CYBERSECURITY REGULATORY UPDATES (SINGAPORE)

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Health Sciences Authority
Evolving Regulatory Requirements to Manage Cybersecurity risks

Pre-2010
MD regulatory controls were based mainly on the principles of Quality, Safety and efficacy.

2014
Prior to 2014, cybersecurity risks are managed largely through post-market regulatory controls in Singapore.

After 2014, regulators globally have acknowledged the need to better regulate MD cybersecurity risks.

From 2016
HSA implemented preliminary regulatory requirements into our pre-market registration process.
APRIL 2020

Regulatory Guidelines for Software Medical Devices – A Life Cycle Approach
HSA’s Cybersecurity Requirements and Controls
1. Secured by design
2. Risk Management
3. Post Market Plan and Obligation
SHARED RESPONSIBILITY

Medical Device Manufacturers

Healthcare Institutions

Regulators

Medical Device users

Vulnerability finders