## Quality Management Maturity Spectrum Assessment



Life sciences manufacturers have diverse quality management capabilities - from emerging companies that are still struggling with foundational processes and data, to established, global industry leaders that have extensive quality management infrastructures and leverage advanced analytics to meet their quality objectives.

Find out where your company falls on the quality management maturity spectrum by taking a look at the following checklist. When reviewing this checklist, consider your current level of maturity in each of these areas and whether your capabilities align with where you want to be in your quality management evolution.

	Early Stage Companies	Mid-Stage Companies	Advanced Companies
Policies and Decision Making	✓ Little governance in quality systems ✓ Limited internal quality oversight ✓ Very little external supplier oversight	<ul> <li>✓ Limited governance in quality systems</li> <li>✓ Moderate internal quality oversight</li> <li>✓ Limited external supplier oversight</li> </ul>	<ul> <li>✓ Extensive governance in quality systems</li> <li>✓ Strong internal quality oversight</li> <li>✓ Strong external supplier oversight</li> </ul>
People/Talent	✓Employees are task versus quality oriented	✓Employees understand impact on quality but still primarily task oriented	✓ Leadership has established a true culture of quality that extends throughout its operations and out to external business partners ✓ Employees not only understand their impact on overall quality but take steps to improve it
Process Optimization	✓ Quality functions in a silo outside of other departments	<ul> <li>✓ Quality's reach extends into other departments but mainly reactive versus proactive</li> <li>✓ Quality team is primarily based in company's headquarters, limited quality representation in off-site/ remote locations and facilities</li> </ul>	✓ Quality permeates throughout the organization, with quality professionals in the right places at the right times with the right knowledge and skills to drive improvements

Integration	✓ Very little integration  – each department/ function acts independently with its own systems and processes  ✓ Difficult to determine how each component of the business impacts the other in terms of quality	✓ Some IT integration of quality with other departments/ functions, ability to share information but still largely manual  ✓ An understanding of how each component's quality impacts the others' but difficult to enact change that impacts quality across the board	<ul> <li>✓ Quality is tightly integrated with all other departments/ functions throughout the enterprise</li> <li>✓ All stakeholders operate collaboratively within a common, electronic quality platform</li> <li>✓ This integration extends out to external business partners</li> </ul>
Data	✓ With a reliance on manual, paper based processes, quality data is scattered, difficult to access, likely inaccurate, incomplete	✓ Data is stored electronically in separate systems, no single, comprehensive source of quality data, still facing data quality challenges	✓ Company leverages an enterprise quality management system (EQMS) to establish a single source of accurate, complete and comprehensive quality data ✓ Digitization of quality processes and data positions company to leverage Industry 4.0 technologies (e.g. AI, ML)
Actionable Business Insights	<ul> <li>✓ Major challenge to gain insights from the data</li> <li>✓ KPIs are focused on compliance, task completion, and process efficiency</li> </ul>	<ul> <li>✓ Can perform analytics but can be manual and time/labor intensive</li> <li>✓ KPIs still weigh heavily on compliance</li> </ul>	<ul> <li>Can easily perform advanced analytics</li> <li>✓ Balanced scorecard with KPIs focused on all quality elements: Product quality, safety, efficacy and continuity of supply, compliance</li> <li>✓ KPIs closely aligned to broader corporate objectives</li> </ul>

Founded in 1994, Sparta Systems is the world's premier provider of cloud and on-premise quality management software. We offer the tools, analytics, and expertise that speed up quality and compliance. Companies in life sciences, consumer products, discrete manufacturing and more, rely on Sparta.