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Documented review of the dentist's requirements

A cornerstone of the Dental Appliance Manufacturers Audit System (DAMAS) is the control of documents. While not a particularly glamorous activity, document control is an essential preventive measure ensuring that only approved, current documentation is used throughout the organization. Inadvertent use of out-of-date documents can have significant negative consequences on quality, costs and customer satisfaction.

Dental Laboratories depends on their customers and therefore should understand their needs, should meet their requirements and strive to exceed their expectations.

A Simple documented system or procedure should be established specifying how reviews of dentist requirements (Rx) will be controlled. This may consist of subsystems or procedures that address the requirements under DAMAS Management System Specifications.

The documented system should also consider the exponentially growing volume of digitally generated and transmitted data, such as digital Rx, in-office digital impressions and in-office digital scan and design. Attention must be paid to how a scan and design of a dental product input and output data is managed, how dentist's scan data is imported and exported, and how digital technology integrates with the laboratory manufacturing audit system.

The following procedure applies to the control of Rx, including electronic and external, which calls for quality requirements affecting quality such as methods, regulations, procedures and instructions, pertaining to the dental prosthesis Manufacturer's Audit System.

The laboratory should clearly control:

a. The dentist work information Rx by reviewing the product selected by the dentist, and it's compatibility with manufacturer recommended prep design and product indications. A qualified lab personnel then determines needs for alternative product, or modification to current design. Once the modifications have been agreed upon, a Document Change Request (DCR) order is generated for dentist approval.

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b. The extra elements received from the dentist that are essential to case planning success, a.g. multiple impressions, study models, face bow, etc. Such elements must be inventoried upon receiving the case and controlled throughout the manufacturing process to ensure that they are used as required by the dentist.

c. All dentist supplied raw materials and parts, a.g. implant parts, attachments, alloys, etc., will be inventoried at the time of receipt as to the quantities received of each type, lot number, batch number and expiration date (if any). The inventory list should accompany the list throughout the manufacturing process, then transferred to the final document (invoice) accompanying the finished product.

d. The steps taken in authorizing the design before initiating the manufacturing process. It's recommended for the laboratory to develop a multipoint check system before the start of manufacturing the product. The laboratory may consider validating and approving: 1) the information supplied by the dentist (Rx), then, 2) the design elements requested, and 3) raw materials supplied by the dentist. All stages of quality control must be carried out by a skilled person who's also authorized to initiate Document Change Request (DCR) form if needed.

   According to the FDA, since 1984, the major causes of devise remake and failure has been identified as due to lack of quality controls.

e. Any, and all changes requested or made to the original work information (Rx) originally provided by the dentist. The recommended changes may be due to, a.g. poor impression, unclear margins, etc., but once it's agreed upon and approved a Document Change Request (DCR) form will be established with the dentist approval and signature along with the processing party who initiated the DCR form. The DCR form is a vital tool to ensure that only necessary changes are made, and are communicated to all affected parties (dentist, lab technician and administrative staff) and approved changes are actually carried out as agreed upon.

   If amendments to prescriptions are not controlled, the case schedule and budget will be destroyed before the laboratory and dentist recognizes that anything has happened.

f. The outsource protocol for a complete product, or just a stage of the manufacturing process for this product when outsourced to third party/outsource facility.
   Such protocol should include: 1) the transfer of information and case design elements

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to a third party or outsource facility; 2) the quality control measures that are in place at third party during the manufacturing process; 3) the quality check points required once the production at third party is completed and returned to the originating laboratory; and finally, 4) the protocol to deal with rejected products that are received from third party facility due to nonconformity.

g. The invalid, or obsolete work information Rx/document to assure against unintended use. The obsolete or invalid document should be marked as "Uncontrolled, and be segregated or disposed of as state and or federal law permits. Any obsolete documents that are kept for either legal, reference or other purposes must be clearly identified through markings, separate storage areas, or other means, and should be marked as Archived.

What are the key benefits to being customer focus?

1. Increased revenue and market share obtained through flexible and fast responses to market opportunities
2. Increased effectiveness in the use of the organization's resources to enhance customer satisfaction
3. Improved customer loyalty leading to repeat business.

What can being customer focus lead to?

1. Researching and understanding customer needs and expectations
2. Ensuring that the objectives of the organization are linked to customer needs and expectations
3. Communicating customer needs and expectations throughout the organization
4. Measuring customer satisfaction and acting on the results
5. Systematically managing customer relationships
6. Ensuring a balanced approach between satisfying customers and other interested parties (such as owners, employees, suppliers, financiers, local communities and society as a whole).

Measuring success

Here are some suggested metrics to how can you measure the performance of your document control process:

1. **User satisfaction** – Periodically survey your employees regarding the usability of your documentation. Use the results to improve the format of your documents and training of your authors.

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2. **Document errors** – Track the number of document revisions due to information mistakes in your documentation. Results will often reveal weaknesses in your review and proofreading processes.
3. **Up-to-date** – Count the number of document revisions or audit discrepancies stemming from a document that is out-of-date. This will tell you whether your periodic document reviews or obsolete document provisions are effective.
4. **Cycle time** – Measure the time it takes a document to be developed or revised from initial draft to release. Work to improve the efficiency of your document control process as you would any other business process.
5. **Cost** – Consider tracking the costs associated with your documentation including developing, revising, storing, retrieving, distributing, filing, auditing, reviewing, approving, etc. Of these potential costs, document retrieval is often an expensive hidden cost generated when individuals must search endlessly for a document because of inadequate indexing, organization, storage or training.

Results of the performance measures of your document control process can help you determine how to drive continual improvements into your entire Dental Appliance Manufacturer's Audit System.

If you are looking to improve your laboratory's efficiency, reduce waste, improve customer service, provide a competitive edge, reduce risk, increase profitability, and most importantly provide a formal process to help meet FDA QS/GMP requirements, Call us today at (661) 810-2446 or visit us on-line at www.azarandassociates.com

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