Case for Quality

Risk Management
Risk Management Lessons Learned

• Start early in the product lifecycle (don’t wait for launch). Should be a living document, not thought of as an event and forms to be completed.
• Prior to risk analysis, insist on a clear intended use statement
• Focus is only on Health and Safety
• Consistency through the product lifecycle using a standardized list of hazards and harms from design to process
• FMEA Risk Priority Numbers are used to prioritize action and do not quantify hazard/patient risk
• All hazards, hazardous situations and harms must be addressed in the Risk Trace Matrix (Hazard Analysis)
• Flexible use the right tools for input, not just FMEA (add quotes above)
• Safety is ultimately provided by risk control measures and going beyond compliance
• All harms (pre- or postmarket) should be assessed by medical/clinical personnel with appropriate expertise
• Information for safety can be used as a risk control as long as it provides instructions/actions. Disclosure of residual risk cannot be construed as risk control.
• Horizontally deploy risk management learnings.
Risk Management

Glossary

• **FMEA - Failure mode effects analysis.** A bottom–up (inductive) risk analysis technique in which the consequences of a potential individual failure mode are identified and evaluated.

• **FMECA - Failure Mode, Effects and Criticality Analysis:** Extension to the FMEA that includes a means of ranking the impact of potential failure modes to allow prioritization of counter measures.

• **Harm:** Physical injury or damage to the health of people, or damage to property or the environment.

• **Hazard:** Potential source of harm.
Glossary

• **Hazardous situation**: circumstance in which people, property, or the environment are exposed to one or more hazard(s).

• **HHA/HHE**: Health hazard assessment/evaluation.

• **Lifecycle**: All phases in the life of a medical device, from the initial conception to 'final decommissioning and disposal.

• **Medical Device Quality**: is the result of ensuring that features and characteristics of a product that define its ability to consistently satisfy customer needs are realized, and the products:
  - achieve desired uniformity, reliability, and performance
  - are safe, effective, and provide usability
Glossary

• **Overall residual risk**: Summary of all individual risks remaining after risk control measures have been implemented.

• **Residual risk**: Risk remaining after risk control measures have been taken.

### Risk Analysis: Systematic use of available information to identify hazards and to estimate the risk.
Glossary

- **Risk Assessment**: Overall process comprising a risk analysis and a risk evaluation.

- **Risk Control**: Process in which decisions are made and measures implemented by which risks are reduced to, or maintained within, specified levels.

- **Risk Evaluation**: Process of comparing the estimated risk against given risk criteria to determine the acceptability of the risk.

- **Risk Management**: Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling and monitoring risk.
Risk: Combination of the probability of occurrence and severity of harm.

Risk-benefit: Documented residual risk compared to proposed medical benefits of the intended use.
**Safety**: Freedom from unacceptable risk.

satisfy customer and user requirements and expectations regarding design, production, delivery, and service.

**Sequence of events**: Series of events that can lead to a hazardous situation or harm.

**Severity**: Measure of the possible consequences of a hazard.