## V. APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES

**Risk management is considered to be an essential requirement for medical devices under Medical Device Directive, ISO13485 and FDA Quality System Regulation (QSR). EN ISO 14971: Application of risk management to medical devices Has been formally recognized by FDA and by Health Canada; the European Union has adopted it as a harmonized standard; Japan has designated it as a Japanese Industrial Standard; and Australia has made it their "de facto" standard for risk management.**

**Purpose is to determine the possible risks associated with the use of a medical device in order to anticipate the design, manufacturing, inspection, controls and/or labelling indications required to reduce the risk of product failure for the end-user and patient as low and as far as possible.**

**Risk management can promote innovation, leading to a reduction in the number of customer complaints, lowered service and support costs, fewer disruptions from field actions**

### References

**EN ISO 14971 standard and FDA's guidance documents on Human Factors Engineering. The International Medical Device Regulators Forum (IMDRF) GHTF/SG3/N99 & GHTF/SG3/N15R8, local regulation.**

**This sub-system is intended to assist medical device manufacturers with the integration of a risk management system into their existing quality management system. The session details the use of risk management in the life cycle of medical device including the use of the ISO 14971 standard and FDA's guidance documents on Human Factors Engineering to provide a clear understanding of what techniques to use and when they should be implemented. Practical workshop activities on use of risk analysis techniques. Procedures and forms will be provided.**

- ☐ **What is risk management - Basic Terms and Concepts**
- ☐ **Risk management process flow**
- ☐ **Risk analysis techniques**
  **Fault Tree Analysis (FTA), Failure Modes Effect Analysis (FMEA)**
- ☐ **Incorporation of Risk analysis in device life cycle**

### Our services:

**A. Risk Management Training for Medical Device Companies**

**This training is conducted on-sites. The training session tailored to the needs of your organization regarding this sub-system.**

**B. Risk Management Auditing for Medical Device Companies**

**Full or partial internal Risk Management audit - ISO and FDA QSR. We provide internal auditing services which allow for an independent review of this part of your quality system.**

**C. Risk Management - System Implementation Consulting and maintenance**

**Gap analysis, design solution (custom made system), standard operating procedures, implementation, training, verification of effectiveness, and follow up.**