# BENEFITS OF IMPLEMENTING A QUALITY SYSTEM

## DID YOU KNOW

The U.S. Food and Drug Administration (FDA) regulates dental laboratories. FDA has a right to inspect dental labs.

## FDA's TITLE 21 REQUIREMENT

Domestic or foreign manufacturers of medical devices are required by FDA to have "a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices intended for commercial distribution in the United States. 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."

## 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.

## KEY FEATURES OF A QUALITY SYSTEM

- Determines applicability and FDA registration
- Assigns management responsibility
- Defines purchasing controls
- Establishes traceability of patient contact materials
- Standardizes production and process controls
- Defines acceptance criteria of final product
- Reviews complaints and non-conforming product
- Creates Corrective and Prevention Action procedures
- Controls Labeling and Packaging
- Explains handling, storage, distribution and installation of materials and finished items
- Creates records retention and change controls

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# 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 cost |
| ■ Employee competency improved | ➲ More productive, higher quality and better-skilled employees |
| ■ Forced review of suppliers and 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 to customers | ➲ Evidence that your Quality System is audited by a recognized third party |
| ■ Meet FDA's Quality System Regulation | ➲ Conforms to governmental regulations |

# BENEFITS OF BECOMING A DAMAS CERTIFIED LAB

The DAMAS specifications closely mirror the U.S. Food and Drug Administration's Quality System/Good Manufacturing Practices (QS/GMP) regulations.

DAMAS helps you meet the FDA's QS/GMPs and provide you with a dental laboratory operation specific plan. The DAMAS Specifications provide a clear-cut process for improving documentation in every facet of laboratory operations including: dental prescriptions/work authorizations; patient contact materials; subcontractor/supplier agreements; material and equipment purchases; employee training; maintenance and calibration of equipment; labeling; customer complaints; and material traceability.

**Who should become DAMAS certified?**

DAMAS certification is for you if you are interested in promoting the fact that you go above and beyond governmental requirements by becoming certified to an internationally recognized quality management system specific to dental laboratories.

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