



Understanding Dale Dental's Decision: DAMAS vs. ISO9001: 2000

This paper has been prepared to offer clarification to the dental laboratory industry regarding Dale Dental's decision to obtain ISO9001: 2000 certification rather than the DAMAS Standard certification. It also explains and summarizes the results from research into the DAMAS Standard and the ISO9001: 2000 International Standard as it relates to meeting the existing requirements of the FDA's 21 CFR Part 820.

Authored By: Carter D. Thompkins
Vice President, Client Operations
Integrated Management Systems

Understanding Dale Dental's Decision, DAMAS vs. ISO9000

Purpose

This paper has been prepared to offer clarification to the dental laboratory industry regarding Dale Dental's decision to obtain ISO9001: 2000 certification rather than the DAMAS Standard certification. It also explains and summarizes the results from research into the DAMAS Standard and the ISO9001: 2000 International Standard as it relates to meeting the existing requirements of the FDA's 21 CFR Part 820.

What is DAMAS?

The Dental Laboratories Association of the United Kingdom (DLA) has developed a management and production system for laboratories called the Dental Appliance Manufacturers Audit Scheme (DAMAS).

DAMAS has been developed in partnership with the British Dental Association, the General Dental Practitioners Association, Dental Protection, the Department of Health, AMTAC Certification Services LTD, the British Dental Health Association, the British Dental Trades association and Denplan LTD. The DAMAS Standard was originally introduced in the mid 1990s as an alternative to ISO Certification. Both ISO9001: 2000 & ISO13485 are organizationally comprehensive QA systems, with ISO13485 being an extended version of ISO9000, specifically aimed at medical device manufacturing in a mass production basis.

DAMAS was created because it was believed that both formally recognized ISO systems were "over-prescriptive for the custom-made laboratory" and required "excessive time and costs over and above a specifically laboratory-directed system." Additionally, EN46000 (traceability), introduced at this time required a management system in place as an operating base in respect of Patient Contact Materials as required by the Medical Devices Directive (MDD) and the Medical Devices Regulation (MDR).

DAMAS is a voluntary scheme that essentially is a third party audit against a set of criteria called the DAMAS Management System. As stated in the training section of the DAMAS manual, page 4 of 47: "...DAMAS is not an internationally recognized standard, as for instance ISO9000, but is adopted under the United Kingdom Accreditation Service rules for certification," (meaning EU specific). The third-party audit firm utilized by the National Association of Dental Laboratories (NADL) for DAMAS audit inspections is an ISO-certified audit firm and its primary work worldwide is conducting ISO audits.

The NADL owns the rights to the DAMAS process in North America. While it is recognized that the market environment and regulatory oversight is different in North America than Europe, a modified version of the DAMAS specification standards is being created for use in North America. All comparisons and observations made in this document are based on the DAMAS standard as it currently exists and is marketed to North American laboratories at the time of this writing. The NADL has an appointed representative on the DAMAS Advisory Group in the U.K. and this group will review

Understanding Dale Dental's Decision, DAMAS vs. ISO9000

formal recommendations for North American modifications for formal approval in the second quarter of 2005. This will allow necessary modifications to the DAMAS specification standards for the North American market.

Specification Requirements of DAMAS

The DAMAS requirements are based upon the sound quality management system principles specified in ISO 9002, which was defunct as of December 2003. However, these principals have been adapted and simplified to meet the requirements of the MDD and the MDR, which are specifically EU Regulations and are not relevant to the FDA's requirements or expectations of compliance to 21 CFR Part 820. They were adapted to reflect the practical nature of manufacturing dental appliances, for example, reliance on the manufacturing skills of competent dental technicians, rather than on extensive documented procedures or work instructions. All of which makes it particularly suitable for 'one man' operations and smaller laboratories.

As noted above, the DAMAS standard was designed for compliance with European regulatory requirements. It has not yet been fully updated with a focus on compliance with U.S. standards. The following table explains the requirements of FDA 21 CFR Part 820 and how those requirements are addressed by DAMAS and ISO9001: 2000 programs.

The FDA has indicated that not all sections of CFR Part 820 are relevant to the dental laboratory setting. In addition, it appears as if FDA inspectors would not seek compliance with the full body of Part 820 depending on the business nature of the specific laboratory and the products these laboratories manufactured. The FDA will likely provide more specific notations of applicable sections of CFR Part 820 in a guidance document expected to be released in early 2005.

FDA 21 CFR Part 820, DAMAS, and ISO9000: 2000 Comparison Model

FDA Requirement 21 CFR Part 820	DAMAS	ISO9001: 2000
820.5 Quality System	4.2.1 Management System	Clause 4
820.40 Document Controls	<i>(Requiring dental appliance manufacturing system compliant to MDD and MDR.)</i>	4.1 Quality Management System
820.180 Records		4.2 Documentation Requirements
820.181 Device Master Record	4.2.2 Legal and System Documentation	4.2.2 Quality Manual
820.184 Device History Records	<i>(Specifically requiring only that the MDD, MDR and DAMAS specification be retained.)</i>	4.2.3 Control of Documents
820.186 Quality System Record	4.11 Control of Records <i>(Same as Clause 4.2.4 of ISO)</i>	4.2.4 Control of Records

Understanding Dale Dental's Decision, DAMAS vs. ISO9000

21 CFR Part 820	DAMAS	ISO9001: 2000
820.20 Management Responsibility	<p>4.1.1 Conformity Policy <i>(Stating conformance to MDD and MDR and DAMAS by formal and public quality policy and objective statement or by public statement of conformity.)</i></p> <p>4.1.2 Management Representative <i>(Without the ISO requirements of reporting to top management on the performance of the QMS and any need for improvement, and ensuring internal promotion of awareness of customer specifications.)</i></p> <p>4.15.2 Management Review <i>(Only requires the review of prior internal audits)</i></p>	<p><u>Clause 5</u></p> <p>5.1 Management Responsibility</p> <p>5.2 Customer Focus</p> <p>5.3 Quality Policy</p> <p>5.4.1 Quality Objectives</p> <p>5.4.2 QMS Planning</p> <p>5.5 Responsibility, Authority and Communication</p> <p>5.5.2 Management Representative</p> <p>5.5.3 Internal Communication</p> <p>5.6 Management Review</p>
820.25 Personnel	<p>4.6 Training <i>(Not including training on internal auditing.)</i></p>	<p><u>Clause 6</u></p> <p>6.1 Provision of Resources</p> <p>6.2.1 Human Resources</p> <p>6.2.2 Competence Awareness and Training</p> <p>6.3 Infrastructure</p> <p>6.4 Work Environment</p>

Understanding Dale Dental's Decision, DAMAS vs. ISO9000

21 CFR Part 820	DAMAS	ISO9001: 2000
820.30 Design Controls	4.3 Documented Review of the Prescriber's Requirements	<u>Clause 7</u> 7.1 Planning of Product Realization
820.50 Purchasing Controls		7.2.1 Determination of Requirements Related to the Product
820.60 Identification	4.4.1 Materials	7.2.2 Review of the Requirements related to the Product
820.65 Traceability	4.4.2 Subcontractor/ Supplier Approval	7.2.3 Customer Communication
820.70 Production and Process Controls	4.4.3 Purchasing	7.3.1 Design and Development Planning
820.72 Inspection, Measuring and test Equipment	4.4.4 Verification of Purchased Materials	7.3.2 Design and Development Inputs
820.75 Process Validation	4.5 Defined Manufacturing Processes	7.3.3 Design and Development Outputs
820.80 Receiving, In-Process, and Finished Device Acceptance	4.7 Maintenance and Calibration of Equipment	7.3.4 Design and Development Review
820.86 Acceptance Status	4.8 Cleanliness	7.3.5 Design and Development Verification
820.120 Device Labeling	4.9 Documented review of the Finished Product	7.3.6 Design and Development Validation
820.130 Device Packaging	4.10 Defined Handling and Packaging	7.3.7 Control of Design and Development Changes
820.150 Storage	4.13 Labeling	7.4.1 Purchasing
820.160 Distribution		7.4.2 Purchasing Information
820.170 Installation		7.4.3 Verification of Purchased Product
820.200 Servicing		7.5.1 Control of Production and Service
		7.5.2 Validation of Production Processes
		7.5.3 ID and Traceability
		7.5.4 Customer Property
		7.5.5 Preservation of Product
		7.6 Control of Monitoring and Measuring Devices

Understanding Dale Dental's Decision, DAMAS vs. ISO9000

21 CFR Part 820	DAMAS	ISO9001: 2000
<p>820.22 Quality Audit 820.90 Nonconforming Product 820.100 Corrective and Preventive Action 820.198 Complaint Files 820.250 Statistical Technique</p>	<p>4.14 Complaints 4.15.1 Internal Audits</p>	<p><u>Clause 8</u> 8.1 Measurement, Analysis and Improvement 8.2.1 Customer Satisfaction 8.2.2 Internal Audit 8.2.3 Monitoring and Measurement of Processes 8.2.4 Monitoring and Measurement of Processes 8.3 Control of Nonconforming Product 8.4 Analysis of Data 8.5.1 Continuous Improvement 8.5.2 Corrective Action 8.5.3 Preventive Action</p>
<p>The FDA does not require third-party (ISO or DAMAS) registration.</p>	<p>4.2.3 Registration with the Competent Authority is mandatory for compliance. <i>(Currently requires registration and open access of all documentation to all interested parties, customers included)</i></p>	<p>Registration is optional.</p>

Understanding Dale Dental's Decision, DAMAS vs. ISO9000

Summary

Using 21 CFR Part 820 as the governing guideline as indicated by the FDA, one may conclude that a dental lab following the DAMAS standards -- as currently drafted -- may need to add certain further procedures or systems to fill potential gaps between DAMAS and FDA's QSR standards. However, it is yet to be determined for those dental labs not currently being regulated by the FDA until a formal guidance document is released.

Aside from the overall requirements within the DAMAS standard for adherence to the EU, MDD and MDR, there is some comparative relevance to the FDA's currently accepted guidelines. The ISO9000 Standard being implemented by Dale Dental meets or exceeds the FDA requirements and additionally provides requirements for analysis of processes toward continuous improvement, requires that internal communication be utilized for the development of the organization and that management have an active part in this analysis process. It should therefore be noted that Dale Dental's compliance to the ISO9000 standard does satisfy the requirement of DAMAS section 4.4.2 for subcontractor approval.

In comparison, using ISO Clauses as the defining factor, the following potential shortcomings exist as it relates to DAMAS meeting at least the requirements identified by 21 CFR Part 820.

- Clause 4: DAMAS does not meet the Quality System Procedures/Work Instruction development requirements, nor is there indication for the need or use of the DAMAS Compliance System Manual template currently provided by NADL.
- Clause 5: 21 CFR Part 820 requires a quality policy, organizational structure, defined responsibilities, authorities and defined organizational interrelations. In DAMAS, There is no requirement for formal provision of the required resources, quality management system reporting by the management representative, nor is there a requirement for quality system procedures.
- Clause 6: The requirement for training needs analysis, reporting of defects and errors post training, and procedures defining this process are not addressed in DAMAS.
- Clause 7: DAMAS does not address design control at all as it relates to Part 820.30.2.i referencing "devices automated with computer software" as is the case with CAD/CAM dental systems used at Dale Dental and many other laboratories throughout North America.
- Clause 8: DAMAS has no guidelines for the handling of nonconforming product, the "Complaints" section does not address corrective and preventive actions to accountability, nor does it requires analysis of the effectiveness of the actions taken. Additionally, the requirement by 21 CFR Part 820.250 for statistical analysis is not addressed.

In short, the statement made on page 4 of 47 of the DAMAS Manual Training section about ISO being "over-prescriptive for the custom-made laboratory" and that self-certification to avoid the need for visits from the Medical Device Agency (EU), are fair provided the laboratory has no plans to submit their operations to FDA review. Being

Understanding Dale Dental's Decision, DAMAS vs. ISO9000

that Dale Dental has made this decision, the requirements outlined above relative to 21 CFR Part 820 become relevant. A dental lab choosing to submit its operations to FDA review could potentially need to include certain additional compliance systems or procedures, over and above DAMAS, to comply fully with FDA's QSR requirements depending on the nature of its manufactured product line.

About Dale Dental

Dale Dental was founded by David Lesh in January 2000 and is based in Richardson, TX. It is the country's first dental technology lab dedicated to working exclusively with other dental labs. The company's mission is simple: to serve as an outsourcing supercenter, offering dental labs access to the most state-of-the art dental technology available and providing dental technology manufacturers fast-market access to these labs. Without serving dentists directly, Dale Dental's outsourcing supercenter gives dentists the opportunity to maintain their critical lab relationships without finding new labs for every new product. Additional information on Dale Dental may be found on the company's website at www.daledental.com.

About Integrated Management Systems

Integrated Management Systems is dedicated to providing consulting services to companies in North America seeking to improve their management systems, with emphasis in the quality and environmental management fields. IMS' mission is to develop the resources within an organization to maximum capability by providing tailored instruction and consulting; and to provide management with the tools and assistance to systematically identify and solve problems and reduce cost, maintain operational peak effectiveness to increase market share, and utilize the existing resources to maintain a loyal and satisfied customer base. For more information please visit www.IMS-Quality.com.