

# FDA 21 CFR Part 820

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To deal with these challenges and to comply with rigorous FDA regulatory requirements, SoftExpert Excellence Suite is an integrated web-based management system, designed to help medical device companies to fully meet 21 CFR PART 820 regulations.

With SoftExpert Excellence Suite such organizations can easily and effortlessly:

- Achieve 21 CFR PART 820 compliancy quicker.
- Employ industry-proven solution that is seamlessly integrated.
- Reduce the cost involved to comply with FDA regulations.
- Increase end user acceptance and productivity.
- Monitor and report product defects.
- Automate the required regulatory data collection of device-history records.
- Manage product complaints and adverse events.
- Manage closed-loop CAPA processes.
- Communicate quality issues.
- Modify procedures to suit unique business requirements.
- Access procedures while maintaining complete document security.
- Maintain complete audit trail records.
- Eliminate rework.
- Manage product specifications.
- Maintain accessible and secure product information.
- Minimize costs by saving on consulting services.
- Ensure the authenticity, integrity, and confidentiality of electronic records.
- And much more ...

SoftExpert Excellence Suite provides organizational efficiency, process control, and flexibility to help simplify the tasks involved in managing data and information. It will also help your organization make better decisions in managing the content and process that drive your business.

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Each SoftExpert module addresses key compliance issues as shown below:

## Compliance Mapping

Product	FDA Compliance and Requirements
<a href="#">Document &amp; Records Management [EDM/RM]</a>	<ul style="list-style-type: none"> <li>• Manage the creation, review, approval, and distribution of documents.</li> <li>• Ensure changes to documents are reviewed and approved by authorized personnel.</li> <li>• Communicate approved changes to the appropriate personnel in a timely manner.</li> <li>• Document the Quality Management System.</li> <li>• Prevent unintended use of incorrect documents.</li> <li>• Automate document protection and retention rules.</li> <li>• Show enterprise-wide involvement in the process of document changes.</li> <li>• Remove or disable obsolete documents to prevent unintended use.</li> <li>• Ensure only the latest document versions are available for use.</li> <li>• Keep record of document change.</li> </ul>
<a href="#">Nonconformance Management</a> <a href="#">Corrective and Preventive Actions</a> <a href="#">Customer Complaint Management</a>	<ul style="list-style-type: none"> <li>• Maintain procedures to control product that does not conform to specified requirements.</li> <li>• Streamline the complaint-handling process and reduce the lifecycle from submission to resolution.</li> <li>• Define the responsibility for review and the authority for the disposition of nonconforming products.</li> <li>• Ensure that disposition of nonconforming products are well documented.</li> <li>• Integrate the corrective and preventive action process with other quality processes.</li> <li>• Provide customizable reporting capabilities to help managers monitor entire quality management life cycle.</li> <li>• Streamline the process for identifying, evaluating, reviewing, and handling of nonconforming materials, parts, and finished products.</li> </ul>
<a href="#">Audit Management</a>	<ul style="list-style-type: none"> <li>• Streamline and effectively manage the audit process.</li> <li>• Provide advanced tracking capability.</li> <li>• Automate scheduling of all recurring audit-related activities.</li> <li>• Ensure the quality system is in compliance with the established quality system requirements and determine the effectiveness of the quality system.</li> <li>• Provide quality audit reports for management review.</li> <li>• Keep record of audit dates and results.</li> </ul>

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<p><a href="#">Business Process Management [BPM]</a></p>	<ul style="list-style-type: none"> <li>• Streamline the entire change control procedure for faster turnaround.</li> <li>• Ensure production (and installation) processes are defined, planned, and documented.</li> <li>• Ensure processes are monitored and controlled.</li> </ul>
<p><a href="#">Competencies and Training Management</a></p>	<ul style="list-style-type: none"> <li>• Easily identify training needs.</li> <li>• Ensure that all activities are correctly performed by the right personnel.</li> <li>• Automate assignment and monitoring of training sessions.</li> <li>• Allow sequencing of training courses, so after a prerequisite is completed, the next course is automatically launched.</li> <li>• Provide group sign-off feature for verifying training of large groups of employees.</li> <li>• Keep record of all trainings carried out.</li> </ul>
<p><a href="#">Gage Calibration Management</a></p>	<ul style="list-style-type: none"> <li>• Ensure that all inspection, measuring, and test equipment are suitable for their intended purposes and are capable of producing valid results.</li> <li>• Check that equipment is routinely calibrated, inspected, checked, and maintained.</li> <li>• Ensure no unregistered or overdue equipment is used.</li> <li>• Assess measurement validity if found out of calibration.</li> <li>• Ensure measurement uncertainty and equipment capability are known.</li> <li>• Identify equipment which does not need to be calibrated.</li> <li>• Trace equipment measurements to national or international standards.</li> <li>• Document calibration steps for each piece of equipment.</li> <li>• Keep record of all calibrated equipment.</li> </ul>
<p><a href="#">Statistical Process Control</a></p>	<ul style="list-style-type: none"> <li>• Verify acceptability of process capability and product characteristics.</li> <li>• Ensure that required characteristics of processes and products are monitored and measured.</li> <li>• Document procedures to implement and control the statistical techniques identified.</li> <li>• Identify variations in processes.</li> <li>• Ensure action plans are taken when out-of-control signals are detected.</li> <li>• Monitor the process for key constraints that correlate to final product quality.</li> <li>• Develop practices that ensure minimal variation.</li> <li>• Alert specified users when a process is trending out of control.</li> <li>• Provide closed-loop feedback to appropriate process controllers to bring the process back in control.</li> </ul>
<p><a href="#">Material and Product Inspection</a></p>	<ul style="list-style-type: none"> <li>• Maintain procedures for acceptance of incoming products.</li> <li>• Ensure incoming materials are inspected or verified as conforming to specified requirements.</li> <li>• Document acceptance or rejection of inspected material.</li> <li>• Ensure final inspection is performed prior to release of finished product.</li> <li>• Keep record of the results of supplier evaluations and follow-up actions.</li> </ul>

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<p><a href="#"><u>Asset Maintenance Management</u></a></p>	<ul style="list-style-type: none"> <li>• Keep records of all maintenance work.</li> <li>• Ensure unique identification of each piece of equipment.</li> <li>• Keep records of equipment calibration and maintenance.</li> <li>• Document equipment instructions – usually supplied by the manufacturer.</li> <li>• Ensure equipment operates within specifications.</li> <li>• Provide maintenance schedule to ensure no equipment is overlooked.</li> </ul>
<p><a href="#"><u>Project and Service Management</u></a></p>	<ul style="list-style-type: none"> <li>• Ensure projects are initially planned then approved.</li> <li>• Estimate initial project time, costs, and deliverables.</li> <li>• Identify, document, review, and approve all project changes and modifications.</li> <li>• Ensure critical path assessment.</li> <li>• Provide WBS &amp; Milestone plan.</li> <li>• Keep record of all project meetings.</li> <li>• Ensure project tasks are performed and verified.</li> </ul>
<p><a href="#"><u>Failure Mode and Effect Analysis</u></a></p>	<ul style="list-style-type: none"> <li>• Maintain procedures to control the design of the device in order to ensure that specified design requirements are met.</li> <li>• Identify significant design or process characteristics that require special controls to prevent or detect failure modes.</li> <li>• Ensure the design output meets the design input requirements.</li> <li>• Ensure problems are prevented from occurring.</li> <li>• Maintain plans that describe or reference the design and development activities.</li> <li>• Define responsibility for implementing design plans.</li> <li>• Ensure plans are reviewed, updated, and approved as design and development evolves.</li> <li>• Keep record of all design reviews and verifications.</li> </ul>
<p><a href="#"><u>Risk Management</u></a></p>	<ul style="list-style-type: none"> <li>• Provide qualitative and quantitative risk management.</li> <li>• Provide key risk indicators for tracking risk metrics and thresholds.</li> <li>• Automate the process of identifying, measuring, and monitoring operational risks.</li> <li>• Track material risks and quantify risk costs.</li> <li>• Enhanced visibility of the risks impacting the organization.</li> <li>• Provide statistical and trend analysis capabilities.</li> <li>• Keep record of risk history.</li> <li>• Provide an audit trail of actions taken and risk status.</li> </ul>