Meet 7 Common Oversights by Medical Device Execs

Absent solid test strategy

Thinking about testability early and ensuring there's enough time and capacity to write and execute tests.

Compliance isn't used to add value

Seeing compliance as an end in of itself, rather than a way to increase value through increasing quality.

Zero over-the-air updates

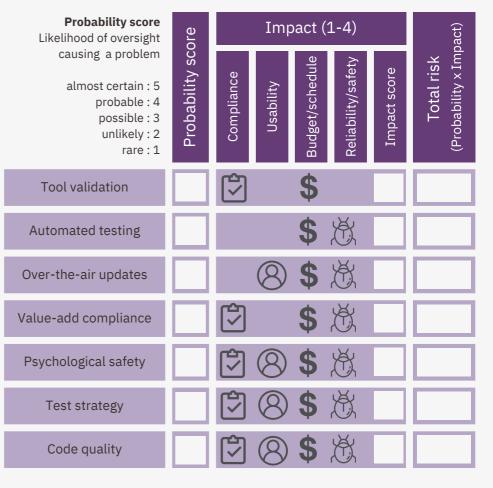Found a bug post-release? Being able to release updates when needed can reduce the need for device recalls.

Not using automated testing

Automated testing has come a long way in recent years. Test smarter, not harder with automated test rigs.

Fix your biggest risk

Bluefruit Software

Probability score
Likelihood of oversight causing a problem

almost certain : 5
probable : 4
possible : 3
unlikely : 2
rare : 1

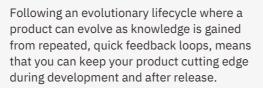|	Probability score	Impact (1-4)					Total risk (Probability x Impact)
		Compliance	Usability	Budget/schedule	Reliability/safety	Impact score	
Tool validation		☑		$			
Automated testing				$	🐞		
Over-the-air updates			👤	$	🐞		
Value-add compliance		☑		$	🐞		
Psychological safety		☑	👤	$	🐞		
Test strategy		☑	👤	$	🐞		
Code quality		☑	👤	$	🐞		

Continuous Improvement Is Essential

If you follow traditional, more Waterfall, methods of product development then you increase the risk of your medical device being out of date before it launches.

Following an evolutionary lifecycle where a product can evolve as knowledge is gained from repeated, quick feedback loops, means that you can keep your product cutting edge during development and after release.

Invest In Quality

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Using unvalidated tools

Regulations demand that your tools are tested before initial use.

Poor psychological safety

The earlier colleagues report concerns and share their ideas, the more costs saved and value added.

Code quality isn't invested in

Code readability and test coverage aren't visible but they inevitably impact reliability, safety and performance