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# 100 Notable People in the Medical Device Industry

By:  
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## COVER STORY

The medical device industry consists of products, processes, and technology. These are covered in almost every issue of *MD&DI*. But it also consists of people, without whom none of the amazing advances in medical science and technology would be possible.

In this issue, *MD&DI* honors some of the people who make these advances possible and who ensure that those devices can treat patients safely and effectively. If we tried to list everyone who has made a significant contribution to medical technology, we would have to publish an issue larger than a phone book. So we're highlighting 100 of them on the following pages.

It wasn't easy coming up with a representative list. We started with nominations from readers, Editorial Advisory Board members, and staff. We took those who made particularly notable contributions to the industry and made sure that we had as diverse a group as possible. On the list you'll find a sampling of inventors, executives, consultants, engineers, academics, and regulators. Some of them you'll know from previous coverage in *MD&DI* or accolades elsewhere. Others you might be hearing of for the first time.

We hope you enjoy their stories.

**Frances Akelewicz**  
Founder  
Practical Solutions

Consults for U.S., Canadian, and European organizations...ASQ-certified quality engineer and quality auditor...participates in industry and FDA panels on design control and product submissions.

**Dave Albert**  
Senior Scientist

NAMSA

Advocates chemical and material characterization in medical devices...has more than 25 years of lab experience in biochemistry and pharmacology... member of AAMI and several other industry organizations.





**David Auth**  
Board of Directors, CoAptus Medical

Invented Rotablator...invented and coinvented devices for endoscopic control of gastric bleeding, an electrosurgical device for transcatheter hemostasis, and bipolar forceps for neurosurgical bleeding.



**R. Lewis Bennett**  
President

SpineMedica LLC

Has more than 50 years of experience in industry...has held senior positions at NuVasive Inc., Sofamor Danek, and Smith & Nephew... founder of Howmedica Corp.



**John Bentivoglio**  
Partner

King & Spalding LLP

Recognized lawyer with expertise in regulatory counseling, compliance program development, advertising and promotion, and civil and criminal investigations...thought leader for the device industry.



**Mortimer Berkowitz III**  
President and Managing Dir.

HealthpointCapital

Responsible for \$450 million investments into musculoskeletal industry...instrumental in increasing the revenues of four device companies.



**Donna Bibber**  
President

Micro Engineering Solutions

Specializes in tiny microscopic components and assemblies...has helped hundreds of development engineers complete their goals of compliance for minimally invasive surgical devices.



**Laura Bix**  
Asst. Professor

Michigan State University School of Packaging



Vice-chair of ASTM Committee D10.32, Committee on Consumer, Pharmaceutical, and Medical Packaging...U.S. expert on ISO/TC 122 inclusionary packaging guideline.

**Tom Black**

VP of Sales and Marketing

B. Braun Medical Inc., OEM Division

Has more than 20 years of OEM industry experience with B. Braun...frequently speaks on trends and management issues...expertise sought by industry publications.



**George Blank**

Founder

The MedTech Group

Founded plastics technology firm dedicated to engineering and manufacturing of disposable medical products 30 years ago... corporate research sponsor of the Memorial Sloan-Kettering Cancer Center.

**Marlene Bobka**

Vice President

FOI Services Inc.

Began educational audioconferences that address critical issues in the device industry...provides industry with unpublished FDA information via the Freedom of Information Act...speaker and author for RAPS.



**Steven Boggan**

President and CEO

BioHorizons Inc.

Has grown a small dental implant company into a firm that has a 35% annual growth rate...recently acquired dental software company ILS to enable users' access to software technology.

**John Broad SM, RM, NRM**

Senior Consultant

NAMSA California

Has been a leader in industrial microbiology and sterilization for nearly 30 years...has served on several standards committees for AAMI and ISO.



**Brian Brockway**  
President, CEO, and Chairman

Transoma Medical Inc.

Has written more than 25 articles in bioengineering and medical publications...holds more than 25 patents in the field of implantable medical devices...in the industry for more than 25 years.



**Art Burghouwt**  
Executive VP

Concordia Medical

Developed custom resorbable and regenerative implants...submitted a patent for 3-D structures created from bioresorbable nonwoven BioFelt...more than 20 years of experience in biomaterials.



**Devon C. Campbell**  
Eng. Manager, Primary Staining

Ventana Medical Systems Inc.

Engineer of two MDEA-winning products...mentors students to pursue careers in medical field...established engineering internship program.



**Thomas Colonna, PhD, JD**  
Asst. Professor

Johns Hopkins University

Spearheaded internship program for CDRH and Johns Hopkins University...works in school's bioscience regulatory affairs to promote understanding of device regulations.



**Kevin L. Cornwell**  
Chairman & CEO

Utah Medical Products

Heads firm that makes products for women's and children's health... In 2005, the company defeated FDA in court over inappropriate enforcement actions.



**Art Coury**  
VP, Biomaterials Research

Genzyme Corp.

Focuses on polymeric biomaterials for implantable electronic, hydrogel, and drug-delivery devices...received 2007 Innovation and Technology Development Award of the Society for Biomaterials.



**Barrett C. Craner**  
Director, Quality Assurance

Lipid Sciences Inc.

Four certifications from ASQ, and RAC certification from RAPS...on the White House Council on Y2K (medical devices)...Pacific Region Industry Perspective speaker at 2006 FDA centennial celebration.



**Robert Crockett, PhD**

Assoc. Professor, Interim Chair of Biomedical and Engineering

California Polytechnic State Univ.

Developed MEDITEC program to facilitate projects between students and device OEMs...develops materials and manufacturing processes.



**Jim Dandeneau**  
President

Putnam Plastics

Promoted coextrusion as technique for manufacturing catheter tubing applications...helped develop technology that has enabled medical device companies to design more-sophisticated catheters.



**Richard DeRisio**

VP, Global Regulatory Affairs

Advanced Medical Optics Inc.

Formerly VP of global regulatory affairs at Kinetic Concepts Inc.... more than 25 years of regulatory and professional management experience in the medical device industry.



**William Duffell Sr.**  
Director, Government Relations

Gambro BCT Inc.

Helps foster relationships between industry and FDA, focusing on education...part of a group that worked with FDA to develop the first AAMI course and QSR exam.



**Signe Erikson, PhD**  
Director of R&D

SurModics

Ophthalmology Business Unit

Key to the invention and development of the I-  
vation system that delivers drugs to the back of the eye...winner of  
SurModics' Catalyst Award for her contributions.



**David R. Fischell, PhD**  
CEO

Angel Medical Systems

Founder and cofounder of nine device firms...holds 86 patents...  
inventions include arterial access needles, balloon catheters, and  
neurostimulators...helped design BX Velocity and Cypher stents.

**Donald A. Goer, PhD**  
Chief Scientist and Cofounder

Intraop Medical Inc.

Expert on linear accelerator technology...developed Varian's cancer  
therapy equipment...Intraop provides the only mobile and self-  
shielded electron linear accelerator.



**Matthew Gregoire**  
Director of Operations

Gyrus ACMI Inc.

Made strong contributions to Gyrus's urology division...supports  
training and leads development of new digital technology...seeks  
ways to make technology affordable to patients.

**Ames Gross**  
Founder and President

Pacific Bridge Medical

Frequent speaker and author on Asia business development and regulatory issues...his  
firm has helped more than 200 companies get a foothold in various Asian countries.



**Warren Grundfest**  
Professor of Bioengineering

UCLA

Pioneered pulse ultraviolet excimer lasers for biomedical applications...consults to ODE and to the Army's West Coast Telemedicine and Advanced Technology Research Center.



**Sunil Gupta**  
Assoc. Director

Statistical Programming Quintiles

International healthcare industry expert and speaker...developed best practices in SAS statistical programming training courses...wrote three books on SAS software.



**Craig Hashi**  
Chief Technical Officer and Cofounder

NanoVasc Inc.

Developed nanotechnology to address need for small-diameter vascular grafts with high patency rates shown at six months... cofounded NanoVasc to license the technology.

**Djoerd Hoekstra**  
CEO

Biocoat Inc.

Brought Biocoat from a small set of patents held by the nonprofit research arm of a college to a player in the biocompatible coatings industry...company is now entering the in vitro fertilization market.



**William H. Howell**  
First Principal Asst. for Acquisition

U.S. Army Medical Research and Materiel Command

Runs product development and acquisition for the Army...works on adopting medical technologies for the battlefield.

**Gary Hutchinson**  
President and CEO

Precision Dynamics Corp.

Heads patient identification products firm, focusing on patient safety and quality...company developed the first patient ID wristband and helped pioneer bar coding and RFID systems in the patient setting.



**Edmond Israelski**  
Human Factors Program Manager

Abbott Laboratories

Cochair of AAMI's human factors engineering standards committee... member of the ISO-IEC work group on device usability, and of the NAS committee on human-system design support.



**Jerome Jackson**  
VP, R&D

Stellartech Research Corp.

Developed RF heating and ablation systems for cardiology, gastroenterology, urology, and skin-tightening applications...named inventor on 34+ U.S. patents...

25+ years of product development.



**Mark C. Jones**  
President and Founder

Fortress Medical Systems LLC

Launched Clindex, the first integrated software for medical device trials...enables firms to conduct clinical trials efficiently and cost-effectively with validated tools.



**Deborah Kacera**  
Senior Product Manager

Pilgrim Software Inc.

Worked with FDA on development of new CDRH eMDR program, providing input into eMDR document requirements to improve the efficiency of the eMDR submission process.

**Raju Kammula, PhD**  
Consultant



### RK Consulting Services LLC

International expert in materials toxicology... guided development of first FDA guidance to evaluate biocompatibility...served as technical expert ISO 10993.



### Larry Kessler Director

Office of Science and Engineering Laboratories

CDRH, FDA

Serves as chair of Global Harmonization Task Force, which fosters regulatory harmonization among developed nations, and provides a blueprint for developing nations.



### Joe E. Kiani Chair and CEO

Masimo Corp.

In the midst of a two-year term as chairman of the Medical Device Manufacturers Association's board of directors...instrumental in getting group purchasing organizations to reform their practices.



### Dirk Kuyper President and CEO

Alphatec Spine Inc.

Achieved significant milestones at Alphatec by improving new technology pipelines, reaching record revenues, and attracting a strong executive team...former president of Aesculap Inc.



### Robert S. Langer, PhD Professor of Chemical and Biomedical Engineering

MIT

Holds 600+ patents...Forbes and Bio World named him one of 25 most important individuals in biotech...only engineer to receive Gairdner Foundation International Award.



**Floyd Larson**  
President

PaxMed International LLC

Chair for Subcommittee ASTM F4 and Subcommittee 8 on dental implants for ADA... regulatory, quality, and clinical trials consultant to orthopedic and dental device firms.



**Mark B. Leahey**  
Executive Director

MDMA

Heads trade association representing small, innovative makers of medical devices, diagnostics, and information systems...lobbies Congress, FDA, and CMS on user fees and reimbursement.

**Karl Leinsing**  
President

ATech Designs Inc.

Inventor of SmartSite needle-free valve...designer of percutaneous mitral valve repair devices, devices to treat abdominal aortic aneurysms, and laparoscopic suturing devices...holds several patents.



**Richard Lovell**  
Director of Marketing

Euromed Inc.

Combined clinical and business background to drive development and sales of wound care, ostomy, and incontinence products, including a 2007 MDEA winner...participates in advocacy groups.

**Igor Malinowski**  
Founder

Laparosound CTO

Founded firm to bridge device industries in United States and Eastern Europe...has written more than 20 papers on devices, ultrasonics, and precision technologies...holds four U.S. patents.



**Gerald E. McGinnis**

Board Chair and Advanced Technology Officer

Respironics

Founder of Respironics...sold firm to Phillips in 2007 for more than \$5 billion...internationally published author...holds more than 15 patents.



**Frederic Moll**  
Cofounder and CEO

Hansen Medical

Pioneer in the field of medical robotics...cofounded Intuitive Surgical Inc. and Origin Medsystems...was medical director of Guidant's Surgical Device Division, and is on the board of Mako Surgical.



**Gregg A. Mosley**

President

Biotest Laboratories Inc.

Has more than 35 years of experience as a microbiologist, chemist, and biochemist...has presented courses and seminars for FDA, AAMI, and the American Society for Quality.



**John Murray**

Expert Regulatory Review Scientist [Software Compliance]

Office of Compliance, CDRH

Internationally known expert on regulatory compliance of device software...serves as CDRH's rep on the Part 11 committee.

**Lawrence Muscarella, PhD**

Chief, Infection Control and Director, R&D

Custom Ultrasonics Inc.

Expert in infection control and endoscope reprocessing...editor-in-chief of *The Q-Net Monthly*...developed reprocessing guidelines.





**Michael A. Mussallem**  
Chairman and CEO

Edwards Lifesciences

Heads world leader in heart valve technologies... engineered firm's spin-off from Baxter International in 2000...elected in March as two-year-term chair of AdvaMed's board of directors.



**Richard Nazarian**  
President



Minnetronix Inc.

More than 22 years in product development for artificial heart electronics, cardiopulmonary bypass systems, and laser imaging...patents include telemetry systems for implants and networked cardio bypass systems.

**Thinh Nguyen**  
Director

Director, Office of Combination Products, FDA

Coordinates U.S. regulation of combination products...in previous post as director of ODE's Premarket Approval Section, led effort to ensure that ODE reviewers met MDUFMA goals.



**Robert A. North**  
Chief Scientist



Human Centered Strategies

Has more than 30 years of experience in human factors research... serves on AAMI's Human Factors Standards Committee, which developed the HE-75

standard.

**Daniel Olivier**  
President

Certified Compliance Solutions

Trains firms for field investigators and prepares inputs for FDA validation guidance documents...is an ISO 9001 RAB-certified lead auditor and a reviewer for ISO work group 10.



**Joe Panetta**  
President and CEO

Biocom

Created leadership model for area biotechnology and medical device trade groups...represents more than 570 device, biotech, and pharmaceutical companies in Southern California.



**Albert P. Pisano, PhD**  
FANUC Chair, Dept. of Mechanical Engineering

UC Berkeley

Founder of six start-up companies in drug delivery, sensorized catheters, and MEMS...holds several patents...fellow of the American Society of Mechanical Engineers.



**Ramon E. Poo**  
President

Biorep Technologies Inc.

Holds numerous patents and helped develop equipment to isolate islet cells from the pancreas, enabling advanced-stage diabetics to receive transplants that allow them to live insulin-free.



**Brian Ream**  
Sales Manager

Measurement Specialties

Has provided technical assistance for more than a decade, specializing in precise temperature measurement and helping clients find products with accuracy and stability.



**Mark A. Saab**  
Co-owner and President

Advanced Polymers Inc.

Holds more than 30 medical device patents and has developed 1000 different medical balloons...inventor of the world's thinnest, strongest, and smallest heat-shrink tubing.



**Barry Sall**  
Principal Consultant

Parexel Consulting

Helps firms prepare for FDA marketing applications and provides regulatory assistance for clinical trials and quality systems compliance...provides training on joint efforts with FDA.



**Heber Saravia**  
Consultant

Genesis Design Inc.

Has 15 years of experience in the medical device industry...produced mechanical designs for more than 30 projects including catheters, guidewires, and stent-delivery devices...inventor in 19 patents.



**John Saunders, MD**  
Vice President MR Systems

IMRIS Inc.

Lead developer of high-field MR scanner that takes images in an operating theater without moving the patient during surgery...scanner used in more than 1500 neurosurgeries worldwide.



**Kenneth Schena**  
President and Founder

Schena Ostomy Technologies

Invented an irrigation and cleansing system for a colostomy bag called the Schena Ostomy EZ Clean System, following a colorectal cancer diagnosis more than four years ago.



**Daniel G. Schultz**  
Director

CDRH, FDA

Heads center that is responsible for U.S. regulation of medical devices and diagnostics...has made postmarket surveillance of devices a priority for FDA...implemented a number of reforms mandated by MDUFMA.


**John Scoville Jr.**

Fellow, Regulatory Affairs Sterilization Technology

STERIS Corp.

Active in the AAMI sterilization standards development...has 14 patents for devices in electrosurgery, biological and chemical indicators, and disinfectant sterilants.


**Dean Secrest**

Executive VP of Research and New Product Dev.

US Endoscopy

Developed about 75 types of devices for endoscopy, laparoscopy, plastic surgery, and microsurgery—products that generated hundreds of millions of dollars...holds 15 patents.


**Ronald Sherman, MD**

Cofounder and Laboratory Director

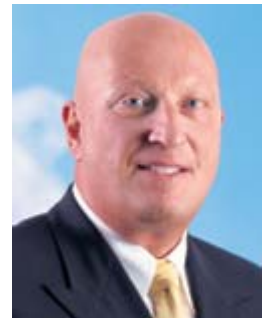
Monarch Labs LLC

Conducted clinical studies of medicinal maggots for treating chronic wounds, leading to Medical Maggots (first live animal to achieve FDA marketing clearance).

**Alan Shortall**  
CEO

Unilife Medical Solutions

Founded company to try to eliminate the transmission of blood-borne diseases such as hepatitis and HIV. He developed a single-use safety syringe to further efforts in this field.


**Patricia Shrader**

Senior VP, Corporate Regulatory and External Affairs

Becton Dickinson

Responsible for all regulatory activities within BD worldwide...frequent speaker at various professional meetings...active in FDLI, AdvaMed, and RAPS.



**Wilmer L. Sibbitt Jr., MD**  
Prof. of Internal Medicine, Rheumatology, and  
Neurology

University of New Mexico

Cofounded companies in interventional radiology  
and cardiology, and magnetic resonance contrast  
agents...supported by NIH grants.



**Paul J. Silver**  
Managing Director

Huron Consulting Group

Compliance and regulatory expert with 20+ years  
of experience...considered a thought leader...  
works with firms to improve operations, mitigate  
risk, and support legal counsel.



**Nancy Singer**  
President

Compliance-Alliance LLC

Founded the Medical Technology Learning Institute within AdvaMed  
to train on FDA/CMS requirements...produces seminars and  
training...conducts benchmarking surveys and shares data.



**Dirk Soenksen**  
Founder and CEO

Aperio Technologies

Founded Aperio to develop digital pathology technologies, including  
digitization of a glass slide...dramatically improved the efficiency and  
quality of pathology services.



**Jeff Sample**  
President

Northern Operations, Mack Molding Co.

Headed Mack's move into medical devices, expanding quality management systems and  
manufacturing technologies...firm is now recognized as successful in the device market.

**Brett Steen**  
Sales Manager, USA



Degania Silicone Inc.

Led the development of polyimide/thermoplastic hybrid tubing designs for microdiameter catheters, which corrected thermal bonding problems and paved the way for assembly bonding.



**Timothy Sullivan**

President and Principal Technical Lead

Mystic Pharmaceuticals Inc.

Developed a novel platform for precise unit-dose and multidose intranasal and ocular delivery of drugs to offer more-efficient packaging and safer dispensation.



**Wayne Taylor, PhD**  
Chairman



Taylor Enterprises Inc.

Expert in process validation, including writing an annex of a GHTF guideline...developer of analyzer software...consults and trains on the Six Sigma approach...frequent author.

**G. Lawrence Thatcher**  
President

Tesco Associates Inc.

Helped develop and select materials for more than 225 medical implants device firms...has worked diligently in the background to advance biomaterials science.



**Donna-Bea Tillman**  
Director



Office of Device Evaluation, CDRH, FDA

Heads office for premarket approvals...began FDA career in 1994 reviewing ob-gyn devices...was ODE deputy director of technology and review policy before being tapped to run office.

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**Roosevelt Tillman**  
Chairman and CEO

Medbio Inc.

U.S. Army veteran boosted local employment by venturing into medical manufacturing...founded company that specializes in contract injection molding and assembly.




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**Gerald Timm, PhD**

Founder and President

GT Urological LLC

Prolific developer of urological devices for incontinence and erectile dysfunction for 40+ years...pioneered research on electrical bladder stimulation and fluid energy transfer systems.




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**Kimberly A. Trautman**  
Medical Device Quality System Expert

CDRH, FDA

Frequent speaker on device quality and regulatory compliance...played significant role in CDRH taking a more risk-based and systems-based compliance approach.




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**Randall Troutman**

Technical Director

Oliver Medical

A noted expert on packaging material selection, shelf-life testing, performance testing, and equipment validation...serves on the AAMI working group for ISO 11607 and TIR 22.




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**Stephen J. Ubl**  
President and CEO

AdvaMed

Has led the world's largest medical technology association since 2005...in previous stint at AdvaMed, headed federal government relations office...named a top association lobbyist by *The Hill* in 2007.



### **Timothy A. Ulatowski**

Director, Office of Compliance

CDRH, FDA

Manages four divisions that promote quality and enforce device and radiological health regulations...has been with FDA since 1974, and with the Office of Compliance since 2003.



### **Manny Villafaña** Entrepreneur

Kips Bay Partners LLC

Leading device industry entrepreneur and marketer...founded several device companies including St. Jude Medical, GV Medical, ATS Medical, CABG Medical, and Cardiac Pacemakers.



### **David Vogel**

President

Intertech Engineering Associates

Facilitates product design compliance with QSR through product verification and validation for software-based instrumentation... frequent industry contributor and speaker.

### **Martin Von Dyck** President

Biosearch Medical Products

Has designed nasogastric feeding tubes, coagulation probe catheters, biliary stents, jejunostomy catheters...architect of medical coatings used to coat urological and cardiovascular microcatheters.



### **Andrew C. von Eschenbach**



**Commissioner**

FDA

Sworn in as FDA's 20th commissioner in December 2006...previously headed the National Cancer Institute and is a cancer survivor himself...is a nationally recognized urologic surgeon and oncologist.

**Les Weinstein**  
Ombudsman

CDRH, FDA

Responsible for independently investigating industry complaints about CDRH...has handled and helped resolve more than 800 complaints and disputes since taking the post in 2000.



**Jan Welch**

Quality System Expert

CDRH, FDA

Identifies and recommends new policy and regulatory approaches in complex situations in which no precedent exists...reviews proposed enforcement actions and determines if they are appropriate.



**Timothy Wells**  
Founder

QualityHub Inc.

Spent 24 years at FDA, cowrote the quality system inspection technique (QSIT) that modernized CDRH's inspection...his firm guides companies to compliance with regulations and quality standards.



**Forrest R. Whittaker**

CEO



Avalign Technologies Inc.

Founded a device outsourcing company focused on precision machined surgical instruments and implants...brings together a comprehensive array of manufacturing capabilities.

**Rance A. Winkler**  
President and CEO



Integrated Molecular Diagnostics LLC

Designed the MammoSite RTS [radiation therapy system], a five-day breast cancer treatment that has replaced a standard six-week treatment...holds more than 50 patents.



**Jean Woloszko, MD, PhD**

VP, Chief Technical  
and Scientific  
Officer

ArthroCare Corp.

Revolutionized the application of RF-generated plasma field to ablation of soft tissue in minimally invasive surgery...holds 27+ patents and 70+ patent applications.

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