

The Trusted Authority in Digital Dental Manufacturing

FDA cGMPs Title 21 CFR 820 Compliant
Quality Management System Development Program

This program provides CAD/CAM dental laboratories, orthodontic dental laboratories and dental milling centers that now fall under FDA oversight, with a practical and affordable implementation of a Quality Management System that is designed specifically for their dental operations.

Axsys Dental Solutions, in partnership with evo820 utilizes information from the laboratory regarding the CAD and CAM software, scanners, mills, furnaces, vacuum systems and case tracking software to build their complete, customized Quality Management System.



ABOUT US

Axsys Incorporated provides digital technology solutions from the leaders in CAD/CAM software. For over 24 years Axsys has helped literally thousands of clients in every industry, from one-man shops to Fortune 500 companies, successfully implement sophisticated CAD/CAM/CNC systems, increase productivity and realize greater profits. We couple this unique capability with experienced dental professionals to provide our clients with a distinct advantage- what we call the Axsys Advantage.

Based in Carson City, Nevada, evo820 was founded by dental lab professionals to help CAD/CAM dental laboratories nationwide evolve into entities that are FDA 21 CFR 820 compliant. Through the company's innovative platform, dental labs are able to satisfy the FDA's requirements by following a practical and affordable implementation of a customized Quality Management System.

Using our combined experiences in the dental implant and abutment manufacturing processes, regulatory compliance and years involved in the dental laboratory, we have constructed a Quality Manual that is specific to the digital laboratory. We have excluded sections, and validated their exclusion, of areas where the digital dental laboratory is not involved in certain processes and do not require documentation.

Utilizing this knowledge of the dental implant manufacturing processes and the digital workflow provides us with the ability to construct a QMS that will satisfy the FDA but not over burden the dental lab or milling center with unnecessary tasks associated with maintaining a Quality Management System.

QMS For Every Sized Laboratory

Dentists are asking everyday about using legal, FDA cleared custom abutments. Dental laboratories are concerned about the FDA potential overreach. evo820 was founded by dental industry professionals to provide laboratories a pathway to regulatory compliance through a practical and affordable implementation of a Quality Management System that is specifically designed for the CAD/CAM dental laboratory.

With the FDA now determining how to regulate CAD/CAM manufactured implant

supported restorations, It is critical that the dental laboratory owner understand this determination requires milling centers or dental laboratories processing CAD/CAM abutments (either Titanium custom abutments or hybrid Titanium base custom abutments) to have a Quality Management System (QMS) in place and register with the FDA.

Quality Management System

The evo820 Quality Management System (QMS) enables Laboratories to take the necessary steps to becoming FDA 21 CFR Part 820 compliant by adhering to FDA regulations. You receive a cloud based Quality Management System utilizing our custom designed application that include SOPs, logs, forms and work instructions customized to your laboratory. You can access it anywhere, which dramatically improves your laboratories ability to comply with the FDA. Download, print and view with just the click of a button.

Business Tools

By utilizing our services, you receive a membership in the Association of Compliant Dental Laboratories.

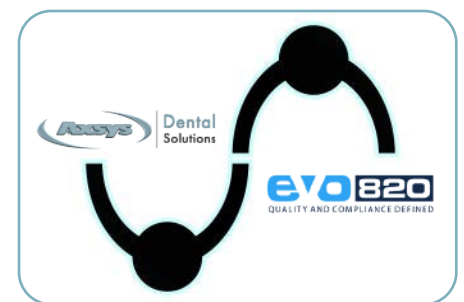


The ACDL is a newly formed organization that will also have a searchable database of compliant dental laboratories that dentists can use to find labs compliant with the FDA Guidelines.

Stickers will be available to put on invoices you send to dental offices that show your commitment to dental excellence and membership in the ACDL.

What We Provide

- Quality Manual with SOP's, and training forms.
- Initial Installation, Operational and Production Qualification (IQ/OQ/PQ).
- Complete QMS customized for the dental lab.
- Employee work instructions.
- Cloud Storage of all documents.
- Secure backup of all your documents.
- Form and templates to assist with meeting agendas.
- Online, in person and phone support.
- Regulatory updates.
- Email notifications and newsletter to keep you informed of new FDA actions.



Partners in providing turnkey solutions for meeting FDA dental CAD/CAM regulatory requirements.

The Onboarding Process

1. After a laboratory or milling center contracts with us they complete our "get started" questionnaire.
2. From the information gathered we interview the appropriate laboratory personnel to get a better sense of the internal operations and any unique considerations for the construction of the QMS.
3. Building the Quality Management System takes about 2 weeks then begins the implementation process.
4. The laboratory has options on the implementation process.
 - a. evo820 will provide a presentation to the entire staff on their role in the implementation of the quality system.
 - b. evo820 can do live video conferencing of the QM.
 - c. evo820 can provide a 2 day "on premise" implementation.
 - d. "On demand" training videos are being produced that the client can view at any convenient time to update or implement the quality manual.