

George E. Yanulis

M. ENG., M.S., D. ENG.

216-571-1532

7950 PARK BLVD NORTH #2407 PINELLAS PARK, FL 33781

YANULISG@GMAIL.COM

WWW.LINKEDIN.COM/IN/YANULIS | WWW.GYMEDICALDEVICECONSULTING.COM

PROFESSIONAL EXPERIENCE

President / Subject Matter Expert Clinical Engineering	Medical Device Consulting, LLC Fort Myers, FL	June 2014 - Present
Adjunct Professor Bioengineering Department	Temple University Philadelphia, PA	January 2016 – January 2018
Expert Consultant Clinical Engineering	B. H. Barkalow & Assoc, LLC Newaygo, MI	March 2014 – June 2016
Senior Medical Device Consultant Forensic Engineering Division	Laughlin Engineering Firm, LLC Houston, TX	November 2011- May 2016
Adjunct Professor Engineering/Physics Departments	College of Staten Island Staten Island, NY	August 2009- December 2013
Pre-doctoral Fellow Biomedical Engineering Department	Cleveland Clinic Foundation Cleveland, OH	November 2005- May 2008

EDUCATION

Doctorate in Engineering Biomedical Engineering	Cleveland State University/Cleveland Clinic Cleveland, OH	2008
Master of Science Bioengineering	University of Pittsburgh Pittsburgh, PA	2002
Master of Engineering Biomedical Engineering	University of Virginia Charlottesville, VA	1981
Bachelor of Arts Premedical Studies/Chemistry	Syracuse University Syracuse, NY	1977

MEDICAL DEVICE RESEARCH & DEVELOPMENT EXPERTISE/EXPERIENCES

- Expertise in all types of medical device R&D including surgical forceps
- Expertise in the R&D of orthopedic implants
- Expertise in surgical stapling systems
- Expertise in consulting and the R&D of all types of cardiac systems

- Performing ECG signal detection & cardiac pressure/volume analysis (over 250 sessions)
- Cardiac echo imaging
- Designing pre-clinical device trial formulations for all types of medical devices
- 3 Peer Review Publications in atrial fibrillation and heart failure related to doctoral research; submitting 2 Abstracts, JACC March 11, 2008; and awarded 2 Awarded Innovation Awards (Cleveland Clinic).

Ablation Therapy Systems Expertise

- The NAVISTAR® THERMOCOOL® and EZ Steer THERMOCOOL® Nav Irrigated Deflectable Diagnostic/Ablation Catheter for Treatment of Paroxysmal Atrial Fibrillation (Biosense Webster, Inc.)
- The Arctic Front® Cardiac CryoAblation Catheter for Treatment of Paroxysmal Atrial Fibrillation (Medtronic Cryocath, LP)
- The Therapy Cool Path Duo™ Ablation Catheter, Safire BLU Duo™ Ablation Catheter, and IBI1500T9-CP V1.6 Cardiac Ablation Generator for Treatment of atrial Flutter (Irvine Biomedical, Inc.)
- The R&D of conventional AF ablation used in pulmonary vein isolation (PVI), and those systems used in clinical practice, e.g. units which create circular RF lesions in a point-by-point fashion around the pulmonary valve

Expertise in the Mapping Systems used in cardiac mapping systems:

- The NxT steerable introducer, EnSite Precision™ cardiac mapping system
- The Carto 3 three-dimensional mapping system

MEDICAL DEVICE REGULATORY PROTOCOLS EXPERTISE

- ISO 9001:2015 Quality management systems — Requirements
- A Guide to the EU Directive Concerning Liability for Defective Products (Product Liability Directive)
- Directive 93/42/EEC covering medical devices modified by the directive 2007/47/CE
- ISO 13485 Medical devices -- Quality management systems
- ISO 10993-1 - Biological evaluation of medical devices - Part 1
- ISO 14971 - Medical Device Risk Management
- EU-Medical Device Regulations MDR/2017
- Applying Human Factors and Usability Engineering to Medical Devices
- FDA verification and validation procedures
- Design verification/validation and process validation
- MAUDE - Manufacturer and User Facility Device Experience
- Medical Device Reporting - 21 CFR Part 803
- The 510k Process for both cardiovascular and orthopedic implants
- Premarket Submissions for cardiac and orthopedic systems
- Human Factors and Usability Engineering – Guidance for Medical Devices
- European Directive In Vitro Diagnostic Medical Device Directive 98/79/EC (IVDD)
- The CE Marking/conformity assessment process
- Expertise in the 510k process for cardiac devices and cardiac imaging systems
- Expertise in the 510k process for orthopedic implants
- Expertise in all types of medical device research & development (R&D)
- Expertise in the R&D of surgical stapling systems
- Expertise in consulting and the R&D of all types of cardiac systems

- Performing ECG signal detection & cardiac pressure/volume analysis (over 250 sessions)
- Cardiac echo imaging
- Designing pre-clinical device trial formulations for medical devices;
- 3 Peer Review Publications in atrial fibrillation and heart failure related to doctoral research; submitting 2 Abstracts, JACC March 11, 2008; and awarded 2 Awarded Innovation Awards (Cleveland Clinic).
- Review of Urgent Field Safety Notice on orthopedic and cardiac device systems
- ISO 14937:2009 - Sterilization of health care products
- MEDDEV 2.7.1 rev 4 and Clinical Evaluation Reports (CER) for Medical Devices
- ISO/TR 80002-2:2017 - Medical device software -- Part 2: Validation of software for medical device quality systems

PUBLICATIONS

Lim P, **Yanulis GE**, Verhaert D, Greenberg NL, Grimm RA, Tchou PJ, Lellouche N, Wallick DW. Coupled pacing improves left ventricular function during simulated atrial fibrillation without mechanical dyssynchrony. *Europace*. 2010 Mar;12(3):430-6. doi: 10.1093/europace/eup440

Yanulis GE, Lim P, Ahmad A, Popović ZB, Wallick DW. Coupled pacing reverses the effects of persistent atrial fibrillation on the left ventricle. *Ann Thorac Surg*. 2008 Sep;86(3):984-7. doi: 10.1016/j.athoracsur.2008.03.085

Yanulis GE. A novel cardiac pacing paradigm for atrial fibrillation and heart failure patients [dissertation]. [Cleveland (OH)]: Cleveland State University; 2008 May. 106 p.

Cingoz F, **Yanulis GE**, Ching E, Fukamachi K, Wallick DW. Use of conventional dual chamber pacemakers with custom lead adapters to induce atrial fibrillation or heart failure in dogs. *Ann Thorac Surg*. 2007 May;83(5):1858-62.

ABSTRACTS

- Two abstracts presented on heart failure research at American College of Cardiology meeting
 - March 2008

PRESENTATIONS

- Rutgers Medical School, Cardiology Department
 - March 2013
- Rutgers College of Engineering, Biomedical Engineering
 - 2012
- Cleveland State University
 - April 2008

HONORS / AWARDS

- Cleveland Clinic Research Innovation Award
 - September 2008
- Cleveland Clinic Research Innovation Award

George E. Yanulis

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M. ENG., M.S., D. ENG.

- October 2007
- Honorable Discharge, USAF Medical Service Corp, 1st
 - March 1989
- Superior Achievement Award, United States Patent Office
 - 1983
- Member of Tau Beta Pi Engineering Honorary

PROFESSIONAL AFFILIATIONS / SOCIETIES

- Association for the Advancement of Medical Instrumentation
- Heart Rhythm Society
- IEEE Engineering in Medicine & Biology