1. A Program for Manufacturers

This program provides a number of services to help manufacturers optimize the quality and safety of their medical products.† These services include:

I. Quality Assurance and Regulatory Affairs:

- Resolving quality deviations identified during an internal or external (e.g., FDA, ISO) audit;
- Opening and completing corrective and preventive actions, or "CAPAs," to satisfy a FDA's request or finding following an inspection; and
- Providing advice about a device's labeling.

II. Design Control, Validation and Verification:

- Performing design control activities; and
- Helping manufacturers comply with the FDA's *Quality System Regulation* (QSR), to ensure the safety and effectiveness of medical devices.

III. Simulated and Clinical In-Use performance testing:

- Performing and managing simulated and clinical in-use validation tests as required by the FDA to validate the labeling claims of certain medical devices, including flexible endoscopes.

IV. Risk Management:

- Performing an analysis that assesses the risk of harm due to a deviation or fault mode; and
- Performing a root cause analysis to determine the cause(s) of an identified deviation.

V. Targeted Advertising:

- Using the #1 Google search rankings of Dr. Muscarella's blog (*EndoscopeReprocesing.com*).

† These services are provided by Lawrence F Muscarella, PhD – an expert in infection control, product development, and both the design and FDA-regulation of medical devices. Dr. Muscarella is the president of *LFM Healthcare Solutions, LLC.*

LFM Healthcare Solutions, LLC
L.F. Muscarella, Ph.D., President
P.O. Box 684, Montgomeryville. PA 18936

Medical Device Manufacturer
123 Main Street
Chicago, IL 60601

A Program Designed to Help Manufacturers Optimize the Quality, Safety, Effectiveness, and Marketing of their Medical Products

2. The Program's Objectives

Designed for manufacturers of medical devices, the objectives of this program are to:

- Ensure that the highest quality and safety standards of a manufacturer's medical devices and related products are maintained;
- Reduce a manufacturer's costs & legal exposure;
- Target and Optimize a manufacturer's advertising;
- Prevent a medical device's recall or significant field correction, the FDA's issuance of a warning letter, and/or the signing of a consent decree;
- Prepare manufacturers for internal audits and both FDA and ISO inspections and reviews;
- Ensure the manufacturer's compliance with the FDA's *Quality System Regulation* (QSR); and
- Ensure the completeness of the manufacturer's quality, design, validation and verification files.

3. Program's Mission

This multi-faceted, customizable program aims to help manufacturers comply with federal regulations and, by doing so, reduce costs and legal exposure while ensuring the manufacturer's medical devices perform as intended, are safe and effective, and are not recalled. This mission is achieved through this program's commitment to excellence and quality.

4. The Program's Other Services

Additionally, Dr. Muscarella's program of quality provides a number of other services and strategies for manufacturers of medical devices, including:

I. Technical Monographs, Product Overviews:

- Writing a technical overview that conveys to healthcare staff, in an easy-to-read format, the quality, safety and performance of a medical device (*sample*: http://tinyurl.com/q26eea8).

II. Writing Peer-Reviewed Articles, Education:

- Writing a white paper describing a product's performance, safety and quality;
- Writing other types of research articles, too;
- Providing educational seminars to healthcare staff discussing a manufacturer's technology;
- Lecturing to healthcare practitioners during manufacturer-sponsored educational seminars (that provide "CEUs") about infection control and endoscope reprocessing, among other topics.

III. Marketing and Product Development:

- Strategizing with manufacturers about the development and launching of new products; and
- Optimizing how a medical device is advertised, positioned and sold in the marketplace.

IV. Internal Bottlenecks:

- Resolving design, regulatory, quality, safety, or another type of "roadblock" that is preventing a manufacturer from receiving a FDA clearance or otherwise marketing one or more of its products.

5. LFM Healthcare Solutions, LLC

This program is designed by Lawrence F Muscarella, PhD, the president of *LFM healthcare Solutions, LLC*.

6. Research & Other Experience

Dr. Muscarella has almost 25 years of experience in the following healthcare disciplines, among others:

- infection control and prevention;
- both flexible and rigid instrument reprocessing;
- risk management and quality assurance;
- simulated and in-use protocol development;
- design validation and verification; and
- 510(k) applications and clearances.

7. Lectures & Courses

In recent years, Dr. Muscarella was a guest lecturer for *The Society of Gastroenterology Nurses and Associates* (SGNA), speaking to all of its members during a general session (St. Louis, MO; 2009). He has also lectured in England, Canada, and across the U.S.

8. Education & History

With almost 25 years of experience, Dr. Muscarella received his Ph.D. in engineering from the University of Pennsylvania in 1990. From 1995 until early 2013, Dr. Muscarella was the chief of infection control for a manufacturer of washer-disinfectors for flexible endoscopes. In 1995 he founded the popular infection control newsletter, *The Q-Net Monthly.* In 2013 Dr. Muscarella founded LFM Healthcare Solutions, LLC.

LFM
Healthcare Solutions, LLC

Want a Quote, Got a Question? Contact:

Lawrence F Muscarella, PhD, President
LFM Healthcare Solutions, LLC
P.O. Box 684, Montgomeryville, PA 18936
⇨ Email: Larry@LFM-HCS.com for a timely reply.

9. Confidentiality & Excellence

Dr. Muscarella's program is committed to excellence, integrity and confidentiality.

10. Educational Blog

In 2012 Dr. Muscarella founded the well-read and popular blog "*Discussions in Infection Control*," which may be used by manufacturers to advertise a medical product. Visit: *EndoscopeReprocessing.com*

11. Newspaper Quotes, Research

Dr. Muscarella's work has been discussed in *USA Today, The Boston Globe, Newsday, Sacramento Bee, Pittsburgh Post-Gazette, Winston-Salem Journal,* and *The Seattle Times,* among other newspapers, as well as on the front pages of *The Wall Street Journal, Investor's Business Daily*, and *The San Juan Weekly.*

12. Medical Publications

-- Dr. Muscarella has published over 150 articles, many in the peer-reviewed medical literature. His articles focus on infection control, instrument reprocessing, disinfection and sterilization, risk management, and the FDA's regulation of medical devices.

-- Dr. Muscarella's articles have been published in: *The Journal of Hospital Infection, American Journal of Infection Control, Infection Control and Hospital Epidemiology, Endoscopy, Gastrointestinal Endoscopy, Chest, and The World Journal of Gastrointestinal Endoscopy,* among other medical journals.