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CONNECT
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Software Validation Best Practice in Regulated Industries

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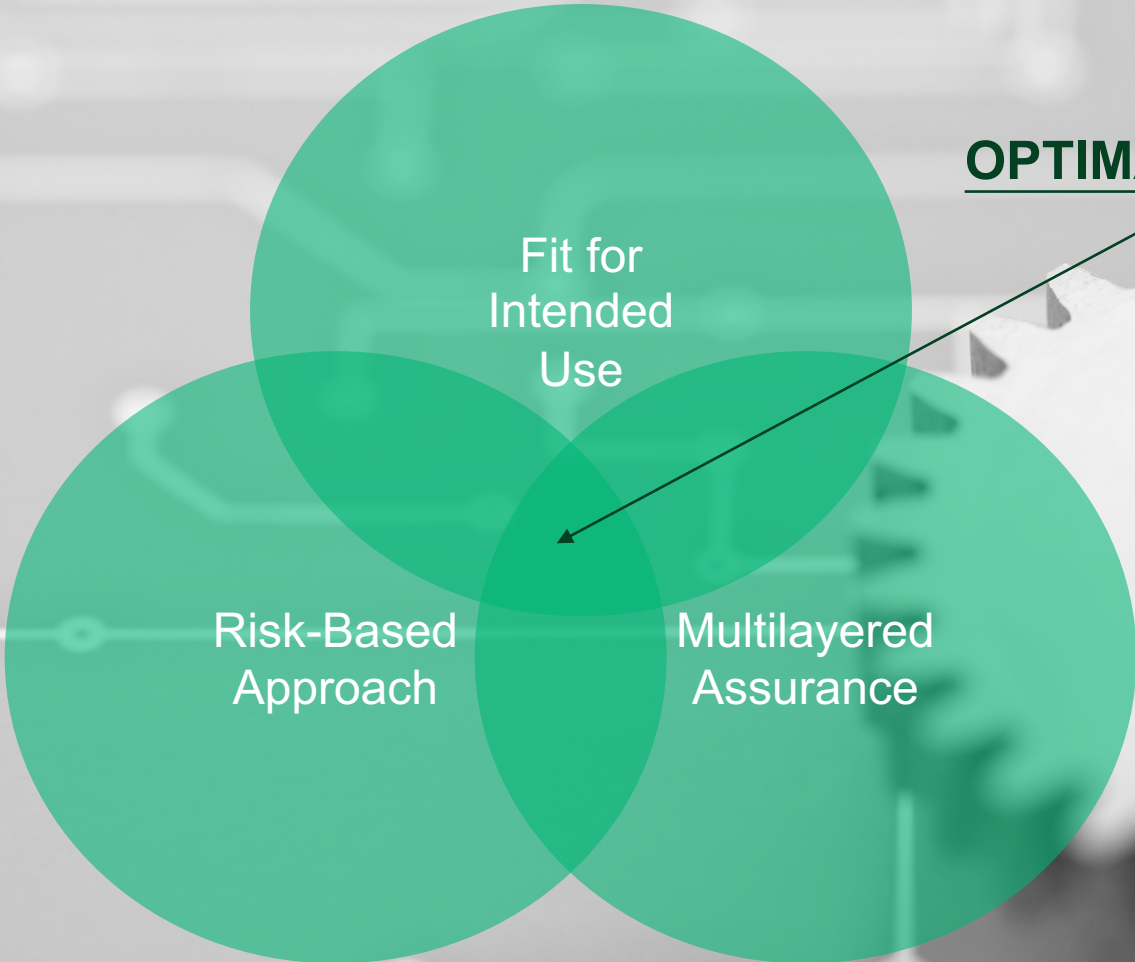
The Importance of Planning

Managing Changes & Revisions

~80% of medical device recalls attributable to software are due to *revision errors*.

Questions?

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Architecture Plan / Master Validation Plan

Operation, Maintenance, and Regulatory Documentation

Analytics and Operations

Manufacturing Execution System (MES)

Systems Management	Test Management	Data Management	Real-Time Dashboards	Operations Modeling

Application Software

Test UI	Sequence Editor	Data Connectivity

Test Architecture/Sequence

Test Steps	Debug UI

Abstraction Layers

Instrument Drivers/Configuration Tools

DUT Control Functions

DUT Handler Functions

Station Health and Operation Functions

Instrumentation

Analog & Digital I/O	Digital Multimeter	Waveform Generator and Oscilloscope
FPGA Based I/O	Switch	Source Measure Unit
Programmable DC Power Supply	RF Instruments	Instrument Control and Synchronization

Infrastructure

Rack: Mechanical, Power, and Safety	Display	Computer/ Controller	Sensors, Antenna, etc.	Fixture and Chamber	Connector/ Mass Interconnect	DUT Handler

Device

DUT

■ NI PRODUCT   ■ BUILT USING NI PRODUCTS   ■ BUILT USING NI ECOSYSTEM TOOLS   ■ FROM END USER OR THIRD PARTY