

# Quality Systems for the Orthodontic Laboratory



## Quality Management Systems (QMS)

SafeLink can help your business determine the scope of your Quality Management System based on the products you are manufacturing and offering to your customers. 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. Having SafeLink's Quality Consultant assist your business is the most beneficial method of developing your [Quality Management System](#).

### Product-Focused QMS

Looking to meet FDA's requirements for a certain product you are manufacturing? This Product-Focused Quality Management System (QMS) is designed to assist you in development of a Quality System that follows FDA's Title 21, Chapter I, Subchapter H – Medical Devices, Part 820 Quality System Regulation and any other FDA regulations applicable to your desired scope. This service is applicable to Class II medical devices only, such as sleep appliances, sequential aligners, etc.

### All-Encompassing QMS

Exploring more ways to improve your business? This Quality Management System (QMS) is designed for the lab that desires an extensive QMS which goes beyond simply FDA compliance. The goal of this QMS is to improve your overall business model for productivity, efficiency and profitability by minimizing errors. A well-structured quality system provides methods for determining the root cause of complaints and reducing reworks/remakes. Ultimately, it will improve your business. This QMS also follows FDA's Title 21, Chapter I, Subchapter H – Medical Devices, Part 820 Quality System Regulation and any other FDA regulations applicable to your business model.

### Both QMS's include:

- **Initial Consulting** to complete managerial paperwork with coaching, instructional focus, hands on application, and practical writing of SOPS and Work Instructions. Service delivery options are: 2 days onsite, 3 days onsite, or virtual.
- **Electronic Quality System Documentation** of Quality Manual, Standard Operating Procedures (SOPs), and Quality System Forms.
- **Follow-up Quality System Consulting** via phone, email or virtual/web meeting when needed.
- **Assistance with FDA Communication**, such as, an FDA notice or inspection your business may receive, or support with FDA registration if needed.
- **Educational Online Training Courses** to assist you with specific topics as they relate to your quality system.
- **Quality Topic News** emailed periodically with any quality updates affecting the orthodontic laboratory.

### [Requirements & Benefits of a Quality System](#)

Learn more about [FDA Dental Regulations](#)

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## Quality System Internal Audit

Need an Internal Audit to meet FDA requirements? SafeLink can perform this [onsite audit](#) for you to establish conformance with the FDA Quality System Regulation. FDA requires that establishments periodically perform an Internal Audit.

## DAMAS Certification or Recertification

Is your business ready to become DAMAS certified, or seeking DAMAS renewal of certification / DAMAS recertification? SafeLink provides [DAMAS consulting services](#) to help you structure your quality system to comply with DAMAS specifications. SafeLink is an approved DAMAS Certification Auditor. DAMAS provides a system that assists labs operate in compliance with product safety. It provides quality guidelines to help labs improve documentation from orthodontic prescriptions to material traceability.

## UQ System: Cloud-based Quality Manual

This Cloud-based application is designed for implementing and managing a quality system online. It reduces paper and the likelihood of a lost quality manual. UQ offers better organization of all documents, plus links policies, procedures and forms. It increases efficiency and provides an audit trail, simplifying a potentially complex issue. UQ allows for tracking non-conformance to improve quality. It can also manage your health & safety manual. [Learn more](#).

## Quality Connection

Get assistance with your existing quality system, an FDA inspection/response or other quality issue. Includes consulting, FDA assistance, online educational training courses, and quality news pertinent to the orthodontic laboratory.

## Quality Consulting

Already have a quality system in place or considering implementing one and have some specific questions about your business? Contact us for quality guidance or assistance with an FDA inspection/response. Hourly consulting available.

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