

# The Importance and Benefits of End-to-End Risk Management

Risk management plays an integral part of medical device development and supply ensuring devices reach the user in the intended condition, and are used as intended to deliver their intended functions, safely.

**Frequently**, risk management activities are viewed as segregated into Use, Design and Manufacture. Furthermore, 'manufacture' is frequently divided into Manufacture, Assembly and Supply. This is reasonable and often convenient categorisation since the specialists responsible for those activities are often either physically, procedurally and/or structurally separated into different teams or even across different organisations and geographies.

**However**, between those segregated risk management activities, gaps or even holes can form which can easily be filled with assumption and a danger that they aren't filled at all (due to lack of awareness). Every participant in the risk management process has a responsibility to gather and share relevant information from and with their counterparts in the device development and supply chain.

The illustration (right), presents the concept of a risk management 'chain' representing the links between different system elements from the point of view of a device manufacturer, such as Owen Mumford.

**Identified in the illustration are some examples of where gaps can emerge.**

RM = Risk Management

A device is usually designed with intended use steps. A device's performance may vary in ways which do not constitute a functional issue but may influence user interaction of a device, presenting a potential hazard.

Failure modes in a 'design' risk assessment should then be also carefully assessed for effect on 'use risk'.

Acceptable variation in container performance, such as minor scratches, may significantly influence risks in an injection system due to forces applied

Syringe, Stopper, Drug RM

A component's design RM starts with be assumptions about how that component will be manufactured and, more importantly, the controls that will be implemented.

For example, a device may be designed close to its failure limit on the assumption of high quality manufacturing controls.

Initiating manufacturing RM during design development allows those assumptions to be checked and the controls or design modified to reduce risks as far as possible.

