Use of MDSAP - Regulatory Updates (FDA)
FDA QS Inspections

U.S. Food and Drug Administration’s (FDA) Center for Devices and Radiological Health, will accept the MDSAP audit reports as a substitute for FDA routine inspections.

However, all other situations listed under the FDA’s Compliance Program Guidance Manual (CPGM) 7382.845, Inspection of Medical Device Manufacturers, still apply.
# Types of QS Inspections

<table>
<thead>
<tr>
<th>Inspection Level</th>
<th>Type of Inspection</th>
<th>Guide to Inspections</th>
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<tbody>
<tr>
<td>1 (Routine)</td>
<td>Abbreviated</td>
<td>QSI-T – Two subsystems; Corrective and Preventive Actions (CAPA) plus Production and Process Controls (P&amp;PC) or Design Controls (PAC 82845A)</td>
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<td>2 (Routine – Initial)</td>
<td>Comprehensive</td>
<td>QSI-T - The four major subsystems; Management Controls, Design Controls, CAPA and P&amp;PC (PAC 82845B or 82845P or 82A800)</td>
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<td>3</td>
<td>Compliance Follow Up</td>
<td>As directed by inspectional guidance and elements of QSI (PAC 82845C)</td>
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<td>Special</td>
<td>For Cause</td>
<td>As directed by inspectional guidance and elements of QSI (PAC 82845G)</td>
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<tr>
<td>Special</td>
<td>Risk Based Work Plan</td>
<td>As directed by CDRH inspection assignment and elements of QSI (PAC 82845H)</td>
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<tr>
<td>Pre/Post Market</td>
<td>Comprehensive or Abbreviated</td>
<td>Process used by FDA to review and evaluate the safety and effectiveness of Class III medical devices. (PAC 83001, 83001A)</td>
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Program Development

Challenges

• CDRH Reorganization - TPLC
• Resource limitations
• Internal tracking mechanism
• Educating internal stakeholders on the program and benefits to FDA
• Expanding regulatory uses for MDSAP audit reports
• Medical devices regulated by other Centers

Successes

• Consistent source of QS intelligence
• Capability Maturity Model Integration (CMMI) Institute
• Engagement with Auditing Organizations, partner countries and potential affiliate members
• Program implementation and maintenance
• Continual improvement to IT Portal