification is completed
- Submit CIRB application for first in human trials

SGH Research Office (RO)



- All milestones met?
- Safety requirements met?
- Extensive risk assessment completed?

Medical Technology Office

- Prototype evaluation
- Risk and Safety requirements based on ISO 13485:2016
- Advice SGH RO

What should a med-tech project team do before submitting for CIRB?

Complete the Pre-IRB evaluation form and submit it to MTO

Method

How will completing the Evaluation form aid the project?

Probability ✖ Severity = RISK

Project teams will be able to gain better understanding of the potential hazards of their device and put controls in place to mitigate the risk.

Severity

Probability	Very Low	Low	Medium	High	Very High
Very Likely					
Likely					
Possible					
Unlikely					
Rare					

Result

What happens after the form is completed and sent to MTO?

MTO shall be able to advice SGH RO on the possible safety and risk of the projects. SGH RO can then better assess and consider the project's intended use, risk management plan, test protocol prior to the study start-up process.

Conclusion

But our device is very low risk, so why do we need to do this?

Projects with medium or high risks often overlook some of the potential hazards their device may pose. A pre-IRB evaluation will ensure SGH-RO is in a better position to support the projects in a timely manner.