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INTRODUCTION TO THE DENTAL APPLIANCE MANUFACTURER AUDIT SYSTEM - *(DAMAS)*

This is the first in a serious of three to help educate dental laboratories about the Dental Appliance Manufacturer Audit System (DAMAS) requirements in North America.

Introduction

The DAMAS standards are administered by the National Association of Dental Laboratories (NADL) for use by commercial dental laboratories in North America.

The DAMAS Management System Specifications are in compliance with the U.S. code of Federal Regulations, FDA Quality System, and Good Manufacturing Practices. The system is aimed at achieving dentist satisfaction by preventing nonconformity at all stages of the dental appliance manufacturer. It is also aimed at providing a source of objective evidence that will allow a third party to assess a laboratory's conformity with specification requirements.

Terms & Definitions

There are many terms used in association with DAMAS, a short list is provided herebelow to acquaint you with their meaning and use, and to help you when preparing your quality manual.

- ***Supply chain*** - Supplier/Subcontractor - Dental laboratory - Customer
- ***Supplier*** - Party supplying materials to dental laboratory's
- ***Subcontractor*** - Party supplying part constructed of fully constructed dental appliances to the dental laboratory
- ***Dental Laboratory-Party*** responsible for the manufacture of the patient specific dental appliances
- ***Customer*** - Party responsible for prescribing and specifying the design characteristics of a patient specific dental appliance

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- ***Customer complaint*** - Written, electronic or oral communication that alleges deficiencies related to the quality, durability, reliability, safety or performance of a medical device that has been placed on the market
- ***Competence*** - Demonstrated ability to apply knowledge and skills
- ***Nonconformity*** - nonfulfilment of a requirement
- ***Label*** - Written, printed of graphic matter affix to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping document.
- ***Prescription (R/X)*** - Information allowing an understanding of the licensed dental client's requirements for a patient specific dental device.
- ***Third party certification body*** - An independent body accredited to carry our assessments of quality system
- ***Patient specific dental device or appliance (in FDA terms = medical device)*** - The final restoration delivered by the laboratory to the dentist based upon an RX or delivered to another lab based upon a work authorization.

Management System Requirements

Top management is ultimately the responsible body for enforcement of DAMAS Management System in their laboratory. This starts by preparing, and adopting a normal quality policy and quality objective statement, then by periodical auditing and reviewing the policy by management representatives to ensure compliance with the Federal Regulations. It's good practice to display the statement of conformity within the laboratory so that it is open to the public examination and as a reminder to employees about the Federal Regulations.

Here is a summary of DAMAS Management System Requirements as established by the U.S. Food and Drug Administration (FDA). In this article we will address the first five of fifteen requirements that must be met before becoming a DAMAS certified laboratory in North America.

1. **Management system**
   There should be some form of documentation kept available to allow an assessment of compliance. Standard practice would be to collate this documentation into a Manual for ease of reference. Expected performances may be addressed by a generic statement for each type of appliance.

   The laboratory should ensure they know and understand the regulations that apply to their laboratory facility type.

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Registration if required is normally carried out by completing and submitting a registration form to the FDA

2. **Documented review of the customer requirements**
   A simple documented system should be established specifying how reviews of dentist requirements will be collected.

   The system should state how the Rx is reviewed. How special trays and study models are controlled. How and where materials supplies by dentist will be recorded. What checks should be made before manufacturing will start. How amendments to prescriptions will be agreed, recorded and authorized. How information and materials will be dispatched to a subcontractor, what controls should be in place at the subcontractor, what inspection should be carried out when the appliance is returned from subcontractor, and should be done with nonconforming appliances. How prescriptions that have become damaged or unusable should be dealt with

3. **Patient contact materials**
   Satisfactory materials for use in contact with patient body are available from established suppliers to the trade.

   The laboratory must establish a criteria for evaluating and selecting subcontractors, suppliers and material. It also must a system specifying how the purchasing of patient contact materials will be controlled. It is imperative to verify that materials received are those that have been ordered and that the material conform to specified requirements.

4. **Defined manufacturing processes**
   The amount and level of documentation required for process control is usually determined by the level of competence required for personnel to carry out the process.

   A process flow chart must be established that simply describe the manufacturing process, procedure and method and it must be documented ensuring that relevant documentation is controlled during each manufacturing stage. Each step of the flowchart is examined and decided if an in-process inspection is needed.

   A system must be established for keeping suppliers materials instructions for use under control, and to ensure how traceability between the patient and the dentist is maintained.

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Another simple documented system needs to be in place specifying how nonconforming appliances will be controlled. Normally, personnel readily identify and correct nonconforming appliances as they occur by making the correction themselves or by returning the work to the appropriate person for correction. The system also addresses when this type of correction isn't possible. A summary of the corrective action taken should be recorded. The disposition of nonconforming appliances should be treated similarly of a complaint procedure. The dental laboratory ultimately should comply with Device Master Record requirements of U.S. FDA.

5. **Training**
   A simple documented system should be established specifying how personnel training and competency will be controlled. The system should address pre-employment trade tests, induction training, formal academic training, and training in manufacturing and management system tasks including the use of associated computer software. The system should address an individual training record containing confirmation by the individual concerned that they have been trained in the relevant manufacturing and/or management system tasks.

In the next issue we will highlight the following five Management System Requirements as mandated by the U.S. FDA.

- **Maintenance and calibration of equipment**
- **Cleanliness**
- **Documented review of the final product**
- **Defined handling and packaging**
- **Control of records**

If you would like help in preparing a quality manual that fits in with your laboratories requirements, help to fully integrate the system into day-to-day operations, and help to prepare you to go through a third party audit to ensure compliance with the DAMAS specification standards and achieve full certification in the system, call us today at (661) 810-2446 or visit us on-line at www.azarandassociates.com

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