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Designing Cyber-Resilient Medical Devices

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The definition of a medical device encompasses not only capital equipment, but also surgical instruments, patient monitoring, implantables, and even software. The breadth and variety of the field, combined with the critical importance of med devices to life and safety, requires a deliberate, focused approach to cybersecurity to ensure that they are resilient throughout their life cycle.



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Medtronic's Global Security Office (GSO) and Product Security Office (PSO)

The blend of Enterprise Security and Product Security

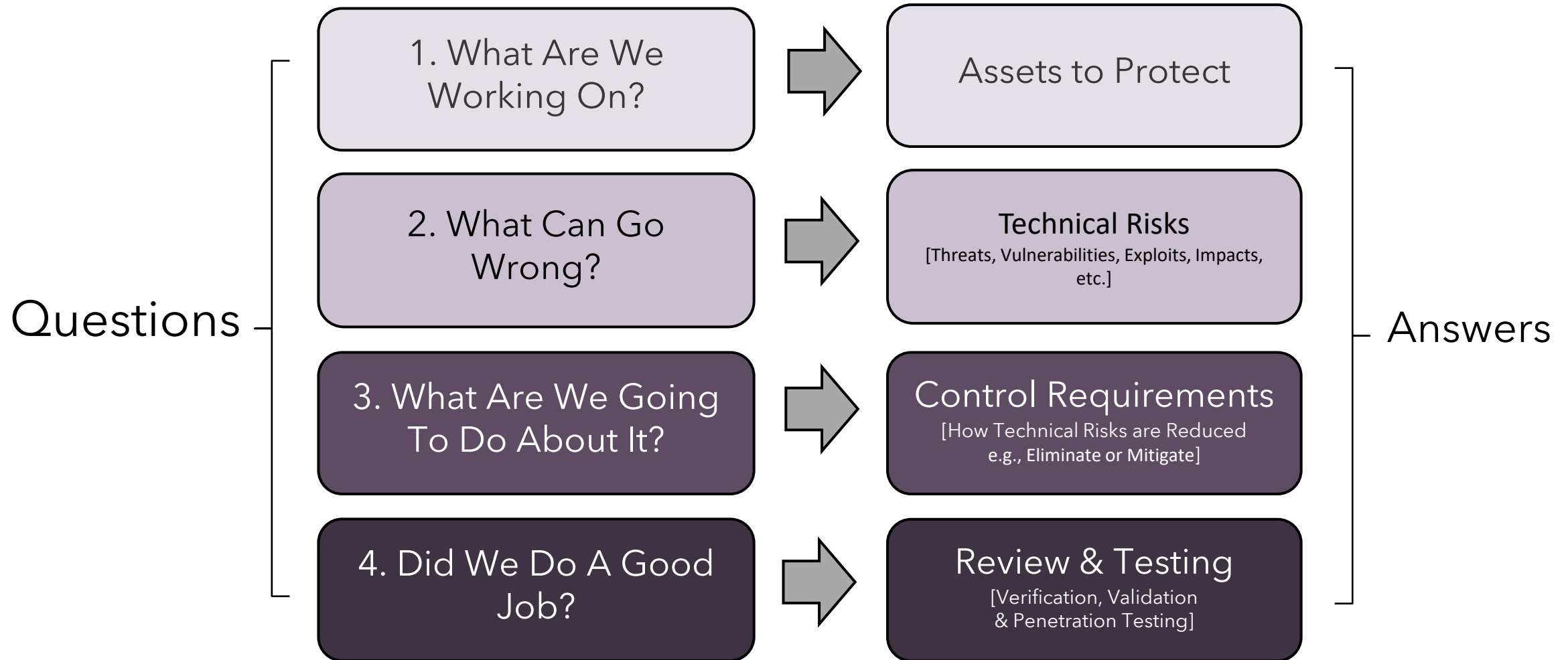
Points to Consider:

- ✓ The GSO reports into the Global IT function. The PSO reports into Corporate Quality.
- ✓ Both teams have a mission to ensure "CIA" (Confidentiality, Integrity, and Availability) within their programs.
- ✓ There is both bifurcation and overlap of duties, and the teams remain tightly connected in support of each other's missions.
- ✓ Relationships within Medtronic along with external parties are maintained both independently and in coordination, depending on the circumstances.

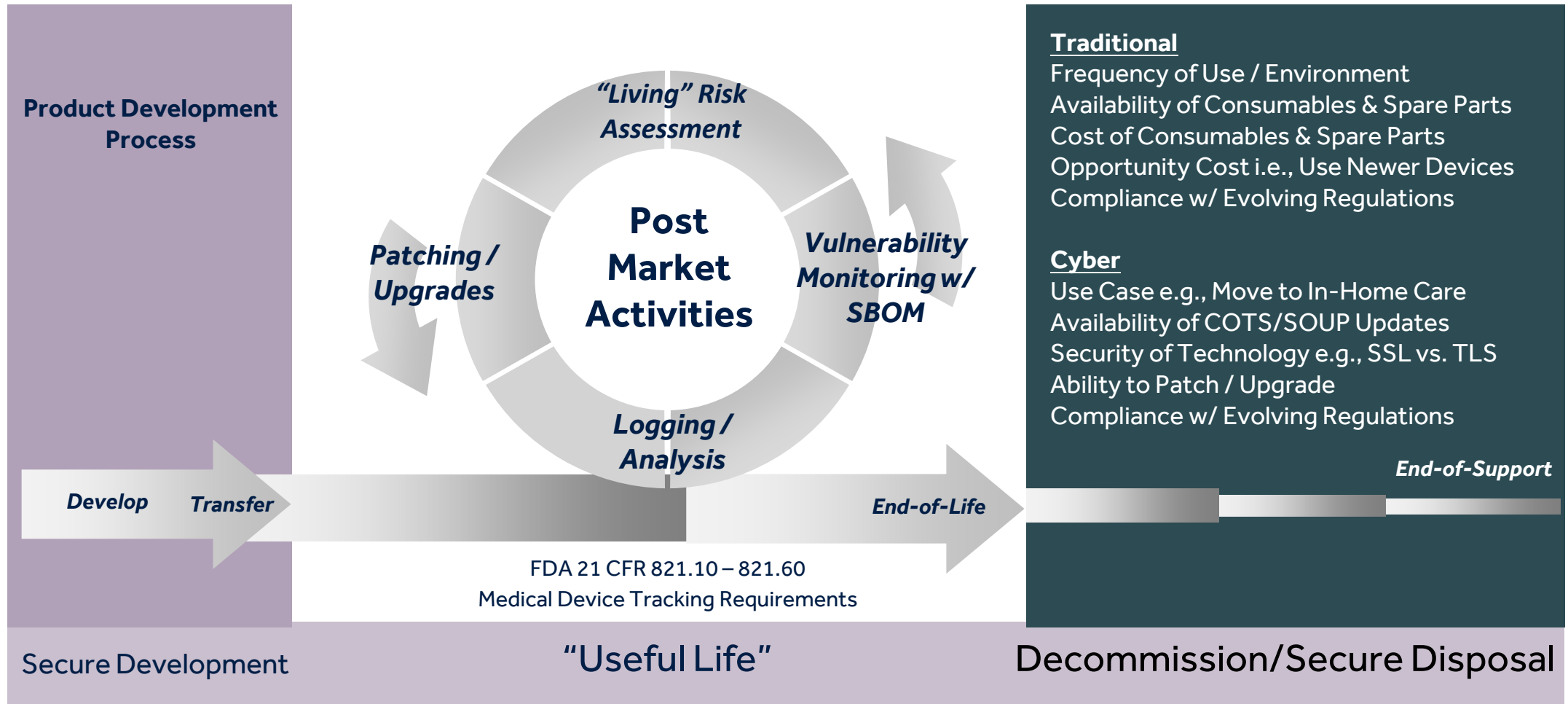
	GSO	PSO
Medical Devices – Capital Equipment, Implantables, Etc.		X
Medical Devices – Cloud, Data, Systems, Mobile Apps, Etc.	X	X
Enterprise IT Systems (SAP, Office,	X	
Manufacturing (Make, Build)	X	X
Distribution/Supply Chain	X	
Third Party Management	X	
External Regulatory Interaction		X
External Cyber Industry Interaction	X	X
Customer Interaction	X	X
Law Enforcement Interaction	X	



Security and Privacy By Design

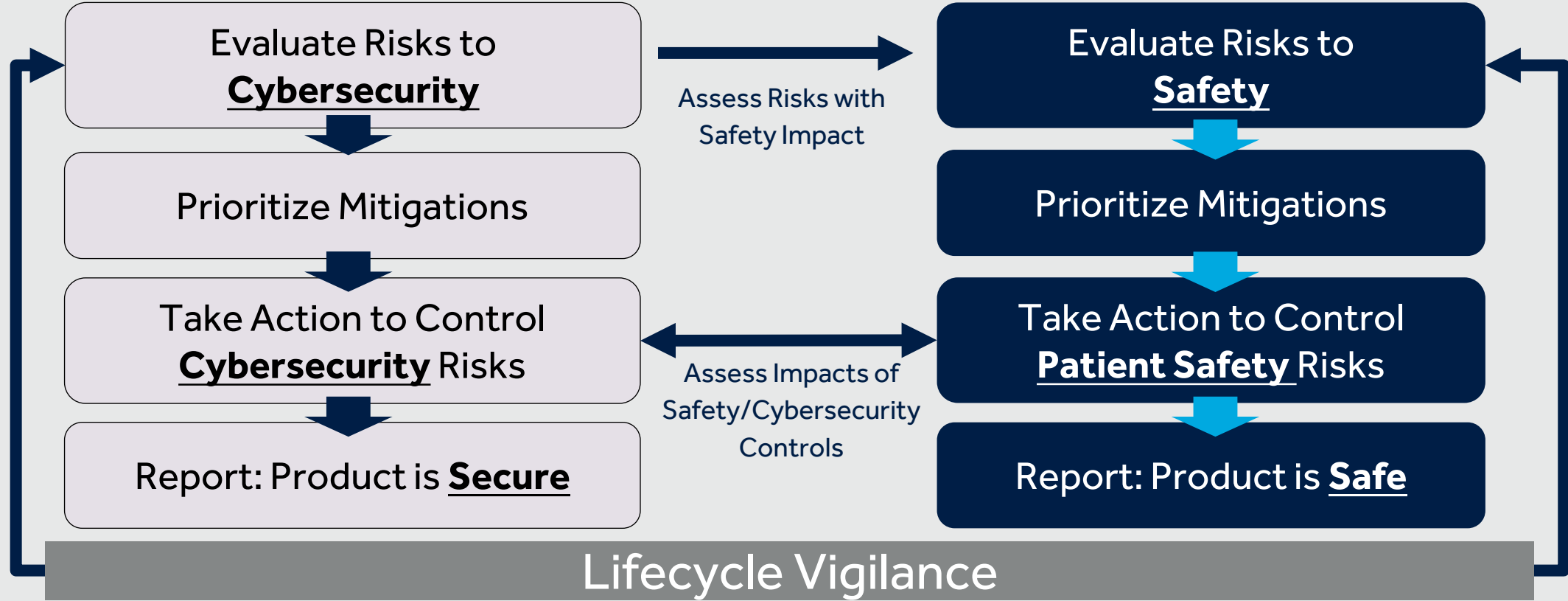


Security Lifecycle Vigilance



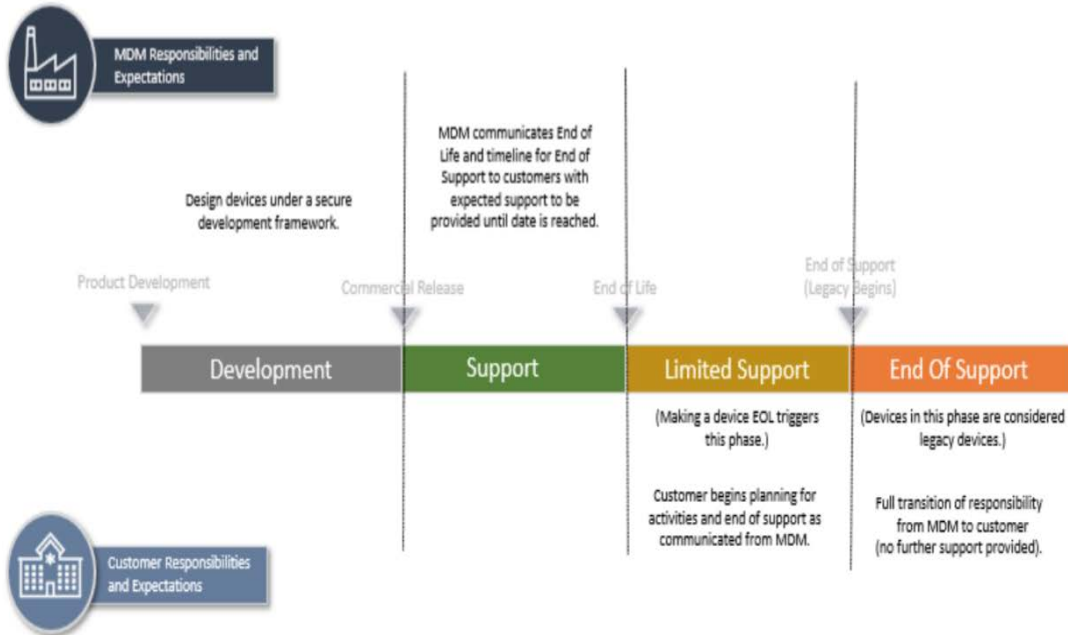
Security and Safety Risk

Product Risk Management

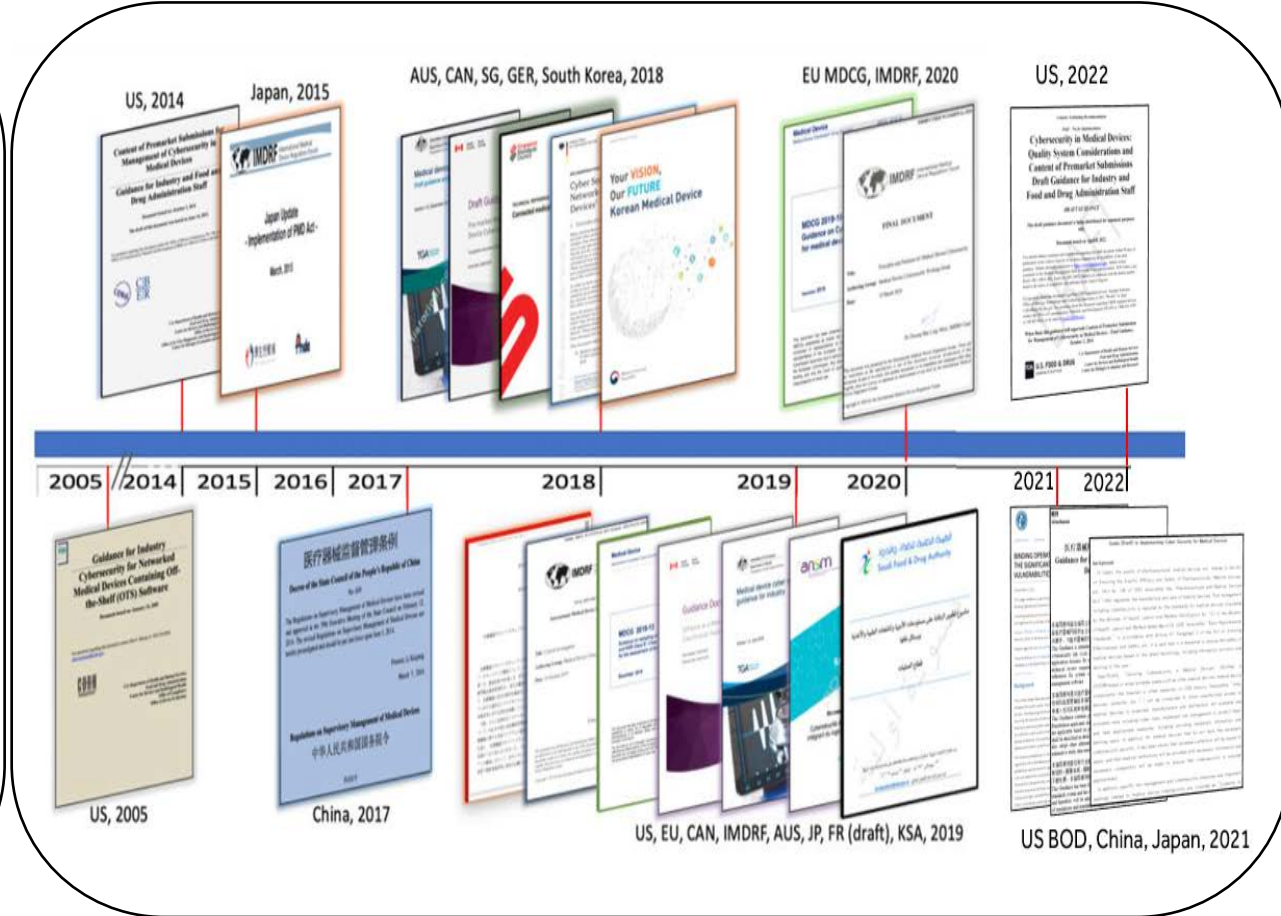


Lifecycle Management and Regulatory Guidance

Cybersecurity and the Total Product Life Cycle



*Medical Device Manufacturer (MDM) follows regional guidance for medical device responsibilities. Support levels may vary and as agreed upon with customers.



When Cloud Meets Medical Devices



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Questions?



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