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.

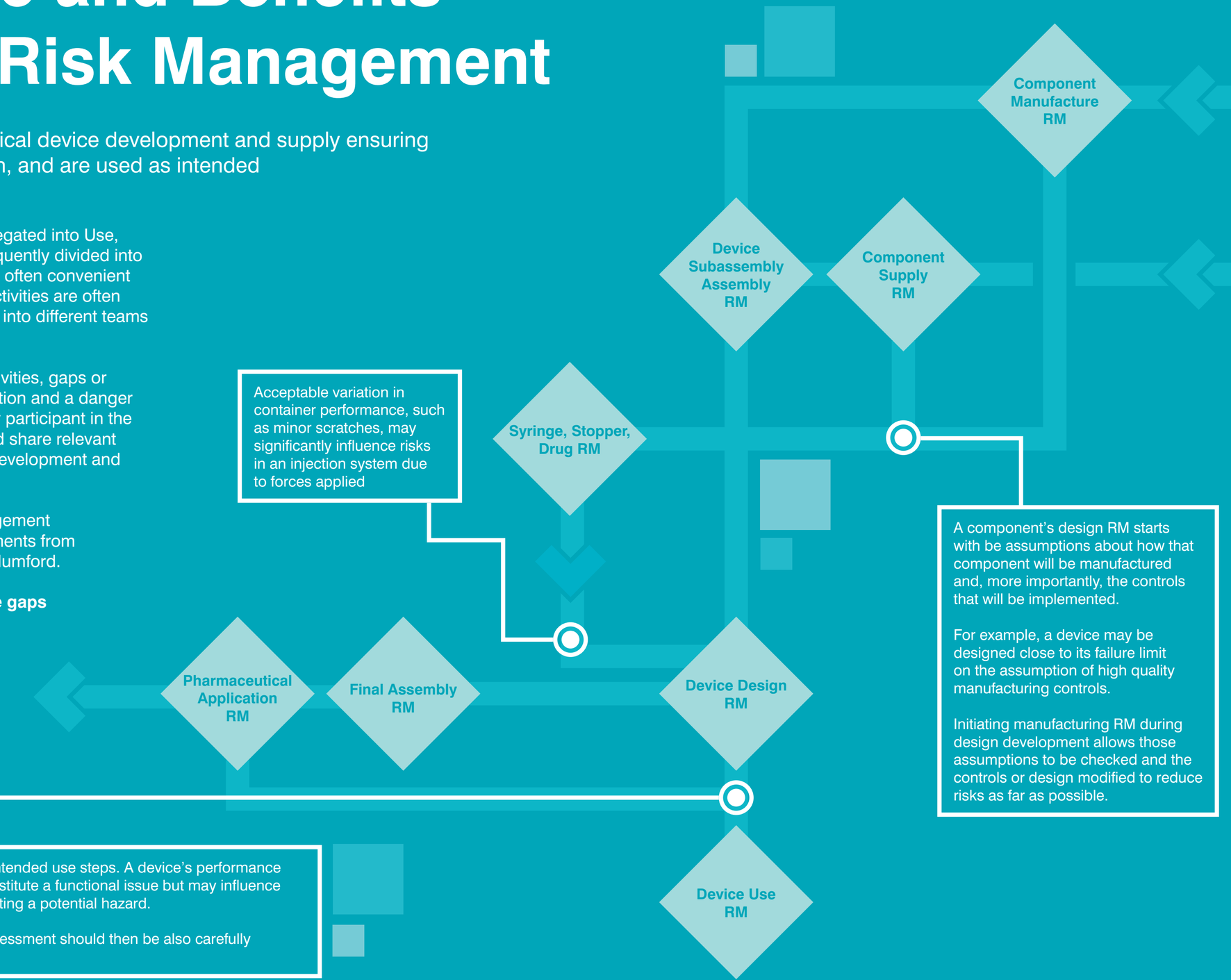
Frequently, risk management activities are viewed as segregated into Use, Design and Manufacture. Furthermore, 'manufacture' is frequently divided into Manufacture, Assembly and Supply. This is reasonable and often convenient categorisation since the specialists responsible for those activities are often 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



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

Parenteral Drug Association (PDA) Universe of Prefilled syringes and Injection Devices conference. Oct 2020
Author: Oli Gould, Design Team Manager - Design Engineering

Owen Mumford
Pharmaceutical Services