

Medical Device Recalls: the significance of patient safety & brand integrity

ANDREW VINCENT, Assoc Offering Management Dir,
IQVIA MedTech

Device recalls have increasingly garnered more scrutiny and media attention in today's consumer driven environment. In 2022, we saw Class 1 recalls hit a 15 year high along with almost 12000 recalls affecting close to 62M products worldwide. With the recent advancements made in digital health and increasing pressures on MedTech supply chains globally, organisations face huge challenges in ensuring the safety & quality of their products. A device recall typically occurs when an organisation is either mandated to or voluntarily withdraws a potentially harmful product from the market to protect patients and maintain brand integrity. In this blog post, we'll explore the factors driving recalls, their impact on businesses and patients, and measures MedTech organisations can take to prevent them.

Reasons for device recalls:

- 1. Software:** recent advancements in digital health and AI have meant greater exposure to development flaws. Cyber security threats have also led to patient data safety concerns, prompting regulators to establish information technology security measures such as <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745> & <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746> for MDR & IVDR.
- 2. Quality issues:** device failures, wrongs specifications, parts issues & false results are all leading reasons behind quality defects recently seen in MedTech recalls, resulting in potential risk to patients.
- 3. Labelling errors:** incorrect or misleading labelling can confuse patients, consumers, caregivers & HCP's, leading to misuse or unintended consequences.
- 4. Regulatory Compliance:** increasingly, regulators are placing greater scrutiny on device recalls through measures such IVDR & MDR. In 2022, the FDA published guidance requesting MedTech manufacturers to be "more recall ready".
- 5. Emerging patient safety data:** through robust Post Market Surveillance programs & patient reported adverse events, MedTech organisations can proactively identify potentially unsafe products & take swift remedial action to remove a device once deemed safe but now pose unexpected risks based on new data or reported incidents.



Impact on businesses & patients:

- 1. Damage to brand reputation:** device recalls can significantly tarnish a company's reputation, eroding HCP, patient & consumer trust & loyalty. Brands typically find it challenging in regaining both trust and market share even after the recall issue has been resolved.
- 2. Financial losses:** device recalls often result in share price losses & other substantial financial losses for organisations due to costs associated with recall execution, legal settlements & replacement products.
- 3. Patient safety:** the swift & effective execution of a device recall is critical to protect patients & consumers from potential harm. Prompt & transparent action demonstrates an organizations commitment to patient safety.
- 4. Legal & regulatory consequences:** MedTech organisations which fail to adequately respond to product defects may face lawsuits & regulatory body-imposed fines for non-compliance with safety regulations.

Preventative measures:

- 1. Design & quality control:** rigorous quality control and design control processes effectively implemented to identify & rectify potential issues can mitigate any potential issues before products reach patients.
- 2. Regulatory compliance:** keeping abreast of recent laws and changes to regulatory frameworks and adhering to all relevant regulations is vital to reducing risk of device recalls.
- 3. Transparency:** open & honest communication with all stakeholders across the device value chain is crucial for maintaining & demonstrating accountability & responsibility.
- 4. Effective recall strategy:** a robust strategy, insourced or outsourced, that encompasses policy/planning/product development/communications/logistics & IT, can mitigate the impact of a device recall on your business.
- 5. Proactive monitoring:** encouraging patients, carers & HCP's to report potential issues as well as an effective Post Market Surveillance program, insourced or outsourced, can help identify potential problems early on.

CONCLUSION

Medical device recalls are a reality that every MedTech organisation must face at some stage in today's global market. Prioritizing patient safety & implementing stringent quality control measures can significantly reduce the likelihood of recalls and their associated costs & negative impacts. As MedTech organizations scale up across the world, having an effective recall strategy that has global reach, is swift & effective, demonstrates an organizations commitment to patient safety & helps preserve brand reputation. By being transparent & striving for quality excellence, MedTech organizations can ensure that their products consistently meet the safety standards of regulators & by doing so, maintain patient, carer & HCP trust & loyalty.

To learn how IQVIA MedTech can help, [click here](#).