Automated Processes

The Context
Device manufacturers often use software as part of production and the quality management system. §820.70(i) requires validation of the software for its intended use according to an established protocol. This applies to both software purchased from an external vendor and software developed in house. The deciding factor is the use of the software, not its source.

The Warning Letter
On February 4, 2016, FDA sent a Warning Letter to Eolane Vailhauques, a manufacturer of galvanic skin response measurement devices, in Vailhauques, France. The Warning Letter was the result of an FDA inspection.

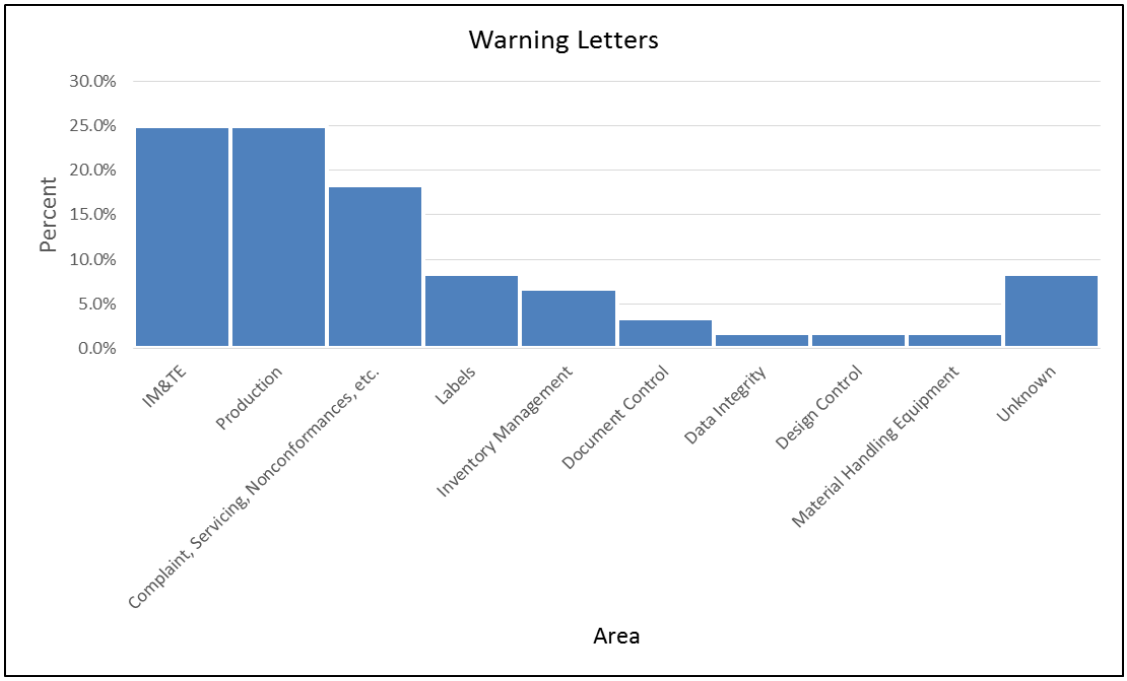
The Issue Cited
The Warning Letter cited a failure to validate software used in the QMS as required by 21 CFR §820.70(i).

The citation says, "[Your] firm did not have documentation to demonstrate that the … computer data processing software, developed in house, was validated for its intended use. Your firm has installed and has been utilizing the software since 2005 for documenting and monitoring nonconformances with customer complaints, suppliers, internal/external audits, CAPA, and internal facility defects."

The firm to the inspection, and FDA said, "We reviewed your firm's response and conclude that they are not adequate. [Y]our firm did not provide software validation documentation. The response did not include documentation that your firm has performed a comprehensive analysis of additional software packages to ensure that they were adequately validated. The response did not indicate if personnel will be trained on how to operate the [software]."

The Requirement
The Quality System Regulation requires, in §820.70(i), "When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.

Recommendations
Identify any software used in production or the QMS. Since software is very common, you may need to review procedures, include software verification in audit checklists, review device history records, and observe work. The figure below shows areas cited in Warning Letters for lack of software validation.



For every piece of software used, from an Excel spreadsheet at a workstation to the company's Enterprise Resource Planning system. Be sure there is a statement of the intended use, a protocol to conduct the software validation, documented tests cases showing they passed the test, and a report summarizing all of the activities. Each of these documents should be reviewed, approved, signed, and dated. They are all quality records, so also subject to the company's record retention policy.