

## [YEAR] Strategic Quality Plan (example)

(Example) Quality Policy: “This company assures that our products are of high quality and are safe for their intended use. Our employees are highly competent. We are committed to designing quality into our products and processes. We strive to continually improve every aspect of our business. Our company maintains an effective Quality Management System and is in compliance with all applicable standards and regulations.”

No.	Quality Policy Element	Near Term (NT) / Long Term (LT)	Quality Objective	Metric	Assigned to:	Status / Remarks
01a	Assure product is of high quality.	NT	Baseline	\$ scrap as a percent of cost of goods sold		Quarterly review
01b	Assure product is of high quality.	NT	Baseline	\$ rework/repair based upon cost of goods sold		Quarterly review
01c	Assure product is of high quality	NT	Baseline	Returned Material Authorizations versus \$ Sales		Quarterly review
01d	Assure product is of high quality.	NT	Baseline	Order Cancellations versus \$ Sales		Quarterly review
02a	Assure product is safe for intended use.	NT	Baseline	Expense of resolving adverse events as a percent of \$ Sales		Quarterly review
02b	Assure product is safe for intended use.	NT	Baseline	Adverse events reported as a percent of units sold		Quarterly review
03.	Personnel are highly competent	LT	Establish an effective professional development	Attain 20% annual engagement in program		Quarterly review

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04.	Commitment to designing quality into products and processes	LT	program consisting of: <ul style="list-style-type: none"> <li>• manufacturing area apprenticeships</li> <li>• machinist/quality inspection certifications education/certification per the employee manual</li> </ul>	4 posted employee commitments per month, minimum		Quarterly review
05.	Striving to continually improve every aspect of our business	LT	Ongoing: conduct one employee interview per week and post results on company intranet as well as via HR (newsletter, etc.) Baseline	Unique Preventive Actions initiated and implemented for Product / Process Improvements versus Cost of Goods Sold for each Department		Quarterly review

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06.	Maintain an effective Quality Management System	LT	Baseline Audit-based Quality Management System Nonconformities	Nonconformities per Process Owner Internal Audit Area over time		Quarterly Review
07a	Compliance with all applicable standards and regulations	NT	Attain ISO 13485:2003 certification and Vendor Approvals	Successful 3 <sup>rd</sup> Party and Customer Quality Management System Assessments		3 <sup>rd</sup> Party and Customer Quality Management System Assessment Outcome Reviews
07b	Compliance with all applicable standards and regulations	NT	Achieve successful outcome for FDA 510(k) submittal	Receive market approval from FDA		Complete by: [date]
07c	Compliance with all applicable standards and regulations	NT	Achieve successful outcome for first Establishment Inspection by FDA representatives	Receive Medical Device Manufacturing Facility License from FDA Representatives		To be expedited pending completion of ISO 13485:2003 Certification or dealt with upon arrival of FDA, whichever comes first.
07d	Compliance with all applicable standards and regulations	NT	Attain CE marking	Pass Notified Body Assessment		Notified Body Assessment scheduled for: [date]