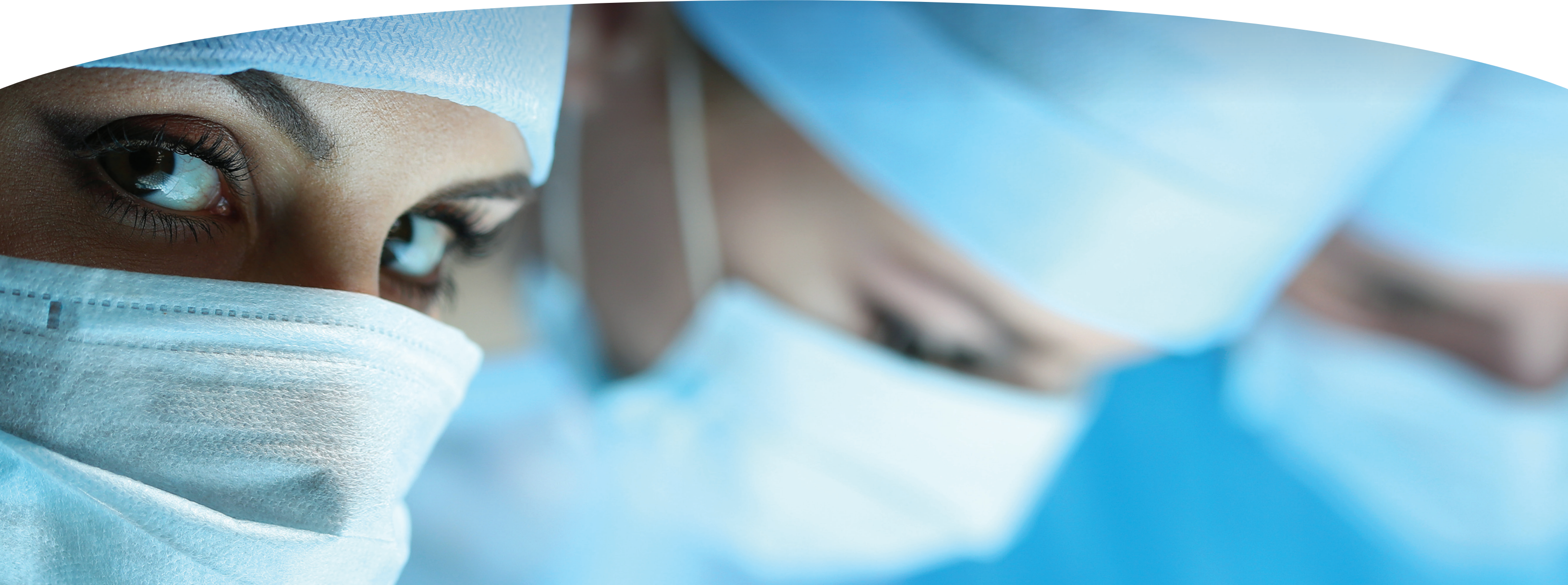




# ARCHIMEDES

Center for Healthcare and Device Security

Celebrating more  
than a decade  
of security  
education and  
research





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# A Letter from Our Founder



Dear Friends of the Archimedes Center for Healthcare and Device Security,

It's incredible to think how much has changed — and how so many challenges remain unsolved — since I founded the intellectual pillars and community mission of Archimedes in 2008. At that time, already over half of all medical devices relied on software to function and healthcare providers were routinely using implantable medical devices incorporating wireless technology to treat and manage chronic ailments — including cardiac arrhythmia, diabetes, and Parkinson's disease. And yet despite the growing proliferation of software-dependent, wireless medical devices, security and privacy remained afterthoughts, if they were thought of at all, in many systems.

Archimedes was established to shine a light on the need for balancing medical device safety and effectiveness with security and privacy. Our mission initially focused on helping medical device manufacturers navigate the operational hazards of cybersecurity implementation and prepare them for future challenges of FDA requirements. After hosting the very first Leadership Workshop on Medical Device Security, we quickly recognized that the conversations needed to expand to include hospital, pharmaceutical, regulatory, and research groups. Only by working collaboratively and partnering across roles, sectors, and organizations can we identify and solve our common industry-wide problems and create meaningful and effective standards, requirements, and reforms.

Over the last 12 years, Archimedes has worked to create a safe and trusted space where industry leaders and practitioners alike turn to share ideas, ask questions, and get answers through our conferences, peer-reviewed research, and online and in-person trainings. Our corporate membership has nearly quadrupled to include the world's top medical device manufacturers and hospital systems. In parallel, our team has grown, enabling us to support and fund students at the University of Michigan who are making important strides in security research.

However, there is still more work to be done. We live in a time of constant change, rapidly evolving technology, and unparalleled opportunity to improve patient care. And yet the twin threats to patient security and privacy are real and growing. That has not changed. We must continue collaborating, learning, and striving together to make the healthcare industry safer and more secure. Back in 2008, we started the conversation and now we rely on you to advance it.

Stay safe. Stay informed. Join the conversation.

Thank you,

Kevin Fu  
Founder and Chief Scientist



# The State of the Industry

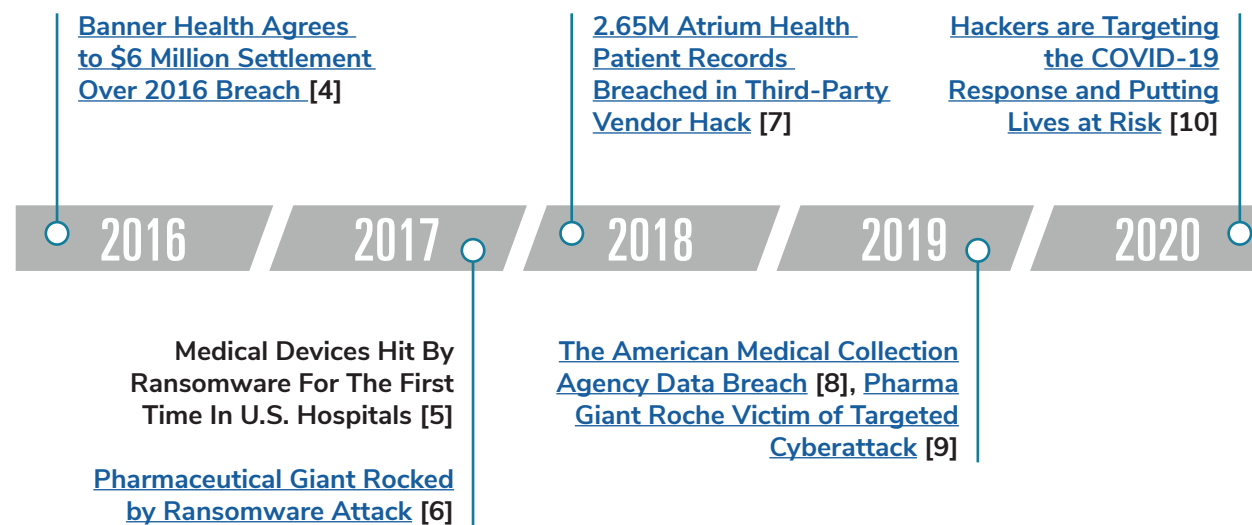
Security in the healthcare industry is at a higher risk than ever before. In an age of rapid digital transformation and an expanding world of connected systems — hospital environments, medical devices, pharmaceutical manufacturers, and government agencies are all vulnerable to attack.

A [report released in 2019](#) by IBM Security and Ponemon Institute revealed that **the healthcare industry has the highest costs associated with data breaches; with an average cost of \$6.45 million — which is 60% higher than the cross-industry comparisons** [1]. Data breaches can have a lasting financial impact and the overall costs associated with cybercrime is, unfortunately, on the rise.

In 2019, over [750 healthcare providers in the U.S. were hit with ransomware attacks](#) putting patient health and data at risk. As a result, 911 systems were interrupted, patient records were inaccessible or permanently lost, surgeries had to be postponed, and some practices were forced to close their doors for good [2].

*Digital transformation has been a business buzzword for decades, and the concept has yielded very positive results over time. But security is often an afterthought, which leaves digital doors wide open for cybercriminals,” said Jon Clay, director of global threat communications for Trend Micro. “Despite the prevalent ideals of digital transformation, lack of basic security hygiene, legacy systems with outdated operating systems, and unpatched vulnerabilities are still a reality. This scenario is ideal for ransomware actors looking for a quick return on investment. As long as the ransom scheme continues to be profitable, criminals will continue to leverage it. [3].*

We are all familiar with the major headlines of the last decade, and these types of cybersecurity incidents are becoming more frequent and sophisticated with each passing year.



While there is no single solution for ensuring healthcare privacy and security, we firmly believe that through corporate collaboration and public-private partnerships we can collectively keep pace, advance the industry, and strategically plan for future security challenges.

# About Archimedes

Archimedes is the premier forum for unbiased education and cross-industry networking and collaboration on healthcare security.

Archimedes brings together **stakeholders from across the healthcare security community** to focus on the topics that matter, solve tough problems, and find out-of-the-box solutions using sound science and solid engineering to advance the industry as a whole.

We provide a safe space where leaders can talk freely, ask questions, and exchange ideas **free from the influence of marketing or salespeople**. We strive to support and fund students who are making strides in security research and educate and inform those currently working in the health delivery, medical device manufacturing, and pharmaceutical manufacturing industries.

## Archimedes Members Include

- Academia & Research Groups
- Health Delivery Organizations
- Medical Device Manufacturers
- Pharmaceutical Companies
- Standards & Regulatory Organizations

## Our Core Values

- Focus on topics that matter
- Develop and improve security standards across the industry and around the globe
- Bring people together through events, collaboration, and partnerships
- Educate and inform on cybersecurity threats and best practices
- Practice sound science and solid engineering
- Fund research to advance the field of cybersecurity in healthcare
- Prepare the future workforce





# Our Team

The Archimedes team brings nearly 50 years of combined industry leading experience to focus on expanding educational and research opportunities in healthcare cybersecurity. We strive to provide our members with unmatched service and support. We are proud to be part of an organization that's built on a strong foundation of personal trust, sound science, and solid engineering.



**KEVIN FU**  
Founder and Chief Scientist

Kevin Fu is credited for establishing the demand for increased medical device security beginning with the 2008 [IEEE paper on defibrillator security](#). Kevin is an Associate Professor in EECS at the University of Michigan where he directs the Archimedes Center for Healthcare and Device Security and the [Security and Privacy Research Group \(SPQR\)](#).

A former [MIT Technology Review TR35 Innovator of the Year](#), Kevin has testified in the House and Senate on matters of information and [medical device security](#) and has written commissioned work on trustworthy medical device software for the Institute of Medicine of the National Academies. He was a member of NIST Information Security and Privacy Advisory Board, the CRA Computing Community Consortium Council, and the ACM Committee on Computers and Public Policy.

Kevin previously co-chaired the AAMI Working Group on Medical Device Security, which developed [AAMI TIR57, Principles for medical device security — Risk management](#), a set of guidelines for manufacturers on developing a cybersecurity risk management process for medical devices that was recognized by the Food & Drug Administration (FDA) in 2016.

Kevin served as a visiting scientist at the FDA, the Beth Israel Deaconess Medical Center of Harvard Medical School, Microsoft Research, and MIT CSAIL. He received his B.S., M.Eng., and Ph.D. from MIT. He also earned a certificate in artisanal bread making from the French Culinary Institute. His baguettes are amazing.



**BILL AERTS**  
Executive Director

Bill Aerts has served as the Executive Director of the Archimedes Center for Healthcare and Device Security at the University of Michigan since 2017. Bill provides leadership in supporting Archimedes members, expanding service offerings, improving day-to-day operations, and remaining active in the medical device security community.

In 2016, Bill retired from his role as Global Director of Product Security within Medtronic's Global Security Office where he helped to build Medtronic's original Information Security Program. A tireless leader and cybersecurity advocate, Bill continues to champion for improving security in healthcare through education.



**SARAH PEÑA**  
Senior Operations Manager

Sarah Peña is the Senior Operations Manager for the Archimedes Center for Healthcare and Device Security. Sarah earned her BA in Business Administration and her MBA from Davenport University, and she has over 12 years of experience working in fast-paced environments. Using the training she received as a seasonal cast member at the Walt Disney World Resorts, she brings unmatched customer service to Archimedes members, sponsors, and partners. Sarah is passionate about helping bridge the gap for women in tech and driving operational excellence at Archimedes to ensure programs

are inclusive and diverse. Motivated by work that makes a difference, Sarah is proud to be an integral member of the Archimedes team.



**KELLY SABO**  
Member Services and Communications Manager

Kelly Parsons Sabo is the Communications Manager for Archimedes Center for Healthcare and Device Security. Kelly has worked in several communications roles in both the public and private sector, including the Minnesota Department of Public Safety, Orthodontic Care Specialists, and Mom Enough. Several years ago, in search of a better life-work balance and to continue her growth in the field of public relations, she started her own communications business, kap pr. Her professional experience spans 20 years and she's excited to bring her marketing and media knowledge to the Archimedes team.



**CONNOR BOLTON**  
Research Associate

Connor Bolton ([connorbolton.com](http://connorbolton.com)) is a fourth year Ph.D. candidate in Computer Science at the University of Michigan in the Security and Privacy Research Group under Kevin Fu. He is originally from Greenville, South Carolina and received his BS in Computer Engineering from Clemson University where he researched ultra-low-power wireless sensor networks.

Connor's current research at Michigan on cyberphysical sensor security focuses on how to mitigate attacks that exploit the physics of sensor design and construction. His research interests include exploring the physical principles of such attacks, designing software and hardware mitigations, and creating tools to aid attack comprehension and mitigation design. At Archimedes, Connor is excited to provide real-world, meaningful assistance to members by applying his background in research to the impactful problems facing medical device security.





## Members



## Business Alliance Partners



# Members & Business Alliance Partners

Archimedes members and partners care profoundly about patient safety, privacy, and working together to improve healthcare security. They support Archimedes' efforts to advance cybersecurity standards and practices through education and collaboration by speaking at our conferences, attending our trainings, and partnering on surveys and studies. Archimedes works with members and partners to help them navigate the operational hazards of cybersecurity implementation and give them the knowledge to move forward with confidence.





# Services

## Education + Networking

“The Archimedes events and workshops continue to be unique gatherings of stakeholders most deeply involved in medical device security. From manufacturers to HDOs to researchers and the FDA, highly informative dialogue happens in an open and safe environment that fosters sharing of perspectives, challenges, and opportunities across the medical device ecosystem.”

**Suzanne Schwartz, Associate Director for Science & Strategic Partnerships**  
Center for Devices & Radiological Health, FDA

### Annual Events

Each year, Archimedes hosts two highly-anticipated events: the Archimedes Leadership Workshop and the Medical Device Security 101 Conference. We keep our conferences small so participants feel comfortable speaking freely about medical and cybersecurity issues with trusted and respected professionals. We do not focus on the latest industry buzz or new product development. Our sessions are carefully curated by our co-chairs and the talks are free from the influence of sales people. We have one of the lowest sponsor-to-attendee ratios in the industry and we guarantee a secure forum for unbiased education and unparalleled networking.

### Leadership Workshop

The Archimedes Leadership Workshop is our flagship event, which first brought medical device manufacturers together in 2008. Today, this private, members-only workshop brings together leadership from academia and research, health delivery organizations, medical device manufacturers, pharmaceutical manufacturers, and regulatory groups. We cap the workshop at 60 attendees and have our membership select topics, which take the form of a series of lightning talks designed to spark deep-dive discussions and meaningful conversations. If you have ever joined us for this workshop, you understand why it is a member favorite.

### Medical Device Security 101 Conference

The Archimedes Medical Device Security 101 Conference is open to member and non-member stakeholders from across the healthcare and device security community. The two-day event provides a top-notch learning environment for those new to the industry as well as established leaders. The 101 conference attracts a global audience where participants have ample opportunity to learn from and network with industry experts. We cap the conference at 150 attendees to ensure everyone has the chance to connect with our speakers and get the answers needed to protect patients, practices, and businesses.

### Webinars

New for 2020, Archimedes launched both public and members-only webinars that occur every two weeks and cover topics ranging from rapid device deployment during COVID-19 to cybersecurity research in the age of IoT. These online sessions follow the format of a 20-minute presentation followed by 40 minutes of discussion, providing another channel for industry players to stay connected and informed throughout the year.

### Member Connect

Archimedes members don't have to wait for one of our annual conferences to connect with their colleagues and competitors. Each member is invited to exchange ideas, discuss problems, and work toward solutions with other members through an array of outlets including our private LinkedIn page, our Whova conference app, our soon-to-launch members-only Slack workspace, and small group sessions that Archimedes will organize and arrange as needed. Members often come to us seeking guidance or direction on tough issues and we're frequently able to connect them with other members or individuals within our network to get them the help they need when they need it.

### Past Sponsors

Sponsors play an important role in supporting Archimedes, enabling us to host one-of-a-kind educational and networking events. Our sponsors allow us to keep our attendance small, which is critical for fostering frank discussions and making real progress on core issues. Previous sponsors include:







# Services

## Customized Onsite & Virtual Training

“When Boston Scientific established its internal product security summit, we needed comprehensive cybersecurity training that could bring our cross-functional team up to a common baseline. We contacted Archimedes because we knew they had the connections with the industry experts that could educate our group on the overall security landscape. The curriculum was tailored to our company’s specific needs and the feedback from attendees was overwhelmingly positive. From the start of our product security journey, Archimedes has been an instrumental partner providing extensive expertise, resources to build our team’s capability, and a trusted forum for information and knowledge sharing.”

**Ken Hoyme, Director, Product Security**  
Boston Scientific

### Customized Onsite & Virtual Training

Archimedes members receive a substantial discount on training packages.

The Archimedes team and its collaborators have taught hundreds of engineers, nationally and internationally, how to effectively incorporate security engineering into the product development lifecycle and regulatory frameworks. We offer customized onsite or virtual training to both member and non-member organizations. Groups that participate in our training will:

- Gain a science-based perspective on healthcare security, cutting through and contextualizing the hype and sensational headlines.
- Learn how to incorporate security engineering principles into hazard analysis, product design/production, implementation, testing, and post-market surveillance.
- Understand when to make a local security decision, and when to call for expert help.

Experts in our community have led the development of medical device security standards, worked at FDA, were commissioned by the National Academy of Medicine to advise on cybersecurity fundamentals in the 510(k) process, and advised the U.S. Congress and White House on federal strategy for medical device security.





# Services

## Survey Support & Consensus-Based Standards Development

“Product cybersecurity is a rapidly changing environment in the medical device industry that requires strong communication between all stakeholders. Having a neutral, well-informed organization like Archimedes is critical in both fostering and facilitating this communication between medical device manufacturers.”

**Alex Kent, Director for Medical Device Product Security**  
Medtronic

### Survey Support

Having access to data can help teams and organizations make better and more informed decisions, which is why Archimedes offers end-to-end survey support for members and select partner organizations. We walk you through each step in the surveying process from development to analysis, and make sure you get the right questions in front of the right audiences.

#### Survey Support Process:

- Consultation during survey development
- Survey construction
- Email distribution to mailing list and through other partner channels
- Creation of a digestible data analysis report

### Consensus-Based Standards Development

New standards and regulations have been created or updated in recent years that have substantially improved healthcare and device cybersecurity. However, there remains a need for additional industry-wide standards that specify security best practices, design and development processes, and manufacturing and usage guidelines independent of the manufacturer or user.

Archimedes excels at bringing the right people and groups together. Leveraging this strength, we are in a position to organize the development of new industry standards through coordinating peer reviews and providing content, publication, and distribution support.



# Growth Plan

With the steady growth Archimedes has seen in terms of members and staff, we are exploring new ways to expand our offerings, influence, and contributions to the global healthcare and device security industry. We've identified the following action plan to drive growth and increase revenue:

## Recruit More Medical Device Manufacturers & HDOs

Medical device manufacturers and health delivery organizations are key target groups for Archimedes. We will continue to tailor our membership program and offerings to both large and small organizations within these segments. Our goal is to grow with care and purpose, recruiting and educating both medical device manufacturers and healthcare systems while maintaining the highest level of service, integrity, and quality.

## Engage Pharmaceutical Manufacturers

Medical device and pharmaceutical manufacturers face many of the same security challenges, making the Archimedes membership program a natural fit for the pharmaceutical market.

Pharmaceutical manufacturers are experiencing an alarming [increase in their vulnerability points](#) in manufacturing and supply chains due to globalization and an increasingly connected world [11]. Manufacturing processes rely on a multitude of IoT devices that may provide previously unforeseen attack vectors.

In 2019, the global pharmaceutical market was valued at just over \$1.25 trillion and it's anticipated to increase by 160% through 2030 [12]. Like any high-growth and highly-connected industry, cyber threats will become more sophisticated and widespread as the market grows. Additionally, with the rise in security risks, there will be more regulations and standards to navigate.

There is a huge opportunity to serve this segment with our current membership offerings; providing insights into global regulations, access to security research, education, and cross-industry knowledge-sharing opportunities. This is an area for Archimedes to significantly increase its membership and revenue, but more importantly, a way for our organization to further contribute to the security industry as a whole.

## Expand Global Reach

As we work alongside members and partners to gain a better understanding of universal needs, we are striving to increase our worldwide presence and reach. Operating at a global level will play an essential role in Archimedes' future growth and impact.





## Drive Future Regulations and Standards

Archimedes has developed close relationships with prominent regulatory and standards bodies and we understand the importance of collaborating with these groups. This understanding and our ability to connect individuals and organizations across the security space put us in an ideal position for organizing, supporting, and driving the development of future security regulations and standards.

## Prepare The Future Workforce

Awareness and education are the building blocks for preparing the future cybersecurity workforce. We take our role in these areas seriously. We've prioritized building strong partnerships to create awareness about healthcare and device security and we provide educational opportunities for professionals and students at every level. Some of the ways we have worked with our partners to reach, teach, and generate interest in the cybersecurity field include:

- Organizing healthcare cybersecurity sessions at partnered conferences, events, and webinars.
- Sending graduate and Ph.D. students from the University of Michigan to hands-on technical events like the DefCon Biohacking Village.
- Funding cybersecurity research in the SPQR lab at the University of Michigan.
- Providing discounted rates to the Archimedes 101 Conference for professionals and students new to the industry.
- [Volunteering in the community to teach youth about cybersecurity, the physics of soundwaves, and about ultrasound technology](#) [13].

While we have made strides in cybersecurity awareness and education, there is still much work to be done in this rapidly evolving field to ensure patient privacy and device security in the healthcare industry. We're currently working on a grant that will enable us to fund the development of entry-level cybersecurity educational materials that we intend to make available to anyone seeking to learn more. Future efforts will continue to prioritize education, research, and collaboration with the goal of making healthcare cybersecurity a top-of-mind concern and an accessible subject matter for professionals and students.







*Membership provides a pathway to get input from industry leaders and collaborate with other professionals and HDOs. The Archimedes leadership conferences have been an excellent source of this networking and industry updates.*

**Soundharya Nagasubramanian**  
Director, R&D, Product Information Security  
Hillrom

*The world of cybersecurity can be a daunting place. Specifically, medical device security is often clouded with misconceptions and a misunderstanding as to what the particular vulnerabilities are and why traditional information technology solutions don't work. Archimedes provides clear insight as to what the problems are and what solutions are needed to drive the industry. We value our partnership with Archimedes because it is the best place to collaborate with a variety of stakeholders for meaningful change.*

**AJ Aspinwall**  
Medical Device Security Specialist, Clinical Engineering  
Norton Healthcare

*Archimedes is a one-of-a-kind program that draws stakeholders from different backgrounds across the healthcare ecosystem, including deep integration with the academic and cybersecurity research communities.*

**Beau Woods**  
Cyber Safety Innovation Fellow  
The Atlantic Council



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