MassMEDIC

THE HEART OF HEALTHTECH

ANNUAL REPORT

2023

CONTENTS

Dear Members,

As we look back on 2023, I'm amazed at all the work which has been accomplished in a business environment that could only be described as chaotic. It seems like the entire year was played out under a cloud of uncertainty.

Despite it all, our industry continues to persevere and grow in Massachusetts, and it remains vital across the globe.

A recent report from JLL cited Boston as among the areas where medtech is "thriving," leading the nation in innovation with PMAs and 510(k)s, coming in second to California in VC-funding and, most interestingly, as the home of the largest concentration of workers employed in manufacturing medical technology, meaning we're not only developing the technologies of tomorrow, we're making it here as well. Massachusetts is truly the heart of healthtech.

At MassMEDIC, we've also worked hard to help secure the future of this industry here. This year, we co-led the proposal team to bring the Investor Catalyst Hub for The Advanced Research Projects Agency for Health (ARPA-H) to Cambridge. The Hub will work with researchers, entrepreneurs, and financiers to speed the transition of basic research into new technologies and medicines.

We also saw great progress on the Life Sciences Re-Authorization Bill, on which we've been working closely with the state leadership to ensure medtech is prioritized. In June, Gov. Maura Healey committed to reauthorizing our landmark law at the BIO International Conference, culminating months of dialogue between our organization and her team.

On the advocacy side, we made some progress with helping improve the payment environment, pushing forward landmark legislation on Capitol Hill on the "Breakthrough Bill." In addition, we remain vigilant about protecting our supply chain, fighting for sensible legislation on ETO and PFAS.

Finally, we produced two cornerstone events this year that will be part of our annual calendar for years to come. We expanded our Medtech Impact Symposium & Gala to a full day conference and dinner, which celebrated the impact of medical device technology on patients' lives. Second, we introduced our First Annual MassMEDIC Golf Tournament, which not only provided an amazing day on the course but gave attendees exclusive access to state leadership and opportunities to deepen relationships with industry peers. Stay on the lookout for ways to get involved in these two great events next year.

Thank you for your continued support of The Massachusetts Industry Device Council (MassMEDIC) this year. On behalf of the team, we are glad you are a part of our membership.

Brian Johnson
President
MassMEDIC

MassMEDIC
THE HEART OF HEALTHTECH

Q&A

with Mary Anne Heino

Mary Anne Heino
CEO, Lantheus
Chair, MassMEDIC
Board of Directors

What is your "Why Medtech™" story? How did you get into healthcare, and what inspires you about the work you do?
I entered the healthcare field as a nurse, and my journey from there led me to a diverse career in the pharmaceutical and medical device industries. The guiding principle throughout my career has been putting the patient first. This "patient first" mindset has been my inspiration, reminding me of the profound impact our work can have on people's lives. I'm deeply committed to improving health outcomes and championing scientific advancement, which is what drives me in the medtech industry. I'm not only committed to the success of Lantheus, but to the success of the industry overall. I'm a dedicated board member, currently serving on the Lantheus Board of Directors, as Chair of the Board of Directors for MassMEDIC, and on the Executive Committee for the Massachusetts Business Roundtable (MBR), a public policy organization with a mission to strengthen the state's economic vitality and competitiveness and maintain Massachusetts' role as a center of medtech innovation within the global economy.

Lantheus has had a lot of success over the last few years, to what do you attribute it? The success of Lantheus over the past few years can be attributed to a combination of factors. First and foremost, the incredible team at Lantheus has made our success as the leading radiopharmaceutical-focused company possible. We've achieved significant milestones, including strategic acquisitions, FDA approvals, and product launches, which have positively impacted both patients and the company. Our commitment to diversity, inclusion, and fostering an environment built on trust and common purpose has played a significant role in our growth and success.

What are your goals for the future of Lantheus? Our goal for the future of Lantheus is centered on continuing to advance our purpose to "Find, Fight and Follow® disease to improve patient outcomes." We will continue to focus on innovation and expanding our presence in the radiopharmaceutical industry to go further for patients. This includes developing innovative therapeutic products and cutting-edge diagnostic tools including Artificial Intelligence tools to address a wide range of medical conditions. We also remain committed to diversity and inclusion, ensuring that our workforce is representative of the broader community and that we continue to support women in leadership roles.

How have you balanced a family and a growing career, to today being a CEO? Balancing family and a growing career is an intricate dance, rooted in my unwavering passion for both roles. It's essential to have a supportive family, and I'm grateful for their understanding and encouragement. Additionally, a supportive work environment that values work-life balance is crucial. At Lantheus, we live our Value to "Let People Be Their Best" by introducing flexible policies and employee resource groups to address individual employee needs, which has allowed me to lead a thriving organization while maintaining a fulfilling family life.

Do you have any advice for other women looking to excel in the healthcare industry or in business in general? First and foremost, be open and courageous in your career journey. Start by aligning your initial steps with your true passions, as this will be the driving force behind your success. Seek out mentors who can guide and support you on your path, and never hesitate to ask for assistance when needed. Embrace your goals and capabilities without self-doubt, because your unique perspective as a woman can be a powerful asset.

Remember that diversity and inclusion are not just buzzwords but strengths that can drive innovation and success. Research has shown that more diverse companies have a higher growth rate. Part of your leadership journey should involve bringing others along with you to support your shared goals.

Always keep in mind that doing what's right for your organization, your patients, and yourself should be your guiding principle. One of the most important lessons I've learned in my career is that if you don't ask for what you want or need, you're not likely to receive it. Many opportunities and avenues for growth are available, but you have to be willing to seek them out. Consider exploring roles or tasks that stretch your abilities and take you in different directions from your current path. Most importantly, have courage and confidence in yourself – it makes everything else possible.

Lantheus

FOUNDED 1956

OF EMPLOYEES ~800

RESULTS >6 million patients' lives impacted in 2023

ABOUT Lantheus is the leading radiopharmaceutical-focused company, delivering life-changing science to enable clinicians to Find, Fight and Follow disease to deliver better patient outcomes. Headquartered in Massachusetts, Lantheus has been providing radiopharmaceutical solutions for more than 65 years. For more information, visit www.lantheus.com.

What do you see as the biggest opportunities for medtech companies in the New England region? New England is a hub of innovation in the healthcare and medtech sectors. The region provides fertile ground for collaboration between industry, academia, and healthcare institutions. This collaborative environment presents an excellent opportunity for medtech companies to advance research and development, especially in the fields of precision diagnostics and therapeutic solutions. The region's strong talent pool and access to cutting-edge research facilities also contribute to these opportunities.

What are some of the challenges? Despite the opportunities, medtech companies in New England face challenges, including regulatory hurdles, the need for continuous innovation, and intense competition for top-tier talent. In addition, the cost of living in Massachusetts remains a challenge to attracting and retaining talent. Staying at the forefront of technological advancements and navigating complex regulatory landscapes can be demanding. However, with a commitment to quality, innovation, and patient-centric solutions, these challenges can be overcome.

> "Most importantly, have courage and confidence in yourself - it makes everything else possible."
>
> **Mary Anne Heino**

In what ways does MassMEDIC support the ecosystem? MassMEDIC plays a vital role in supporting the medtech ecosystem in Massachusetts, serving as a platform for networking, knowledge sharing, and advocacy within the industry. MassMEDIC connects organizations, fosters collaboration, and provides resources for companies to thrive. It also advocates for policies that promote innovation and growth in the medtech sector. MassMEDIC also plays an important role in addressing the various challenges by having a significant public policy and advocacy presence.

As Chair of the Board, I'm proud to be part of an organization that supports the industry's success and overall healthcare advancement in the region.

AliraHealth

Patient-Enabled Solutions for MedTech

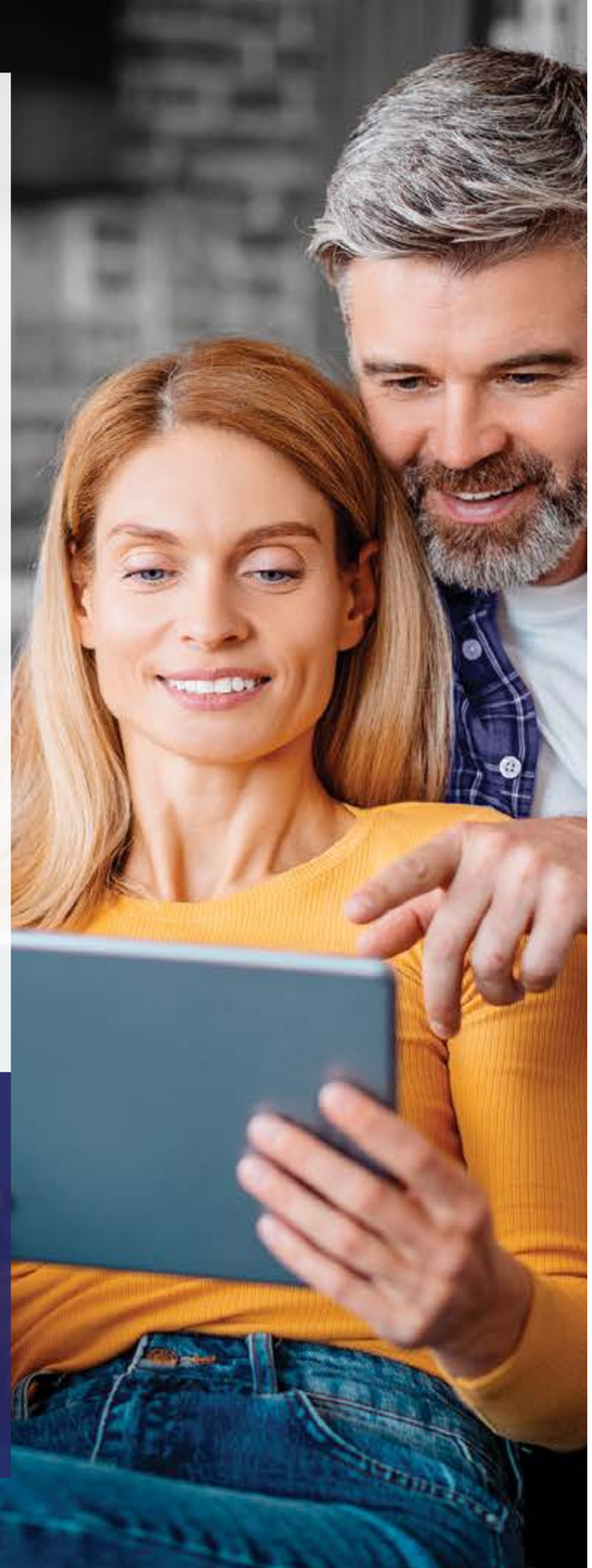
Alira Health is a global healthcare firm whose mission is to humanize life sciences in partnership with patients.

We provide clinical, consulting, and real-world solutions enabled by patient-centric technology. Our teams complement the expertise of our clients with a full spectrum of services across their entire lifecycle.

Connect with our team to discuss how we can drive collaborative change in the MedTech industry

Contact us at
info@alirahealth.com

www.alirahealth.com



ARTEREX

Leading global contract manufacturer of high-precision solutions for medical and life sciences companies

Arterex delivers high quality, innovative solutions from initial development to full scale production. As a unique **one-source solution** for medical device design and manufacturing, we consolidate various aspects of the manufacturing process enabling us to streamline production, reduce costs, improve quality, and increase overall efficiency.

ARTEREX

9 state of the art manufacturing facilities with **11** Clean Rooms and over **520K** manufacturing space on **3** continents with **1200** employees... and growing.

- **Formula Plastics** | Fully Integrating Molded Plastic Parts into Medical Devices
- **Kabo** | Wide Array of Medical Procedure Bags
- **Luc & Bel** | Fluid Management Products
- **ModenPlast** | Extrusion of PVC, and PVC DHEP FREE Tubing
- **NextPhase** | Complex Single-Use Devices (SUD), Electromechanical Devices (EMD), and Active Implantables

FORMULA PLASTICS An ARTEREX Company | kabo An ARTEREX Company | LUC & BEL An ARTEREX Company | ModenPlast An ARTEREX Company | NextPhase MEDICAL DEVICES LLC An ARTEREX Company

Scan here for your complimentary project review.

inquiries@arterexmedical.com | +1 (480) 344-5000

Let's work together

www.arterexmedical.com

COMMITTING to the Commonwealth

Insulet Corp. is dedicated to growing its workforce and manufacturing operations in Massachusetts.

It's one of the reasons the makers of the Omnipod® Insulin Management System built its global headquarters and U.S. manufacturing facility in Acton in 2019 and have added more than 600 jobs in the state since 2016.

Back in 2016, building a domestic manufacturing facility in Massachusetts was not an easy call for Insulet, even if their roots were in the Commonwealth, where it was founded more than two decades ago. Insulet had significant manufacturing operations in China and the easier choice would have been to expand capacity in the country, rather than look homeward in Massachusetts.

But Insulet has never been an organization to shy away from a challenge. Not when it comes to treating one of the world's most prevalent chronic diseases with an innovative medical device, and not when it came to doubling down on their commitment to Massachusetts and building a manufacturing facility in the state.

Company officials at the time, CEO, Patrick Sullivan, COO, Shacey Petrovic, and SVP of Operations, Charles Alpuche, made a bold call to build in Massachusetts. They worked closely with then-Governor Charlie Baker and the Massachusetts Life Sciences Center (MLSC) to keep the company in Massachusetts.

The company utilized the state's Life Sciences Tax Incentive Program, designed to provide incentives to companies of all sizes looking to expand their efforts by creating new, long-term jobs in Massachusetts. Through this program, Insulet committed to hiring a certain number of employees each year in the state. However, as the company grew, its demand for talent began to outstrip the amount of talent available locally, something many original equipment manufacturers face in a market like New England.

Enter MassMEDIC.

"By brainstorming the challenge at hand, it became clear that this was an opportunity for collaboration from a broad industry perspective," said Brian Johnson, President, MassMEDIC. "Because of Insulet's existing relationship with the MLSC, a cross-functional team was established between our trade association, MLSC,

Massachusetts Secretary of Economic Development, Yvonne Hao, views part of Insulet's OmniPod®.

Massachusetts LIFE SCIENCES CENTER
The capital of scientific revolution.

Secretary of Economic Development, Yvonne Hao, speaks at Insulet.

the state, and a number of educational partners to try and meet the challenge and turn it into an opportunity."

The goal? The development of a short-term training program aimed at Insulet's workforce needs to introduce an underemployed population to the opportunity in medtech manufacturing.

A pilot program was born between Insulet, Mount Wachusett Community College and Middlesex Community College, who together applied for a RENEW Grant through the MLSC for $300,000 to develop a 10-week medtech curriculum and train the first three cohorts. The program kicked off in 2023 and continues into 2024 with the plan to train and graduate close to 30 potential employees.

"This program offers a unique opportunity to pre-screen and pre-train potential employees, while engaging with candidates who are highly interested in a career in maintenance or working on a manufacturing floor," said Prem Singh, Senior Vice President of Global Operations at Insulet. "In collaboration with our educational partners, we were able to develop a medtech focused curriculum that allows cohort graduates to hit the ground running on day one."

In parallel, MassMEDIC was having many similar conversations with medtech organizations struggling to find the right kind of talent to fill vacant jobs. An industry roundtable and a follow-up workforce development survey found that most employers were struggling to fill the same handful of skills which included good documentation practices, lab math, sterilization and familiarity with equipment and processes. Armed with this knowledge, the MLSC developed a list of skills and core competencies required for certain roles which would form the basis of their Pathmaker Program.

Pathmaker Program

FOUNDED 2023

AWARDS Grants will be given in the amounts of $100,000 to $750,000 for one (1) year of work.

GUIDELINES Program curriculum is typically 8-10 weeks and covers pre-identified core competencies.

ELIGIBILITY CRITERIA

Applicants must use funds to implement workforce development programs that lead to careers in the life sciences industry.

Awards are given to educational partners, who must collaborate with at least one industry partner to ensure that the program is responding to direct hiring needs. For a full list of eligibility requirements, visit Pathmaker Eligibility Requirements and Evaluation Process.

CONTACT Pathmaker@masslifesciences.com

Secretary of Economic Development, Yvonne Hao, meets a few of the cohort graduates in Insulet's manufacturing facility.

"Because we found many employers were challenged with similar skill gaps, we were able to scale the work we did with Insulet and systematize it into a new program creating custom curricula for each employer," said MLSC Vice President of Economic Development and Partnerships, Jeanne LeClair. "This is how Pathmaker was born."

Due to the support of the Healey-Driscoll Administration's MassTalent initiative, a new strategy for connecting employers to skilled, diverse workers in Massachusetts, Pathmaker was launched earlier this year to further the development and expansion of life science career training programs. Pathmaker awards up to $750,000 per project in direct funding to support organizations that can build and scale career pathways that effectively prepare students for high-demand career opportunities in the life sciences.

> "When a customer order is a patient living with diabetes, a provider or hospital system treating vulnerable populations in the community, not missing an order means the world to us."
>
> **Prem Singh, Senior Vice President of Global Operations at Insulet**

The MLSC has made its first few awards through Pathmaker and continues to accept applications on a rolling basis.

After the completion of their RENEW Grant, Insulet for one, plans to re-apply for support of the program through Pathmaker.

And for their decision to build in Massachusetts? When the world faced global supply chain issues due to the pandemic, Insulet's local facility allowed for enough insulation from external forces to ensure completion of all customer orders.

"When a customer order is a patient living with diabetes, a provider or hospital system treating vulnerable populations in the community, not missing an order means the world to us," said Mr. Singh.

For more information and detailed criteria, visit www.masslifesciences.com/programs/pathmaker.

Massachusetts LIFE SCIENCES CENTER

The Massachusetts Life Sciences Center (MLSC) is proud to support the thriving MedTech ecosystem in Massachusetts and the pioneers who are advancing the modalities to improve patient health.

The MLSC supports innovation, research and development, commercialization, and manufacturing activities in the fields of medical device, diagnostics, digital health, and biopharma.

Learn more about MLSC funding opportunities

masslifesciences.com

ABIOMED

RECOVERING HEARTS. SAVING LIVES.

Abiomed is the industry leader in next generation heart recovery.

Learn more about how Abiomed's innovative heart pumps and product portfolio are helping to recover native heart function at

www.abiomed.com/patients

ABIOMED

Recovering hearts. Saving lives.

To learn more about the Abiomed's devices, including important risk and safety information associated with the use of the devices, please visit: https://www.heartrecovery.com/important-safety-information#welcomeppci

MEDTECH TREND: Advancements in Electronic Implantable Devices

Since the 1950s when the first pacemaker was implanted into a human body, we've had the benefit of electronic implantable devices to help manage chronic and acute conditions. In a space where we've traditionally seen the usage for cardiac and neurological issues, today the market has expanded to include surgical implants, continuous glucose monitoring, custom orthopedics with embedded sensing technology, and implants that address quality of life issues such as a preferred treatment for sleep apnea.

"In the last decade we have seen miniaturization, improved battery technology including conductive recharging, and data gathering tools integrated into implantable devices," said James Mitchell, MD, Chief Medical Officer, Veris Health. "These devices are no longer just a therapeutic – we can now also leverage them as diagnostic tools to allow clinical teams to be proactive and better address the patient's needs."

CLINICAL BENEFITS

- Automates Long-Term Therapy
- Captures Longitudinal Data of Patients with Chronic Diseases, Which Allows Us to Understand Populations of Patients and Be More Proactive in the Care of Patients
- Quality of Data is Unmatched When it Comes From Inside the Body
- Improved Patient Experience, Patient Adherence and Comfort
- Expanded Physiologic Sensing to New Parameters, Providing Access to New Clinical Insights

This article is based on the webinar, "Things to Consider When Developing Electronic Implantable Devices" hosted by Sunrise Labs. Click here to view the full webinar.

With the emergence of new technology, implanted electronic medical devices are revolutionizing the way we access patient data and track trends over time. For example, insertable cardiac monitors can now measure rhythms over many years, including securing accurate measurements for difficult to measure areas of the body externally like inside a pulmonary valve to measure its pressure.

"Surgical implants like a joint replacement or a stent can now be embedded with sensors and data technology that allow us to gather information on the health of the device or the patient," said Dr. Mitchell.

Along with new opportunities for data also comes challenges. Dr. Mitchell warned.

"We need to ensure it is easily packaged, easy to interpret, that the data is meaningful and that it fits into existing workflows like EMR systems."

From the technical standpoint when developing an electronic implantable device, there are many considerations that will impact the size, functionality and usability of the device.

Many times, power limitations will drive decisions in your implantable device design. You'll want to consider features of the device, measurement frequency, communications, algorithmic complexity, sense and drive electronics, data storage and whether you are using an application-specific integrated circuit (ASIC) or a commercial off-the-shelf (COTS) chip.

Adam Jacobs, Chief Technology Officer, Sunrise Labs, reminded us, "There is always a trade-off between redundancy and robustness."

For example, the more features you include in your implantable device, the more power it will need to run those features. This increases the size of the power supply, which increases the size and weight of your device. A larger size can limit where the device is implanted, decreasing its potential usefulness.

> "Use connectivity sparingly – it provides a lot of clinical benefits but ensure the data is going to be used in a meaningful way."
>
> **Adam Jacobs, Chief Technology Officer, Sunrise Labs**

"Batteries are always a concern," said Mr. Jacobs. "Primary cells are the easiest for the patient but if you need more power, you can consider rechargeable solutions. Be mindful that a rechargeable solution adds additional complexity with patient compliance and the actual charging of the batteries."

Connectivity is also a factor to consider. Not only do connected devices need to be cognizant of HIPPA compliance but are now regulated by their own cybersecurity guidance by the FDA.

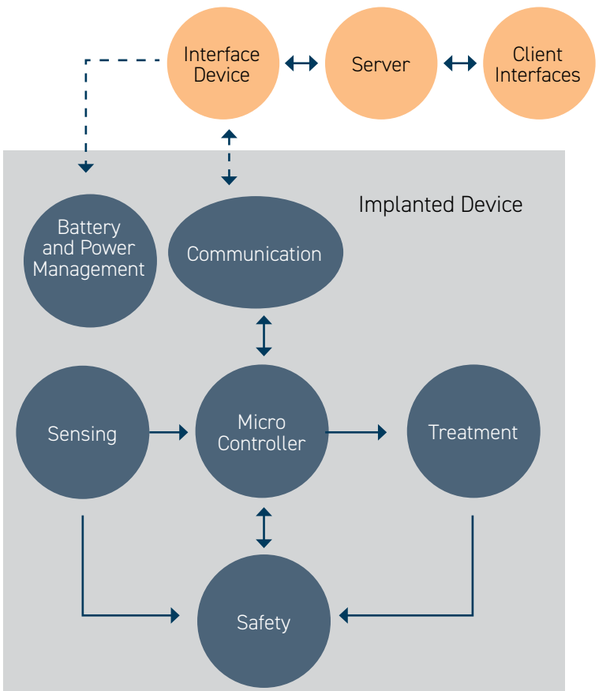
CONNECTIVITY CONCERNS

- Depth of Implantation
- Connection Intervals (How Often You Talk to Your External Device)
- Connection Consistency
- Cybersecurity
- Patient Confidentiality

"Make your product trade-offs wisely," continued Mr. Jacobs. "Get a mult-functional stakeholder group together and really talk hard about the things that provide critical benefit, the things you need to do, and minimize everything to the essentials – or the minimum viable product (MVP)."

Doing so will allow you to get your product to market in the most effective way possible while meeting the needs of your customers and helping those patients who need your device.

Implantable Architecture provided by Sunrise Labs



Making a difference in patients' lives through

Technology & Design

We strive to improve healthcare outcomes through innovative product development

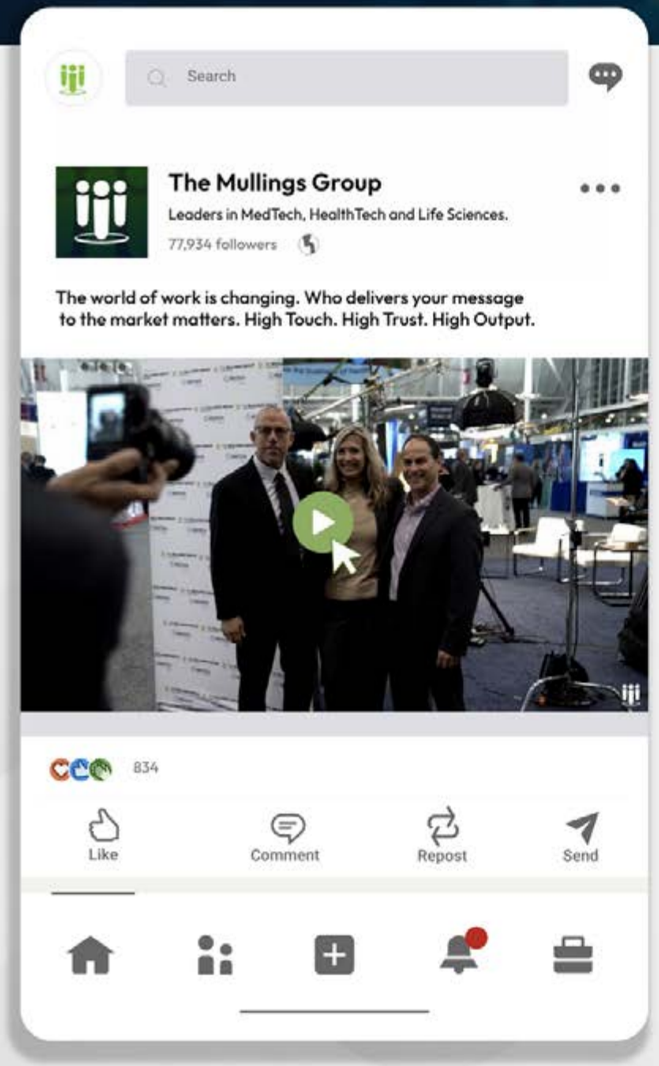
SUNRISE LABS

ISO 13485:2016 Certified

www.sunriselabs.com

MARKET DYNAMICS REQUIRE AGILE SOLUTIONS.

THE RIGHT TALENT, AT THE RIGHT TIME, IN THE RIGHT PLACE.



Executive Search

We do not believe in outrageous retainers. We believe in pay-for-performance. Our team has a combined tenure of over 100+ years with TMG — a rare indicator of success, commitment, and consistency in a high-turnover space.

Contract Recruiting

Our Contract Recruiting team provides fast access to Executive-level talent to accommodate a single need or to build a full team on an interim basis bringing vital skill sets to an organization at the precise time they are needed.

Dragonfly Media

We are the only search firm in the world that has invested in its own in-house media / marketing capabilities so our clients can speak to the market. Our clients have access to our 4,000 sq. ft. state-of-the art production studio where we guide them in their content and messaging. Our precisely engineered studio enables remote production capabilities to our clients worldwide.

View more from The Medtech Conference 2023

THE MULLINGS GROUP COMPANIES

joe@mullingsgroup.com

www.mullingsgroup.com

MassMEDIC
THE HEART OF HEALTHTECH

2023 YEAR IN REVIEW

MassMEDIC By the Numbers

MEDTECH IGNITE
POWERED BY MASSMEDIC

60
STARTUPS THAT HAVE COMPLETED OUR IGNITE ACCELERATOR PROGRAM AS OF 2023

CREATED AND CURATED
100+ HOURS
OF ORIGINAL MEDTECH CONTENT

150
ATTENDEES TO OUR INAUGURAL GOLF TOURNAMENT

FACILITATED
300+
INDIVIDUAL BUSINESS INTRODUCTIONS, MATCHING COMPANIES TO OPPORTUNITIES

400
ATTENDEES AT OUR MEDTECH IMPACT GALA IN 2023

500
ATTENDEES TO OUR WOMEN IN MEDTECH FORUMS IN 2023

MassMEDIC
THE HEART OF HEALTHTECH

BROUGHT FDA LEADERSHIP TO MORE THAN **650** MEMBERS ACROSS 2 EVENTS

PROMOTED
1,000
MEDTECH JOBS

INCREASED OUR LINKEDIN FOLLOWERS:
4,000+

GREW MAILING LIST TO
12,000+

$150 MILLION+
TOTAL DOLLARS RAISED BY IGNITE ALUMNI

EDUCATION

EXPANDED KEY EVENTS AND INTRODUCED NEW OPPORTUNITIES TO EDUCATE AND INFORM OUR MEMBERSHIP

LAUNCHED THE

MEDTECH IMPACT SYMPOSIUM & *Gala*

Featured a Keynote & Designation of MA Life Sciences Week from Massachusetts' Lt. Governor Kim Driscoll

REGULATORY ROUNDUP

The Premier Medtech Regulatory Event in New England

INTRODUCED THE VIRTUAL CYBERSECURITY ROUNDTABLE

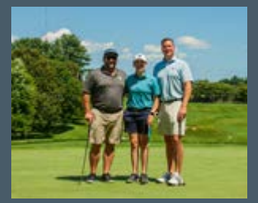
COVERING DEVICE AND DATA SECURITY UPDATES AND BEST PRACTICES

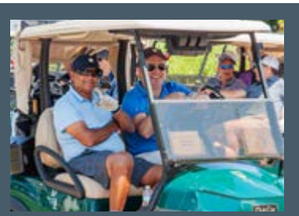
CONNECTION

CONTINUED TO FOSTER COLLABORATION AMONG OUR ECOSYSTEM

INTRODUCED THE MASSMEDIC GOLF TOURNAMENT AT WELLESLEY COUNTRY CLUB FEATURING A KEYNOTE FROM MA SECRETARY OF ECONOMIC DEVELOPMENT, YVONNE HAO

MASSMEDIC GOLF TOURNAMENT





WOMEN *in* MEDTECH

POWERED BY MASSMEDIC

WORKED WITH INTERNATIONAL REPRESENTATIVES FROM GLOBAL MEDTECH COMMUNITY TO ENGAGE WITH OUR REGION, INCLUDING: UK, IRELAND, FINLAND, SWITZERLAND, NETHERLANDS, CANADA, SPAIN & GERMANY

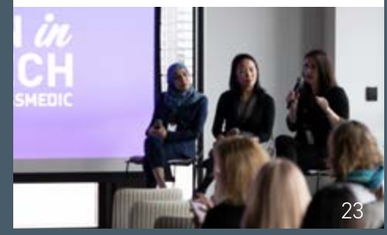
SIEMENS Healthineers

Smith+Nephew

OLYMPUS

cambridge consultants

Part of Capgemini Invent



ADVOCACY

ENSURED OUR MEMBERS HAD A SEAT AT THE TABLE FOR LOCAL, REGIONAL & NATIONAL ISSUES

SECURED MASSACHUSETTS AS THE HOME OF THE ARPA-H INVESTOR CATALYST HUB

COLLABORATED WITH STATE OFFICIALS TO DEVELOP THE LIFE SCIENCES RE-AUTHORIZATION BILL

Represented the Industry on State Committees Including:

- PANDEMIC PREPAREDNESS
- ECONOMIC DEVELOPMENT PLANNING
- LIFE SCIENCES WORKING GROUP

Led Conversations with CMS to Establish a Potential Pathway to Coverage for Breakthrough Devices, with the Bill HR 1691, Ensuring Patient Access to Critical Breakthrough Products Act of 2023

FACILITATED A REGIONAL MEDTECH WORKFORCE SUMMIT AT UMASS LOWELL WITH:

ZOLL, ABIOMED, SHERLOCK BIOSCIENCES, LANTHEUS

AWARENESS

DROVE AND AMPLIFIED AWARENESS FOR OUR MEMBERS AND INDUSTRY

LED THE CHARGE TO CREATE A MASSACHUSETTS LIFE SCIENCES WEEK AND SECURED A STATE PROCLAMATION

HIGHLIGHTED OUR REGIONAL STRENGTHS

Represented Industry at Major Conferences & Programs and Created Opportunity for Member Exposure

BIOMEDevice

OktoberINVESTfest

HEALTH EQUITY SUMMIT

BOYD BIOMEDICAL DESIGN STORIES w/ MassMEDIC

WOMEN'S HEALTH INNOVATION SUMMIT USA

MEDICA

THE MEDTECH CONFERENCE

EXPANDED

WHYMEDTECH™

POWERED BY MASSMEDIC

FEATURED MORE THAN 30+ VOICES

INTEGRATED MEDTECH JOB SEARCH TOOL

2024 YEAR AHEAD

ENCORE BOSTON HARBOR
MARCH 28, 2024

MEDTECH IMPACT SYMPOSIUM & Gala

MASSMEDIC GOLF TOURNAMENT

WELLESLEY COUNTRY CLUB
SEPT. 30, 2024

NEW EVENTS!

MEMBER Mixer

MEDTECH PAYMENT SUMMIT

INTERESTED? EMAIL INFO@MASSMEDIC.COM FOR MORE INFORMATION

STAY TUNED FOR

- First-Line Access to ARPA-H Funding Opportunities
- Updates on the Life Sciences Re-Authorization Bill
- Expansion of Workforce Development Resources Through Why Medtech
- Increase of Collaboration Opportunities with International Medical Device Companies, including: Abu Dabi, Spain, Canada, Finland, Switzerland, Ireland & UK

Q&A

with David Kolstad

David Kolstad
Founder and CEO, Genuity and Spryte Medical
Immediate Past Chair, MassMEDIC Board of Directors

You have a long history of entrepreneurialism. Most recently, you founded and ran Gentuity, and have just launched a new company, Spryte Medical. What is your "Why Medtech™" story? Why do you enjoy working in the industry and commercializing new products?

It all starts with the patient. I have been fortunate to work in several wonderful patient centered companies here in the state and learn so much from so many great people. From starting businesses at a kitchen table to fortune 500 companies, I have been able to experience many exciting phases of a business life, growth and growth challenges. Bringing technology, outstanding people, capital, and world leading clinicians together to address tough global clinical problems while often hard, is both a privilege and extremely gratifying. The impact we have on patients and their families' lives can be a most humbling and worthy endeavor. I can't imagine doing anything else.

Tell me about Spryte Medical. What are your goals for the future of the company?

Spryte Medical's goal is to fundamentally transform and improve stroke patient care. Our imaging platform is enabling the highest resolution imaging of the brain ever. We are accessing the brain through the patients' arteries with our optical fiber and imaging from the inside out for the first time. With this approach we can image vessels, disease, and other important structures at >10x the resolution of today's imaging systems. We believe we will improve clinicians understanding of stroke and other neurovascular disease for better clinical decision making. With our platform's integrated AI capabilities, we are collaborating with our clinical partners to accelerate therapy development, enhance procedural techniques and most importantly, improve patient care worldwide.

Why did you choose to start Spryte Medical in MA? Why have you grown Gentuity and other ventures in the Commonwealth?

One word....talent. Successful medtech businesses require highly knowledgeable and committed patient focused employees. Beyond our internal teams, external partners also play key roles in building this success. Whether they are academic institutions, specialty technology providers, manufacturers, legal advisors, investors, healthcare providers or others, Massachusetts has them all. It is perhaps the most fertile field for medtech companies large and small anywhere in the world.

What piece of advice can you offer those looking to grow a business in MA?

Get involved. Whether MassMEDIC, MassBio, ARPA-H Investment Catalyst Hub, or the Mass Life Science Center, there are a number of great organizations in the state laser focused on our

industry in which you and your business can get involved. From driving policy, delivering the latest information on changes, and bringing together like-minded individuals to share perspectives and collaborate, these organizations are working hard for your business, your employees and our patients at the state and federal levels. These organizations welcome your engagement, and I am confident you will enjoy it and find it time well spent.

What did you enjoy most about your time as Chairman of the Board of Directors for MassMEDIC?

It was my great pleasure to work with Brian Johnson (our president), his team, the Executive Committee, and the Board to make MassMEDIC an even stronger voice at the state and federal level. It was a time of great change. With a return to more in-person activities, engaging with a new Governor and her team, a new Congress with the change to the House, and navigating the SVB Bank failure — all made for a very rich and active tenure. MassMEDIC shone brightly, rose to all of these challenges and opportunities. It is exciting to see them build on this momentum!

GENTUITY

LOCATED IN SUDBURY MA

GENTUITY.COM

ABOUT Crossing new frontiers in cardiovascular care so patients can focus on living. Our goal is to advance medicine, improve the body of knowledge, and improve outcomes in the space of cardiovascular interventional procedures.

SPRYTE MEDICAL

LOCATED IN BEDFORD MA

SPRYTEMEDICAL.COM

ABOUT **Advancing cerebrovascular care through groundbreaking neuro intravascular imaging and AI technologies.**

The Gentuity team celebrates their 510(k) clearance in 2020 for the HF-OCT Imaging System.

MEDTECH TREND: ChatGPT & Generative AI

In recent years, the integration of artificial intelligence (AI) and machine learning (ML) technologies has significantly transformed various industries, and the healthcare sector is no exception. One notable advancement in this domain is the advent of generative AI models like ChatGPT, which have begun to make a profound impact on the medical device industry.

Driving the need for integrating these technologies into our workflows is the shortage and burnout of healthcare workers including nurses, doctors and clinical trial staff, with the ultimate goal of increasing efficiency, enabling more effective healthcare delivery, and increasing diversity in clinical trials.

What is the potential impact of AI and ML technologies on the medtech industry?

1. INNOVATIONS IN PRODUCT DEVELOPMENT

One of the primary ways ChatGPT is influencing the medical device industry is through its contributions to product development. Generative AI models can assist researchers and engineers in ideation, design, and optimization processes. By analyzing vast datasets of medical information, these models can propose innovative solutions for the development of new medical devices. This not only accelerates the R&D process but also promotes the creation of more efficient and patient-centric devices.

A.J. Tibbetts, Shareholder and member of both the AI and Life Sciences and MedTech Practice Groups at Greenberg Traurig, who presented the medtech AI webinar noted above, warns that we shouldn't become overly reliant on AI.

"In any domain, successfully leveraging technologies like generative AI requires a keen understanding of the technology, its limitations, and its data sources, and a dedication to ongoing training and improvement. This is particularly important with healthcare, where inaccuracies or bias could have severe consequences. Having a human-in-the-loop can be important to reduce risk to patients, providers, and others."

This article was written by MassMEDIC using ChatGPT. For more information on generative AI, see Greenberg Traurig's webinar "HealthGPT? Benefits, Risks, and Effective Uses of Generative AI in Medtech."

2. ENHANCED HUMAN-MACHINE INTERACTION

ChatGPT's natural language processing capabilities are instrumental in improving human-machine interaction within medical devices. Devices equipped with conversational interfaces powered by generative AI can effectively communicate with healthcare professionals and patients, facilitating a more intuitive and user-friendly experience. This development is particularly crucial in the context of medical devices where ease of use and clear communication are paramount.

3. PERSONALIZED HEALTHCARE SOLUTIONS

The ability of ChatGPT to process and analyze vast amounts of patient data enables the creation of personalized healthcare solutions. In the medical device industry, this translates to the development of devices tailored to individual patient needs. For instance, wearable medical devices can use generative AI to interpret a patient's specific health data and provide personalized recommendations for treatment, medication adherence, and lifestyle adjustments.

4. IMPROVED DIAGNOSTIC CAPABILITIES

Generative AI is proving to be a game-changer in the realm of medical diagnostics. ChatGPT, when integrated into medical devices, can analyze complex medical data, interpret symptoms, and even suggest potential diagnoses. This augmentation of diagnostic capabilities can lead to earlier detection of diseases, more accurate assessments, and ultimately, improved patient outcomes.

5. STREAMLINED REGULATORY COMPLIANCE

Navigating the regulatory landscape is a significant challenge for the medical device industry. ChatGPT and generative AI can streamline the regulatory compliance process by assisting in the generation of comprehensive documentation, risk assessments, and compliance reports. This ensures that medical devices meet stringent regulatory standards and can be brought to market more efficiently.

> "In any domain, successfully leveraging technologies like generative AI requires a keen understanding of the technology, its limitations, and its data sources, and a dedication to ongoing training and improvement."
>
> **A.J. Tibbetts, Shareholder, Greenberg Traurig**

Mr. Tibbetts continues, "AI tools that generate text are designed to output text that looks right, but not necessarily to produce text that is right. Text may not be factually accurate or may not be appropriate for a particular context. Any text generated with these tools should be approached with caution, particularly when the text is important — including legal submissions, business docs, medical records, and the like. Human oversight and adapting to specific regulatory and business requirements are essential."

6. CONTINUOUS LEARNING AND ADAPTATION

One of the remarkable features of generative AI models like ChatGPT is their ability to continuously learn and adapt. In the medical device industry, this means that devices can evolve over time based on real-world usage and feedback. Updates and improvements can be implemented seamlessly, ensuring that medical devices remain at the forefront of technological advancements and adhere to the highest standards of patient care.

7. DIVERSIFICATION OF CLINICAL DATA

One of the challenges our industry continues to struggle with is the lack of diversity in clinical trials, which puts into question the effectiveness of treatments across different populations. While real patient data is preferred, one area that is under investigation for the potential use of generative AI is synthesizing patient data for clinical trials to help lessen the underrepresentation of minority groups in clinical trials. In the future, ChatGPT could also play a role in addressing staffing shortages in the context of clinical trials.

The integration of ChatGPT and generative AI into the medical device industry represents a paradigm shift in how healthcare solutions are developed, deployed, and utilized. From enhancing product development and human-machine interaction to enabling personalized healthcare and improving diagnostic capabilities, these technologies are poised to revolutionize the way medical devices contribute to patient care.

As the medical device industry continues to embrace the potential of generative AI, we can anticipate even more groundbreaking advancements that will shape the future of healthcare. At the same time, we must continue to learn about the evolving technologies and discover the best uses to elevate our work.

MassMEDIC

THE HEART OF HEALTHTECH

MASSMEDIC.COM

@MASSMEDICOUNCIL

@MASSMEDIC