

Lawrence F. Muscarella, Ph.D.

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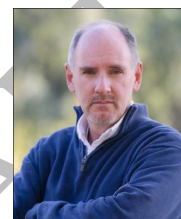
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EMPLOYMENT

- **2013 - Present:** *LFM Healthcare Solutions, LLC* (Montgomeryville, PA), president and founder. Company missions: to improve the quality and safety of health care.
- **1995 - 2013:** *Custom Ultrasonics, Inc.*
- **1991 - 1994:** *ECRI Institute* (Plymouth Meeting, PA), project engineer. (A non-profit company that evaluates the safety of medical devices.)
- **1989 - 1990:** *Temple University School of Medicine* (Philadelphia, PA), a one-year fellowship in the Department of Diagnostic Imaging. *Advisor:* Marvin Ziskin, M.D.



EDUCATION

- **Ph.D.** (1990): *University of Pennsylvania, School of Engineering and Applied Sciences* (Department of Bioengineering, Philadelphia, PA). Dissertation thesis: Muscarella LF. "Fluid exchange in distensible capillaries." *Advisor:* Abraham Noordergraaf, Ph.D.
- **M.S.E.** (1985): *University of Pennsylvania, School of Engineering and Applied Sciences* (Department of Bioengineering, Philadelphia, PA).
- **B.S.** (1983): *Ursinus College* (Collegeville, PA). Major: Physics; Minors: Biology, Philosophy.

EXPERIENCE, QUALIFICATIONS

- Expert, consultant and peer reviewer for medical device manufacturers, healthcare facilities including hospitals, and the public.
- Author of more than 150 papers, many of which are published in peer-reviewed journals.
- Expert in the following disciplines, among others:
 - decontamination, cleaning, disinfection and sterilization of reusable medical equipment
 - causes, mitigation and prevention of healthcare-associated infections
 - aseptic technique and proper operating room protocol and procedures
 - validation and verification of the designs of medical devices (design controls)
 - safety and effectiveness of medical devices
 - labeling and FDA regulation of medical devices
 - simulated and clinical in-use performance validation testing
 - root cause analyses (RCAs) and risk/hazard analyses

- Expert in assessing the risk of disease transmission associated with an infection-control or instrument-reprocessing error or lapse.
 - Experienced in quality control, design controls, regulatory affairs, quality assurance, and risk management.
 - Auditor and peer reviewer of the infection-control and instrument-reprocessing policies, procedures, and practices of healthcare facilities.
 - Experienced in product development, device labeling, branding, sales and marketing, and operations and process optimization.
 - Experienced in company management and other business-related activities.
 - Frequent lecturer in Canada, the U.S., and in the U.K.
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PATENTS

- Lawrence F Muscarella, PhD, Frank Weber. *Method for determining the efficacy of a decontamination process*. US 6,428,746 B1 (Issued: August 6, 2002). [Lawrence F Muscarella: Sole owner of patent.] Learn more: <http://www.google.com/patents/US6428746>
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MEDICAL BLOG (“DISCUSSIONS IN INFECTION CONTROL”)

- Founder of “*Discussions in Infection Control*” – the world’s most replete infection-control blog focusing on instrument reprocessing, hospital infections and bacterial outbreaks, among other related topics. More than 100,000 views to date. Visit: LFM-HCS.com
 - Dr. Muscarella’s blog (“*Discussions in Infection Control*”) was discussed in *Bloomberg Business* on September 17, 2015: <http://tinyurl.com/ncfujcq>
 - Founder, editor of *The Q-Net Monthly*, an infection-control newsletter that was in publication for almost 20 years (1995-2013).
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RECENT WHITE PAPERS

1. Muscarella, Lawrence F. Selection of low-temperature sterilization for the prevention of multidrug-resistant bacterial infections during flexible endoscopy. AMBU: Columbia, MD, 2019. [White paper]
2. Muscarella, Lawrence F. Resistant *Klebsiella pneumoniae* infections linked to flexible intubation endoscopes: Recommendations to prevent infections. AMBU: Columbia, MD, 2018. [White paper] <https://tinyurl.com/yd87azkl>
3. Muscarella, Lawrence F. Risk of flexible endoscopes, including gastroscopes and echoendoscopes, transmitting “superbugs” infections: An important update. Ruhof Inc.: Mineola, NY, 2018 [White paper] <https://tinyurl.com/y78j4uzt>
4. Muscarella, Lawrence F. Enzymatic detergents: Are they the primary cause of TASS? Ruhof Inc.: Mineola, NY, 2018 [White paper]: <https://tinyurl.com/ycnccdfs>

5. Muscarella, Lawrence F. Updated guidance for the prevention of transmission of ‘CRE’ and other related multidrug-resistant “superbugs” during gastrointestinal endoscopy. Ruhof Inc.: Mineola, NY, 2016 [White paper]: <https://tinyurl.com/y8x3gtj8>
6. Muscarella, Lawrence F. Whose instructions should you follow? A guide for resolving inconsistencies in the reprocessing instructions of bronchoscopes and automated endoscope reprocessors. AMBU: Columbia, MD, 2016. [White paper].

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TV, VIDEO, RADIO INTERVIEWS ABOUT “SUPERBUGS” INFECTIONS

- **CNN:** <https://tinyurl.com/w4lzukp>
- **NBC’s The Today Show:** <https://tinyurl.com/uct8pwe>
- **ABC World News Tonight:** <https://tinyurl.com/r2n6o5v>
- **CBS Evening News with Scott Pelley:** <https://tinyurl.com/unrtlpr>
- **NBC Nightly News with Lester Holt:** <https://tinyurl.com/tx6ox2p>
- **CBS (Philadelphia, PA):** <https://tinyurl.com/tyuowr7>
- **Wall Street Journal Live:** <https://tinyurl.com/urhflog>
- **WWL-TV (New Orleans, LA):** <https://tinyurl.com/we8pjnt>
- **NBC-TV4 (Washington, D.C.):** <http://tinyurl.com/hcyvffw>
- **WCNC (NBC Charlotte, NC):** <https://tinyurl.com/swny8o2>
- **Al Jazeera America**

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MORE RECENT QUOTES, VIDEOS ABOUT INFECTIONS, MEDICAL ERRORS

- **USA Today:** “As COVID-19 spread, the feds relaxed rules, and hospitals tried to contain the outbreak. Other infections may have risen.” August 5, 2020. <https://tinyurl.com/y5t9cd9r>
- **WTSP (TV-10 Tampa Bay, FL):** “She went to a Tampa hospital for surgery. Her family says she left with a deadly infection. She’s not alone.” September 9, 2020. <https://tinyurl.com/y529kpro>
- **USA Today:** “A \$100,000 cleaning machine? A 'silver bullet' disinfectant? Businesses cash in on coronavirus panic at schools.” March 8, 2020. <https://tinyurl.com/wcm29a7>
- **Los Angeles Times:** “Disposable medical scope approved by FDA to stop superbug infections.” December 16, 2019. <https://tinyurl.com/ubmnvhg>
- **New York Times:** “Why Are These Medical Instruments So Tough to Sterilize?” August 6, 2019. <https://tinyurl.com/y4ooaefu>
- **Newsday:** “Multi-drug-resistant fungus known as *C. auris* affecting hundreds in New York.” May 4, 2019. <https://tinyurl.com/ur5smv7>
- **Bloomberg Law:** “Breathing tube, catheter shortages stem from sterilization woes.” April 18, 2019. <https://tinyurl.com/tfeys3s>

- **WWL-TV (New Orleans, LA):** “Expert says he warned of machine used in Children's Hospital heart surgeries.” September 12, 2017: <https://tinyurl.com/we8pjnt>
- **Medscape:** “CDC confirms superbug transmission via endoscopy.” January 3, 2014. <http://tinyurl.com/zvcr5mo>
- **Wall Street Journal:** “Clinic Infections Put a Sterilizer of Lab Devices Under Microscope.” December 24, 2004: <https://www.wsj.com/articles/SB110383193120108406>

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PUBLICATIONS IN PEER-REVIEWED MEDICAL JOURNALS

1. Mehta AC, Muscarella LF. Bronchoscope-related “superbug” infections. *Chest* 2020 Feb;157(2):454-469. doi: 10.1016/j.chest.2019.08.003. Epub 2019 Aug 14.
2. Muscarella LF. Use of ethylene-oxide gas sterilisation to terminate multidrug-resistant bacterial infections linked to duodenoscopes. *BMJ Open Gastroenterol* 2019 Aug 5;6(1):E000282.
3. Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae (CRE) and related ‘superbugs’ during gastrointestinal endoscopy. *World J Gastrointest Endosc* 2014 Oct 16;6(10):457-74. <http://bit.do/X7Ff>
4. Muscarella LF. Other possible causes of a well-publicized outbreak of *Pseudomonas aeruginosa* following arthroscopy in Texas. *Advances Infect Dis* 2013 Jun;3(2). <http://bit.do/X7FF>
5. Muscarella LF. Medical errors, Infection-control breaches and the use of adulterated and misbranded medical devices. *World J Clin Infect Dis* 2012 Apr 25;2(2):13-27. <http://bit.do/X7FV>
6. Muscarella LF. Assessment of the reported effectiveness of five different quality-improvement initiatives for the prevention of central line-associated bloodstream infections in intensive care units. *Open Epidemiol J* 2012;5:5-12. <http://goo.gl/LLH3oB>
7. Agrawal D, Muscarella LF. Delayed reprocessing of endoscopes. *Gastrointest Endosc* 2011 Apr;73(4):853-4.
8. Muscarella LF. The investigation and prevention of infectious outbreaks during endoscopic retrograde cholangio-pancreatography. *Endoscopy* 2010 Nov;42(11):957-9. [Featured editorial]
9. Muscarella LF. The study of a contaminated colonoscope. *Clin Gastroenterol Hepatol* 2010 Jul;8(7):577-580.

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DISCLAIMER

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