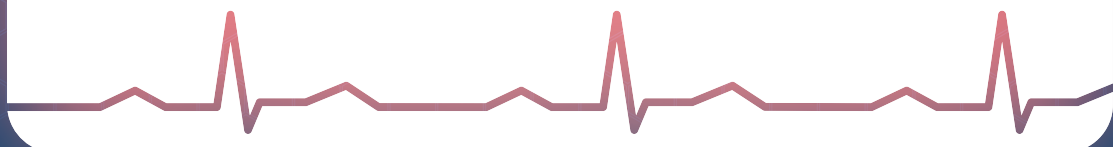
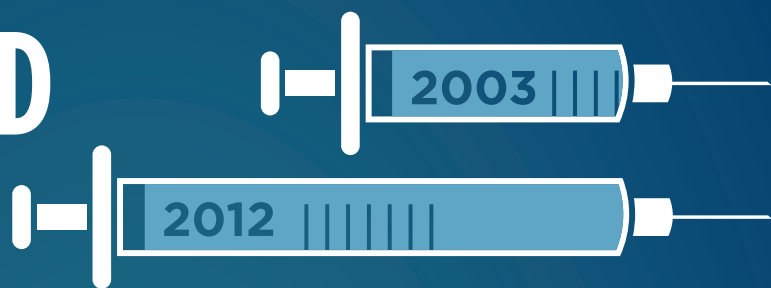


# Medical Recalls

Recalls are every medical device manufacturer's worst nightmare. With every week seemingly bringing more news about new recalls and investigations, how bad is the recall environment? Below are some of the most recent statistics regarding medical device recalls:



According to the FDA, between 2003 and 2012 the number of medical device recalls **DOUBLED**



On a typical day, between **13 and 75 devices** are added to the recall database\*

The largest one-day recall of medical devices occurred in June 2014 when the FDA recalled

**233** **CUSTOMED** products



In Q4 of 2014, **968** separate devices were recalled, making it the largest quarter on record

The most frequent causes for recalls are related to **device design, software and non-conforming material or component issues**



Many of the most common recall challenges can be mitigated with comprehensive, medical-specific ERP software. The right ERP solution can help you manage all your quality needs and pass your audits with flying colors.

**IQMS Means Medical Manufacturing ERP**

\*According to Regulatory Affairs Professional Society (RAPS)