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CRISIS PREVENTION AND RECOVERY, LLC

This job aid is intended to compare and contrast "product software" quality assurance activities and documentation from "tool software" quality assurance activities and documentation.

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	Software "in" the product **runs as part of the intended use**	**Tool software**
US Regulation	21 CFR 820.30(g) Software Validation	21 CFR 820.70(i) Automating a quality system process
Standards	IEC 62304 for Software Process	AAMI TIR 36 provides examples
Risk Scaling of Process?	Yes, using safety risk analysis	Yes, using process risk analysis; "what is risk to product quality if process automation software has failure?"
Custom software	Conformance with IEC 62304	FDA General Principles of Software Validation for guidance.
SOUP (Open source and Off-the-shelf software)	Treated like SOUP under 62304	Treated appropriately based on intended use (which features you are using).
	5.1.1(d) Development plan 5.1.5 Integration plan 5.1.7 Risk management plan 5.2.2(a), 5.3.3, 5.3.4 Requirements 5.3.6 Verify Architecture 6.1 Maintenance plan 7.1.2, 7.1.3 Risk management 7.4.1, 7.4.2 Risk management of changes 8.1.1, 8.1.2 Configuration management	Requirements Configuration Control Verification Validation (as necessary) Change Control
Configuration Management	Yes, per IEC 62304 requirements	Yes, but to manufacturer's defined method.
Bug Tracking	Yes, per IEC 62304 requirements	Good idea
Maintain "validated" state	Yes	Yes
Cybersecurity	Yes, scrutinized heavily in regulatory submission.	No specific requirements although we advise similar process of threat modeling and ensuring cybersecurity controls for high risk tools.
Software Requirements	Yes for all functionality	Yes, but for intended use only
Software Design documentation	Yes, for IEC 62304 Software Safety Class 'C' software. Also, FDA expectations in General Principles of Software Validation guidance document.	Maybe. Depends upon the process risk analysis and subsequent planning.