SOFTWARECPR®
CRISIS PREVENTION AND RECOVERY, LLC

Adrian Gropper, Medcommons Feb 12, 2004

Dear Adrian:

As discussed this is to provide you some information on a possible approach to our support for your development of an FDA compliant quality system and to attaining ISO 13485 registration (medical device version of ISO 9001).

Given the formative stage of your new company and product and your desire to base your quality system on an electronic system(s) rather then paper procedures and records I'd suggest we proceed in an incremental fashion so that we don't spend money and time developing things that then need extensive rework.

In general medical device start-ups face the task of establishing a quality system before having established processes with a track record and before extensive funding is available. Yet regulatory agencies expect product development under formal design and quality system controls. Medical product venture investors know that a compliant quality system is necessary and look for plans for a timely and efficient implementation.

SoftwareCPR® usually follows these principles for establishing a start-up quality system:

- Start simple and let it evolve.
  Efficient quality systems are "fitted" to a company's situation, culture, and product technology. Rather than starting with a pre-configured and perhaps restrictive quality system, SoftwareCPR® starts with the basics. The quality system evolves and matures driven by the company's situation, management philosophy, and expanding needs and capabilities. The end results are a quality system well-suited to the company and management that controls the quality system, not vice versa.

- Start with the foundation, and then build on it.
  A quality system's foundation has three primary components: Management Responsibility and Controls, Information Control (documents, records, training), and Improvement Processes (CAPA). Initially we establish a minimal quality system with these three components in a simple configuration. Additional elements and more detailed procedures are then added. In your case the next major area would be Design Controls.

- Implement quality system tools as the business evolves.
  For example, electronic project management and record keeping tools.

The goal overall is to establish a quality system that not only ensures product quality and regulatory compliance, but is "owned" and supported by management and is integrated into the company's operations and controls and allows selection and configuration of appropriate electronic tools. .

I'd propose that we start with the following first objective and deliverables:

- Establish a basic infrastructure in the form of a partial Quality Manual consisting of
  a. Management control policies and high-level procedures
  b. Basic document, record, and training policies and high-level procedures
  c. Corrective and preventive action Policies
  d. Design Control Policies (high level only)

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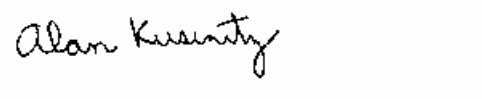
Our estimate for this first step is in the range of $6000-$7500 dollars and is dependent on the ease with which consensus on approaches can be reached in each of the areas being addressed. We would then be in better position to plan additional support and estimate time and cost for achieving ISO 13485.

We look forward to working with you on this

Sincerely,



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