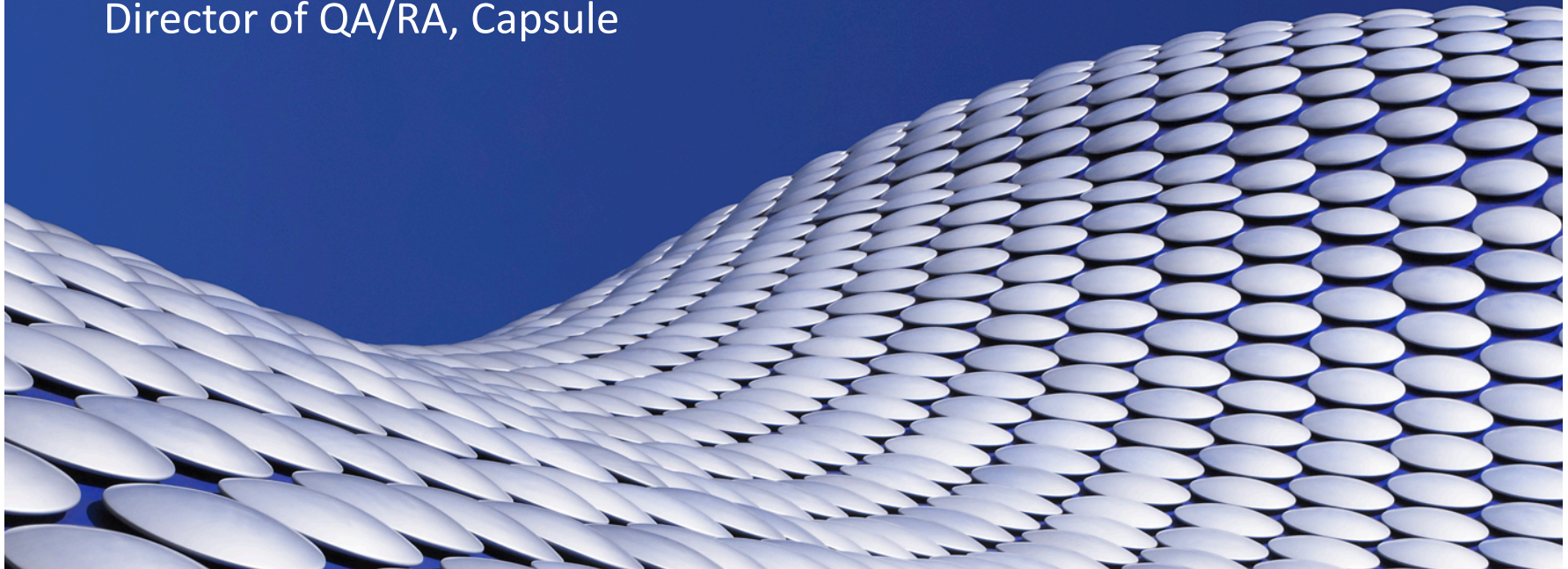


Managing Risk in Systems of Systems

FDA Workshop on Interoperability

Peter Kelley

Director of QA/RA, Capsule

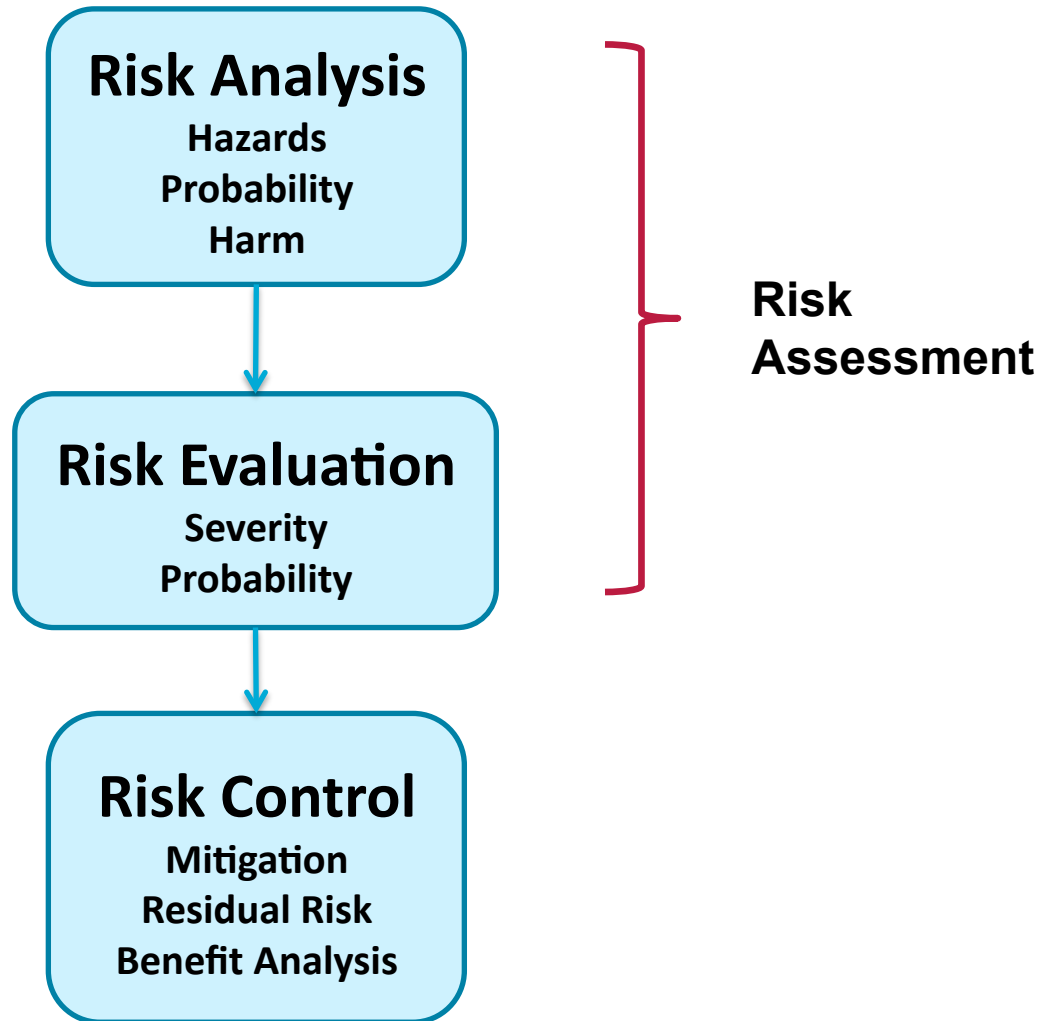


Proposal

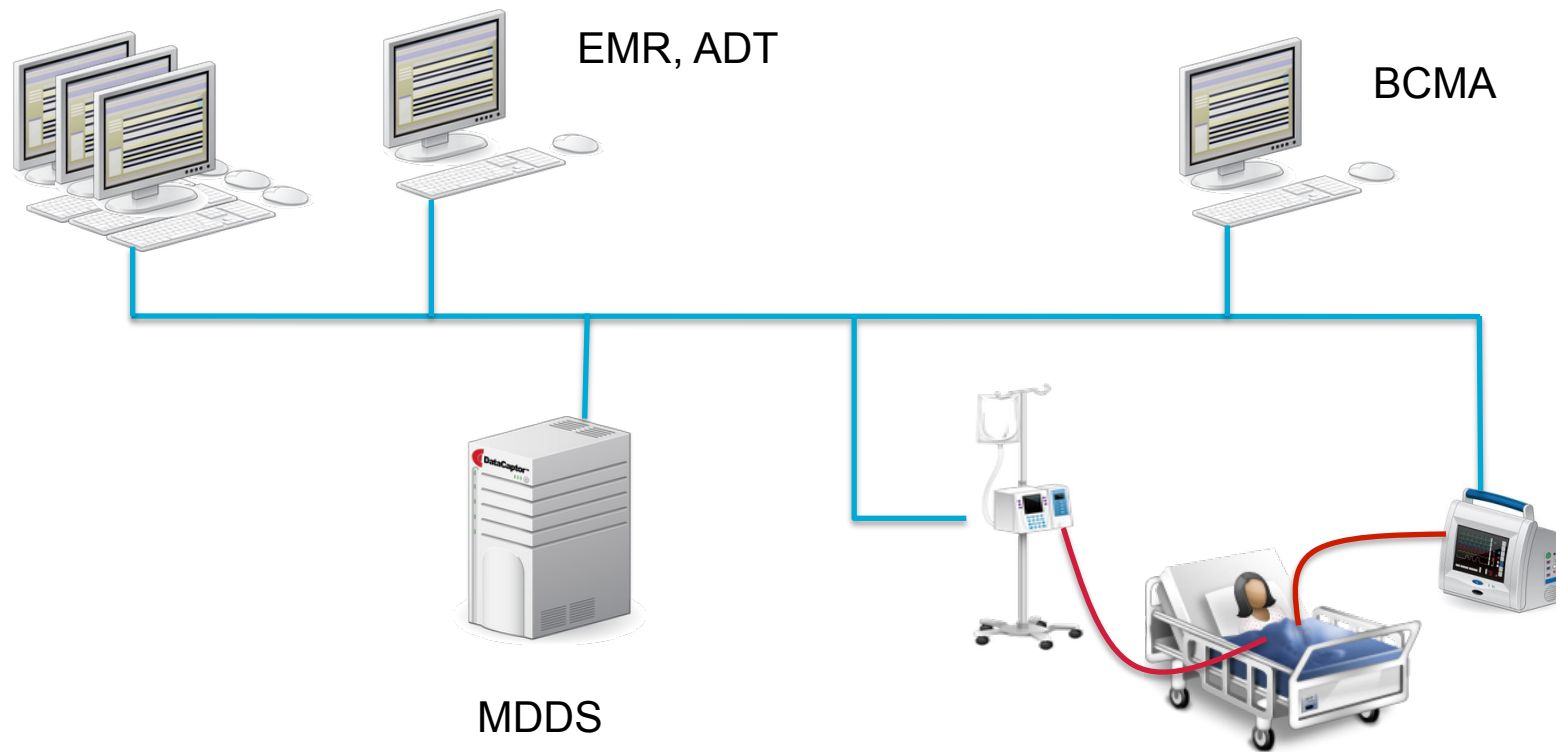
Applying the IHE Process to Risk Management

- ▶ **Apply the IHE process to risk management profiles**
 - Risk Profiles
 - Risk Case Scenarios
 - Standardized Risk Case Mitigations
 - Risk Control Statements
- ▶ **Supports IEC-80001**
 - Forms part of device vendor deliverables
- ▶ **Use best practices from ISO-14971, and IEC-80001**

Risk Management 101



Risk Case Scenario



Risk Profile – Patient Association

➤ Risk Case Scenario

- Hazard – Incorrect Association between Patient and Monitor
- Hazardous Situation
 - Patient A on vasodilator
 - Patient B on vasopressor
 - ADT interaction with EHR incorrectly associates monitor for patient B with patient A
 - BCMA instructs pump for patient A to titrate vasodilator too rapidly
- Harm - Deadly dysrhythmia, irregular heart rate, death
- Severity - Catastrophic

Risk Case Control Example

- ▶ Standardized Risk Case Mitigation
 - All transactions must include PID
- ▶ Verification
 - Standard test protocol
- ▶ Risk Case Control Statement
 - Analogous to Integration Statement
 - Maybe certified by a Notified Body depending on level of risk