

# QUALITY MANAGEMENT SYSTEMS

Whether your business needs a fundamental Quality Management System to meet FDA compliance or desires a more comprehensive QMS to improve your overall business model, SafeLink Consulting is ready to help. Contact us today.

## NEW TECHNOLOGIES/NEW REQUIREMENTS

The development and implementation of new manufacturing systems have resulted in more dental laboratories falling under FDA scrutiny. SafeLink can help your business integrate technology and still meet any regulatory requirements.

## WHO MUST REGISTER WITH FDA

There are many activities performed by dental laboratories that trigger registration with FDA. A SafeLink consultant will help you with making this determination.

## FDA'S TITLE 21 QUALITY SYSTEM REQUIREMENT

The regulation requires that various specifications and controls be established for devices; that devices be designed under a quality system to meet these specifications; that devices be manufactured under a quality system; that finished devices meet these specifications; that devices be correctly installed, checked and serviced; that quality data be analyzed to identify and correct quality problems; and that complaints be processed. Thus, the QS regulation helps assure that medical devices are safe and effective for their intended use. The Food and Drug Administration monitors device problem data and inspects the operations and records of device developers and manufacturers to determine compliance with GMP requirements in the QS regulation."

## BENEFITS & RESULTS OF A QUALITY SYSTEM

BENEFITS:	RESULTS:
■ Standardized processes	➔ Consistent product results in customer retention
■ Defined Quality Control activities	➔ Reduction of remakes
■ Controlled purchasing practices	➔ Control overhead expense and increase profit
■ Scheduled Cleaning requirements	➔ Provides a healthier and safer business
■ Increased life and effectiveness of equipment	➔ Establishes preventative maintenance schedules to reduce repair and replacement costs
■ Employee competency improved	➔ More productive, higher quality, better-skilled workers
■ Forced review of suppliers & sub-contractor's performance	➔ Ensures the quality of materials and service
■ Root cause analysis of remakes and reworks	➔ Reduction in lost time, labor and materials
■ Market a third-party Quality System (QS) to customers	➔ Evidence that your QS is audited by a recognized 3 <sup>rd</sup> party
■ Meet FDA's Quality System Regulation	➔ Conforms to governmental regulations

[Learn more about how to stay on top of FDA Dental Regulations](#)



Premier Provider of Safety Programs & Quality Systems  
Proudly Serving the Dental Community for 30 Years

### QUESTIONS? CONTACT US

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Learn more at: [SafeLinkConsulting.com](http://SafeLinkConsulting.com)