

Quality and Compliance

Teaming up for holistic excellence in the medical device sector



Ethics and
Compliance



Dad, what do you do in Compliance???





7 Hallmarks of an Effective Corporate Compliance Program¹

-  **Implementing written policies, procedures, and standards of conduct**
-  **Designating a compliance officer and compliance committee**
-  **Conducting effective training and education**
-  **Developing effective lines of communication**
-  **Conducting internal monitoring and auditing**
-  **Enforcing standards through well-publicized disciplinary guidelines**
-  **Responding promptly to detected offenses and undertaking corrective action**

Organizational needs of a Corporate Compliance Program



Program Office:

- Designs, implements and maintains policies, procedures, and systems
- Project management
- Reporting channels



Compliance Officers:

- Subject matter experts
- Business partners



Operations:

- Data management
- Running of systems and monitoring
- Communications with regulators and other stakeholders

Are there synergies between Quality and Compliance?



Regulatory
Compliance

Risk
Management

Training and
Communication

Standard
Procedures

Complaint
Handling and
Investigations

Reporting

Thank you

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