
Joint Replacements

Trauma, Extremities & Deformities

Craniomaxillofacial

Spine

Biologics

Surgical Products

Neuro & ENT

Interventional Spine

Navigation

Endoscopy

Communications

Imaging

Patient Care & Handling Equipment

EMS Equipment

Regulatory Affairs and Quality Assurance Policy Corporate Policy Number Nine

**Copies of all Corporate Policies
may be found on
www.stryker.com/corporatepolicies**

2825 Airview Boulevard
Kalamazoo, MI 49002
t: 269 385 2600 f: 269 385 1062



Responsibilities and Procedures:

1. **Commitment to Regulatory and Quality Compliance.** Stryker Corporation is committed to developing, manufacturing, and marketing medical products that are safe and effective and that comply with applicable laws and regulations, including those administered by the United States Food and Drug Administration and regulatory bodies in other countries in which Stryker conducts business. Compliance with these laws and regulations is the responsibility of every employee at Stryker Corporation.
2. **Divisional Presidents.** The President or executive in charge of each Stryker Division (the "Divisional President") has primary responsibility for ensuring that his or her Division complies with all applicable regulatory and quality requirements. The Divisional President's responsibilities include establishing and maintaining: (a) regulatory/quality policies and plans for the Division; (b) systems and procedures that appropriately address each area of regulatory and quality compliance; (c) training programs on regulatory and quality issues for Divisional employees; and (d) an appropriately staffed Regulatory/Quality ("RA/QA") organization, to be headed by the Division's RA/QA Officer, that will assist the Division in meeting its compliance commitments. Additionally, the Division President is responsible for ensuring that the regulatory/quality initiatives identified by the Corporate RA/QA Steering Committee are implemented and reporting on RA/QA matters as set forth in Section 4.A of this policy.
3. **Stryker RA/QA Steering Committee.** An RA/QA Steering Committee, comprised of senior RA/QA Officers from across the Company, will meet at least quarterly and will be responsible for overseeing the Company's quality and regulatory activities on a worldwide basis. The Committee's functions will include: (a) conducting and/or overseeing independent quality systems audits of Stryker manufacturing facilities; (b) reviewing 483s, inspection reports, MDRs, vigilance reports, recalls, warning letters, and other adverse regulatory/quality notices submitted or received by the Divisions and Divisional audit plans and findings to identify RA/QA issues that require global and/or corporate initiative; (c) assisting the Divisions in responding to adverse

RA/QA findings from U.S. or international regulatory agencies; (d) assisting the Divisions in the implementation of initiatives identified in their quality plans or by the Committee; (e) identifying, promoting, and sharing best practices across Divisions; and (f) reporting on RA/QA matters as set forth in Section 4.B of this policy.

4. Reporting.

- (a) The Divisional President shall notify Stryker's Chief Executive Officer and the Corporate RA/QA Steering Committee of all: (1) inspections of the Division's quality systems, products, or facilities by any governmental body or organization; (2) adverse regulatory/quality actions taken by any governmental agency; (3) recalls or other product actions undertaken by the Division; (4) reports of alleged product failures or malfunctions that the Division is required to file with a governmental agency; and (5) other significant regulatory, quality, or product safety issues.
- (b) The RA/QA Steering Committee will promptly report all material regulatory and quality issues to Stryker's Chief Executive Officer, the relevant Divisional Presidents and Divisional RA/QA Officers, and Stryker's General Counsel. The Committee will meet with the Chief Executive Officer at least twice yearly to review the Company's compliance with U.S. and international regulatory and quality systems requirements.