Medical Device Manufacturing
Quality Cheat Sheet

QUALITY SYSTEM & DOCUMENTATION

- 510(k) - Application submitted to the US FDA
- PMA - Pre-Market Approval. Required by the FDA for high risk devices to guarantee safety and effectiveness.
- CE Mark/CE Marking - The official “passport stamp” that tells European Competent Authorities your product has met the appropriate Directives
- Class 1 device - Low risk medical devices
- Class 2a/2b medical device - Includes a wide range of medium risk medical devices.
- Class 3/4 medical device - High risk devices. Class 4 is used assigned in Canada only
- ISO 13485 - International quality management standard for the medical device sector
- FMEA - Failure Mode and Effects Analysis
- QC - Quality Control
- QSP - Quality System Procedure
- QSR - Quality System Regulations
- cGMP - Current Good Manufacturing Practices. Also known as GMP
- cGMPR - Current Good Manufacturing Practice Regulations
- DHR - Device History Record
- DMR - Device Master Record
- NCR - Non-Conformance Report
- CAPA - Corrective and Preventive Action
- CC – Customer Complaint

ORGANIZATIONS & REGULATORY BODIES

- ANSI - American National Standards Institute
- CDC - Centers for Disease Control & Prevention (USA)
- EN - European Standard
- FDA - Food and Drug Administration
- ISO - International Standards Organization
- OSHA - Occupational Safety and Health Administration (USA)