Our recommendations aim to create a more harmonised and efficient regulatory environment in APAC, ensuring patient safety while promoting innovation. Read the full position paper for a comprehensive look at how these changes can drive regulatory efficiency and innovation across the region.

APACMed
The voice of MedTech

Risk-Based Change Management for Medical Device

Patient access to medical devices and IVDDs is delayed and inefficient due to inconsistent change management practices across APAC markets. APACMed proposes a risk-based approach to streamline the process and harmonise regulatory frameworks ensuring timely access to innovations without compromising patient safety.

APACMed
The voice of MedTech

Industry Challenges & Recommendations

Risk-Based Change Approach

Inconsistent regulatory practices across APAC markets often result in delays to patient access for medical devices. Some markets focus on low-impact changes, leading to inefficiencies and prolonged approval times.

➤ OUR RECOMMENDATION

Adopting risk-based change submission pathways

Adopt a risk-based approach to change management by focusing regulatory resources on high-impact changes, enabling faster approvals while maintaining safety standards.

Definitions of significant change

Definitions of "significant change" vary widely across APAC markets, with some regulators using list-based categorisation and others following risk-based flowcharts. This lack of standardisation creates complexity for manufacturers and delays access to critical medical devices.

➤ OUR RECOMMENDATION

Harmonising definitions and categorisation of changes

Align with global standards, such as WHO definitions, to harmonise change management processes and reduce regulatory inconsistencies.

Bundling and supplementary change submissions

Change submission pathways vary across APAC markets, with different approval timelines and requirements. Some markets allow bundling submissions, while others require separate approvals, complicating processes for manufacturers.

➤ OUR RECOMMENDATION

Allowing bundled and supplementary change submissions

Expand risk-based change submission pathways to include bundling and supplementary submissions, streamlining processes and accelerating approvals without compromising regulatory oversight.

Regulatory Reliance

Many APAC markets require full local reviews of medical device changes, even when those changes have already been approved by trusted regulatory authorities in other markets. This leads to unnecessary delays and duplication of work for both regulators and manufacturers.

➤ OUR RECOMMENDATION

Consider reliance pathways

Implement regulatory reliance pathways to expedite approvals by recognising and leveraging decisions from trusted regulatory authorities.

Agile and Flexible Approaches

Due to the rapid advancements of medical devices, frequent updates are more apparent which requires agile and flexible change management processes. Without these, delays in approval can hinder timely updates and impact patient safety.

➤ OUR RECOMMENDATION

Adopting a more flexible and streamlined approach in managing changes to enable innovation

Implement a flexible, streamlined approach by reviewing pre-planned modifications, detailed protocols, and impact assessments during the initial premarket submission.

Transition Measures and Periods

Transition periods for implementing changes are inconsistent across APAC markets, with some regulators allowing concurrent supply of old and new versions, while others provide limited or no transition periods. This creates uncertainty and disrupts supply chains, delaying patient access to essential devices.

➤ OUR RECOMMENDATION

Providing adequate transition periods for regulatory changes

Provide a transition period of at least six months to ensure uninterrupted supply and smoother adaptation to regulatory changes.