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WHITE PAPER

DESIGN CONTROLS: Why Start-Up and Small Medical Device Companies Need to Comply with FDA's Quality System Regulations

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…Your firm's executive management failed to establish, document and implement quality system procedures and instructions as required…

…You informed the investigator during the inspection that you lacked the financial resources to comply with FDA regulations and should be exempt…

- FDA Warning Letter, April 23, 2003

…Your firm does not have adequate resources, including money and personnel, to ensure that finished devices have been manufactured in accordance with the Quality System Regulation…

- FDA Warning Letter, April 30, 2003

…We noted that you have not signed the letter to confirm your firm's official response. You responded that these inspectional observations resulted from your misunderstanding of your firm's GMP status…

…When FDA cleared the 510(k), …[we] informed your firm that your devices were subject to … requirements for annual registration and listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Our inspection documented that your firm has been manufacturing the devices without establishing a quality system since 1997…

- FDA Warning Letter, October 24, 2003

…You received a previous Warning Letter …[in June 1994] regarding your firm's failure to comply with the Good Manufacturing Practice Requirements for Medical Devices… Several of the current inspectional observations regarding your medical device operation are similar to those previously cited… Because of these concerns… [FDA] believes a regulatory meeting is warranted at this time to discuss your compliance with the Quality System Regulation.

- FDA Warning Letter, November 24, 2003

1.0 Introduction to the Quality System Regulation (QSR)

In the early 1990's, FDA announced its intention to revise and update its Current Good Manufacturing Practices (CGMPs) regulations that were first published in July 1978. For the balance of the global community, the ISO 900x standards were gaining recognition and increasing acceptance as voluntary internationally accepted standards for quality. In 1996, ISO 13485 and ISO 13488 were issued, and delineated the particular requirements of ISO 9001 and ISO 9002, respectively, for medical devices.

FDA's current Quality System Regulation (QSR) was published in the Federal Register on October 7, 1996, and became law in 1997. The regulations require any manufacturer, foreign or domestic US, to have a quality system in place for the design and production of medical devices intended for commercial distribution in the United States.

The FDA QSR consists of 20 interrelated topics, and closely parallels the ISO requirements:

- Management Responsibility
- Quality Plan and Quality System
- Contract Review
- Design Control
- Document and Data Control
- Purchasing
- Control of Customer-Supplied Product
- Product Identification and Traceability
- Process Control
- Inspection and Testing
- Control of Inspection, Measuring and Test Equipment
- Inspection and Test Status
- Control of Non-Conforming Product
- Corrective and Preventative Action
- Handling, Storage, Packaging, Preservation, and Delivery
- Control of Quality Records
- Quality Audits
- Training
- Servicing
- Statistical Techniques

While the ISO standards, and other European Community standards are voluntary, the FDA QSR requirements are traceable to the Federal Food, Drug and Cosmetic Act (FFDCA), and strictly enforced. FDA has the Congressional authority to…

> …prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device, but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conforms to current good manufacturing practice…[FFDCA §520[21 USC 360](f)(1)(A)]

2.0 Design Controls

The majority of the QSR's topics are clearly related to manufacturing, production, and commercial distribution activities. However, design controls in particular has its roots in early-stage design an d development activities.

FDA requires that all manufacturers (or specification developers) of Class II and Class III devices follow design controls during the design and development of their devices. The design control requirement additionally applies to Class I devices which are automated by computer software control, and a few other Class I devices. See Section 7.2, Risk-based approach to medical device regulation, for additional details of device Classes.

Start-up and small manufacturers often have only one product. Since most of the device design and development effort usually occurs prior to, and during the clinical evaluation (IDE) phase, it is of key importance that the manufacturer ensures compliance to the design controls requirements. If the manufacturer were to wait until the IDE studies were complete, they would lose the benefits afforded by the design control process.

By not following the design control process, the manufacturer automatically increases the potential for future FDA compliance actions. The author conducted a survey of FDA Office of Compliance Warning Letters currently posted on the Agency's website. Of the 136 Warning Letters from April 2002 to March 2004 related to quality systems for medical devices, 29% detailed inadequate design controls procedures, while another 8% indicated that the company had no quality system in-place at all.

FDA's analysis of device recalls indicated that approximately 40% were attributable to device design defects. Sometimes the original design was faulty, while in other cases, changes made to a product, often to correct one problem, resulted in the modified product exhibiting an additional defect.

FDA believes that the safety, effectiveness and inherent quality of a device are determined and established during the design phase. FDA's design control requirements establish a systematic assessment, a system of checks and balances, that is integral to the design and development process. Informal design and development programs often result in unsafe or in effective devices. Ad hoc engineering development efforts generally do not establish and assess design requirements that are needed to develop a product which is safe and effective for its indended use, and which meets the needs of the end user(s).

The design control regulations [21CFR §820.30] are reprinted in Section 7.1, 21CFR §820.30 Design controls, and address 9 major topics:

- Design and development planning - the on-going organizational efforts to determine and allocate resources (time, financial, personnel, equipment, etc.), identify tasks, and establish the schedule for performing those tasks
- Design inputs - establishes the requirements for the device; ultimately distilled into product specifications
- Design outputs - the outcome of the design process - the finished device itself, plus all of the device design documentation, including schematics, assembly drawings, component drawings, test and acceptance procedures, etc.
- Design reviews - analysis and assessment by objective, qualified personnel to determine, among other responsibilities whether design outputs meet design inputs
- Design verification - generally bench testing of the device to assure that design outputs meet design inputs
- Design validation - generally clinical/user testing of the device to assure that the design meets user requirements

- Design transfer - transmits the finished design to the manufacturing organization to create production procedures, processes, and specifications to control the manufacture of identical, conforming products; design transfer additional includes periodic, randomized testing of production lots to verify consistency of manufacturing and to assure that the product meets defined specifications.
- Design History File - the central repository of all records and documents which demonstrate that the device design was accomplished in accordance with the design plan
- Design changes - evaluation and documentation of modifications and changes to the product for the duration of the product's lifetime, from manufacturing phase-in to end-of-life obsolescence.

Once the design is complete, all devices, regardless of classification, must be properly transferred to production, in accordance with the device master record (DMR) regulations [21CFR §820.181]. The DMR contains all device documentation, including, but not limited to, specifications, drawings, formulations, production process specifications, production equipment, production methods, quality assurance procedures and acceptance criteria, packaging and labeling specifications, and installation, maintenance, and service procedures.

3.0 Attitudes and Adjustments

We're an ultra-small start-up of less than 10 full and part-time personnel. The FDA's QSR doesn't apply to small companies like us.

Not true. The FDA QSR does not discriminate based upon company size, and compliance to the QSR is required, whether the company is small (1-19 personnel), or large (≥250 personnel).

The QSR is, however, intended to be flexible, and FDA recognizes that the small manufacturer may not need the same amount of documentation that a large manufacturer requires. The complexity and length of written records and procedures may also be less for the smaller manufacturer.

FDA does expect and require the manufacturer, regardless of size, to maintain its compliance with the QSR over time. This is especially true for the small manufacturer, who may adopt the "fix it and forget it" attitude. As the Company grows, and/or as products and processes change and evolve, the Company is required to continuously assess and repair as necessary, the adequacy of its quality system.

We make accessories products, such as hemodialysis tubing. By FDA's definition, these are just components, so the FDA QSR doesn't apply to us.

Not true. FDA defines a "component" as…

> any raw material, substance, piece, part, software, firmware, labeling, or assembly, which is intended to be included as a part of the finished, packaged, and labeled device…[21 CFR 820.3(c)]

To minimize the burden on unrelated industries, FDA specifically excludes component manufacturers from compliance with the QSR [21 CFR 820.1(a)(i)], and FDA expects the finished device manufacturer to assure that the components are acceptable for use.

Accessory devices, such as blood filters, hemodialysis tubing, etc. are packaged, labeled, and distributed for health-related purposes, and often separately from the original equipment on which they are suitable or intended for use.

FDA considers these products to be finished medical devices, because they are suitable for, capable of functioning as, or distributed for, health-related purposes. As such, the QSR requirements apply to the manufacturers and distributors of the accessory devices.

We "farm-out" all our engineering and manufacturing activities to an engineering house, so we're not really a "manufacturer."The FDA's QSR doesn't apply to us - if anything, compliance with the regulations would be our engineering house's problem (responsibility), not ours.

Not exactly. FDA has several similar definitions of a "manufacturer" who is required by FDA regulations to comply with the QSR:

> …Manufacturer means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device by chemical, physical, biological, or other procedures. The term includes any person who:
>
> (1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user or consumer;
>
> (2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or
>
> (3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient. [21 CFR §806.2(g)]
>
> …
>
> …Manufacture, preparation, propagation, compounding, assembly, or processing of a device means the making by chemical, physical, biological, or other procedures of any article that meets the definition of device in section 201(h) of the act. These terms include the following activities:
>
> (1) Repackaging or otherwise changing the container, wrapper, or labeling of any device package in furtherance of the distribution of the device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;
>
> (2) Initial importation of devices manufactured in foreign establishments; or
>
> (3) Initiation of specifications for devices that are manufactured by a second party for subsequent commercial distribution by the person initiating specifications. [21 CR §807.3(d)]
>
> …
>
> …any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes, but is not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repackaging, or specification development, and initial distributors of foreign entities performing these functions. [21 CFR §820.3(o)]

While most of the above manufacturer categories are intuitively obvious, several categories deserve additional clarification:

Specification developer:develops specifications for a device that is distributed under the establishment's own name, but performs no manufacturing.

Repackager: packages finished devices from bulk or repackages devices made for the establishment by a manufacturer into different containers (excluding shipping containers).

Relabeler: changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that do not change the original labeling, but merely add their own name.

> ***Contract manufacturer:*** manufactures a finished device to another establishment's specifications. The manufacturing establishment does not commercially distribute the device under its own name.

For contract manufacturing relationships, FDA recommends that the agreement between the manufacturers be documented in a written contract. Written contracts are partially regulated by FDA QSR regulations for Purchasing Controls:

> Each manufacturer shall establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements.
>
> (a) Evaluation of suppliers, contractors, and consultants. Each manufacturer shall maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:
>
> (1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.
>
> (2) Define the type and extent of control to be exercised over the product, services, suppliers, contractors, and consultants, based on the evaluation results.
>
> (3) Establish and maintain records of acceptable suppliers, contractors, and consultants. [21 CFR§820.50]

FDA requires that contract manufacturers of finished devices comply with the applicable requirements of the QSR. In addition, depending on the circumstances, both the contractor and manufacturer may be held jointly responsible by FDA for the activities performed.

By interpretation of the Purchasing Controls regulations, it is reasonable to categorize contract third-party engineering houses as "suppliers" or "contractors." Often, third-party engineering houses may be unaware of, or unwilling to take on, compliance with FDA's QSR requirements. The burden of proof and compliance then falls upon the manufacturer.

In all cases, the business arrangements of a medical device manufacturer do not obviate the Company's obligations for compliance with the FDA QSR.

We're currently doing early concept and feasibility studies; certainly the FDA's QSR doesn't apply to us.

Correct. Unfortunately, the FDA regulations are painfully vague on *when* design controls apply. The official definition is that design controls applay when the device design is transferred from research to engineering. Unfortunately, that transition is equally vague. This author has seen ultra-conseravtive interpretations, in which every screw and nut in a blue-sky feasibility model are fully documented and released, and ultra-liberal interpretations, in which the manfacturer started design controls while selecting final color schemes for device labeling.

A reasonable and fully defensible interpretation of the FDA regulations is the financial test: once a manufacturer decides to develop a design, by committing time, personnel and financial resources, the design controls regulations should apply with full compliance. Even if the design is go-nowhere, and ultimately commited to the corner file cabinet, some aspects of the current design, even deficiencies, inadequacies, and the 'no-go' rationale, may be of value to future engineering efforts.

FDA design control regulations definitely apply to devices undergoing clinical evaluation and validation. The FDA's clinical studies regulations are partially detailed in 21CFR §812, Investigational Device Exemptions (IDE). Devices which have an approved IDE are exempt from the majority of the FDA regulations, including…

- Misbranding,
- Registration and listing,
- Premarket notification,
- Performance standards,
- Premarket approval,
- Banned device regulation,
- Records and reports,
- Restricted device requirements, and …
- Good manufacturing practices, *except for the requirements found in §820.30* [emphasis added]

4.0 Discussion

Start-up and small medical device companies sometimes conclude that FDA's Quality System Regulations [QSR], (formerly current Good Manufacturing Requirements, or cGMPS) do not apply to the current phase of their operations.

This decision is incorrect, and unforeseen consequences, such as costly delays to market introduction, substandard, poor quality, or unreliable product, device recalls, liability litigation, and/or FDA compliance and enforcement actions, can result. FDA publicly posts compliance letters or Warning Letters on the Agency's website on a monthly basis. Of the Warning Letters identifying deficiencies in quality systems for medical devices, nearly 40% relate to early-stage regulatory requirements such as design controls, purchasing, inspection, and supplier/contractor requirements.

Investors and venture capitalists are often focussed upon exit strategies, return on investment, and Company valuation. Since 1997, when the FDA QSR became law, an increasingly significant facet of medical device company mergers and acquisitions is the pre-purchase QSR compliance audit as part of due diligence activities. Companies in acquisition mode retain teams of highly qualified outside consultants to perform these compliance audits, often with an equal or greater thoroughness than the audits conducted by FDA personnel. The results of these third-party consultant audits can directly influence the purchased Company's valuation and the terms of the purchase agreement, if at all concluded.

Outside the M&A arena, executive management may be confronted with the choice between regulatory/quality activities and product sales activities. Management must make a risk-benefit determination before blithefully establishing that initial revenue stream, all the while while making informal internal commitments to backfill the acknowledged and required regulatory information at a future date. Worse, unforeseen regulatory requirements can wreak havoc on the venture's best laid business plans, and can suddenly force executive management into a reactionary, fire-fighting mode of operation. Either mode of operation can be expected to put a few "skeletons in the closet," guaranteeing incomplete FDA QSR compliance, and the possibility of a featured appearance in an FDA Warning Letter.

Company size or development stage is no reason to remain blind to current and future FDA requirements. FDA holds the highest level of executive management responsible for the Company's implementation of a quality system, and for the failures and deficiencies in that system. Thus, Warning Letters are always addressed to the manufacturer's most senior executive manager.

Company executive management must take the time to get informed. Unfortunately, there is no FDA QSR For Dummies® reference book. The FDA website has an (overwhelming) amount of information related to its regulation of drugs, cosmetics, biologics, foods, and medical devices. A crude, albeit highly effective, method for a manufacturer to determine its obligations in the FDA's

QSR regulations,[21CFR §820] is to perform a keyword search."Establish and maintain," for example, requires a written procedure, and "approved," "approval," and "documented" require a form or other form of recordkeeping.

The Company that acknowledges and understands its regulatory obligations early on is better able to incorporate compliance activities and required resources up-front and within the business scedule and model. Planning eliminates "surprises" to venture capitalists, investors, and executive management alike. While product design and development activities are not without peril, early QSR compliance activities make good business sense, improve or,at a minimum, maintain a Company's valuation, and minimize an often-overlooked, but significant source of "Maalox™ moments."

5.0 References

DHHS/FDA. FDA's Electronic Freedom of Information Reading Room - Warning Letters and Responses. < http://www.fda.gov/foi/warning.htm >. Rockville, MD.

DHHS/FDA. Device Advice : Good Manufacturing Practices (GMP) / Quality System (QS) Regulation. < http://www.fda.gov/cdrh/devadvice/32.html >. Rockville, MD.

DHHS/FDA/CDRH. Device recalls: A study of quality problems. HHS Publication FDA 90-4235. Rockville, MD. January 1990.

Office of Inspector General. FDA medical device regulation from premarket review to recall. HHS Publiscation OEI 09-90-00040. Washington, DC. February 1991.

DHHS/FDA/CDRH. Software-related recalls for fiscal years FY83-FY91. Rockville, MD. May 1992.

ISO 9001:1994 Quality systems - Model for quality assurance in design, development, production, installation, and servicing.

ISO 13485-1996 Quality Systems - Medical Devices - particular requirements for the application of ISO 9001.

DHHS/FDA. 21CFR Parts 808, 812, and 820 Medical devices; Current good manufacturing practice (CGMP); Final rule. Federal Register V61:N195. Washington DC. October 7, 1996.

6.0 Revision History

Rev.	Date	Description and Location of Change(s)
A	7/29/03	Initial Release
B	4/9/04	add-in FDA Warning Letter statistics; generally re-organize
C	7/12/04	Minor revisions, typos, mild re-organization
D	3/17/05	Change of URLs, address

7.0 Attachments

- 21CFR §820.30 Design Controls
- Risk-based approach to medical device regulation
- Author Bio

7.1 21CFR §820.30 Design controls

(a) General. (1) Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section, shall *establish and maintain* procedures to control the design of the device in order to ensure that specified design requirements are met.

(2) The following class I devices are subject to design controls:

(i) Devices automated with computer software; and

(ii) The devices listed in the following chart.

Section	Device
868.6810	Catheter, Tracheobronchial Suction.
878.4460	Glove, Surgeon's.
880.6760	Restraint, Protective.
892.5650	System, Applicator, Radionuclide, Manual.
892.5740	Source, Radionuclide Teletherapy.

(b) Design and development planning. Each manufacturer shall *establish and maintain* plans that describe or reference the design and development activities and define responsibility for implementation. The plans shall identify and describe the interfaces with different groups or activities that provide, or result in, input to the design and development process. The plans shall be *reviewed, updated, and approved* as design and development evolves.

(c) Design input. Each manufacturer shall *establish and maintain* procedures to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient. The procedures shall include a mechanism for addressing incomplete, ambiguous, or conflicting requirements. The design input requirements shall be *documented and shall be reviewed and approved* by a designated individual(s). The *approval,* including the date and signature of the individual(s) approving the requirements, *shall be documented.*

(d) Design output. Each manufacturer shall *establish and maintain* procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. Design output shall be *documented, reviewed, and approved* before release. The *approval,* including the date and signature of the individual(s) approving the output, *shall be documented.*

(e) Design review. Each manufacturer shall *establish and maintain* procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development. The procedures shall ensure that participants at each design review include representatives of all functions concerned with the design stage being reviewed and an individual(s) who does not have direct responsibility for the design stage being reviewed, as well as any specialists needed. The results of a design review, including identification of the design, the date, and the individual(s) performing the review, shall be *documented* in the design history file (the DHF).

(f) Design verification. Each manufacturer shall establish andmaintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be *documented* in the DHF.

(g) Design validation. Each manufacturer shall *establish and maintain* procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validation shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions. Design validation shall include software validation and risk analysis, where appropriate. The results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation, shall be *documented* in the DHF.

(h) Design transfer. Each manufacturer shall *establish and maintain* procedures to ensure that the device design is correctly translated into production specifications.

(i) Design changes. Each manufacturer shall *establish and maintain* procedures for the identification, documentation, validation or where appropriate verification, review, and *approval* of design changes before their implementation.

(j) Design history file. Each manufacturer shall *establish and maintain* a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

7.2 Risk-based approach to medical device regulation

In its regulation of medical devices, FDA implemented a three-tiered *risk-based* approach, Class I, II, and III. The higher the Class, the greater the degree of risk associated with the device, and the greater the degree of required regulatory control.

Class I devices present a minimal potential harm to the user, and are subject to the least regulatory control. Class I devices must comply with ***General Controls:***

- Establishment Registration of companies including manufacturers, distributors, repackages and relabelers
- Medical Device Listing with FDA of devices being marketed
- Manufacturing of medical devices in accordance with FDA Quality System Regulations
- Labeling devices in accordance with FDA labeling regulations
- Submission of a premarket notification [510(k)] before marketing a device

Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. Class II devices must comply with…

- General Controls
- ***Performance Standards and/or Special Controls,*** examples including…
  - Special labeling requirements
  - Mandatory performance standards
  - Postmarket surveillance, etc.

Examples of Class II devices include powered wheelchairs, infusion pumps, physiological monitors, angiography catheters, and MRI and ultrasound systems.

Class III is the most stringent regulatory category for devices. Class III devices are those for which insufficient information exists to assure safety and effectiveness solely through general or special controls. A Class III device is a high-risk devices that…

- "…is represented to be for use in supporting or sustaining human life"
- "…of substantial importance in preventing impairment of human health," or
- "presents a potential unreasonable risk of illness or injury."

Devices in this class are subject to general controls, and subject to the premarket approval process, in which the manufacturer is required to establish the safety and effectiveness of the device before marketing it.

Examples of Class III devices which require a premarket approval include replacement heart valves, silicone gel-filled breast implants, coronary angioplasty catheters, and implanted cerebella stimulators.

7.3 Author Bio

Since 1987, James Jochen Rogers has worked in engineering, service, and regulatory affairs capacities for large, small and start-up MRI diagnostic imaging manufacturers. James represented two of the companies to the National Electrical Manufacturers Association [NEMA]'s MR and Ultrasound Sections, and actively participated in the development of NEMA measurement standards, FDA regulations, and international voluntary standards. Through consulting activities, he has broad experience with ultrasound, radiation therapy, bone densitometry, interventional radiology, PACS, lasers, steam sterilizers, and OTC/consumer products.

He is currently General Manager and founder of Coastal Consulting Group, Ltd., providing medical device regulatory affairs, technical publications, good manufacturing practices and custom database development services. Though not a member, Coastal continues active participation and contribution to the NEMA MR Section.

The Company recently acted in a contract product and marketing manager capacity for an MRI accessory, resulting in peer-review publication of original research, and projected revenues in excess of $1M in FY 2004 for the manufacturer.

Coastal is completing development of **Quality: *Now*™**, a comprehensive set of quality system procedures, forms, and guidance documents, intended exclusively for start-up and small manufacturers. This "Quality-System-in-a-Box" is currently undergoing beta-testing, and provides rapid deployment, implementation, and on-going maintenance of a manufacturing quality system compliant with FDA QSR and international voluntary quality system standards. Guidance documents assist the individual manufacturers in developing their manufacturing-specific procedures, while training and an on-going and periodic auditing program assists in ensuring continued regulatory compliance.

For clinical studies, Coastal has experience in outcomes-based and "me-too" comparative clinical studies, developing investigational protocols, CRF's, informed consent forms, and obtain IRB approval, performing clinical research management (setup, maintenance, audits, recordkeeping, annual reviews, closure), and data integrity management, including web-based clinical data capture, with 100+ devices and enhancements documented in clinical investigational protocols, and IRB-approved.

In addition to preparation of laser initial and annual reports, Coastal holds a number of "firsts" in FDA submissions - first "electronic format" 510(k) submission, first laparoscopic ultrasound transducers and system to receive FDA 510(k) clearance), and first MRI-compatible oxygen cylinder (up to 3.0 Tesla). Experienced in MRI, ultrasound, PACS, lasers, radiation therapy, DEXA (bone densitometry) scanners, interventional radiology, minimally invasive surgical, steam sterilizers, OTC IR digital thermometers, with approximately ~70 510(k) submissions successfully received FDA marketing clearance.

Mr. Rogers holds a BS degree in Electrical Engineering and Applied Physics from Case institute of Technology, Case Western Reserve University (1986), a patent for MRI cardiac gating technology, and authored several peer-reviewed journal articles.

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