



BIOMEDICAL DEVICE INNOVATION ZONE

BUSINESS PLAN

November 2015

Biomedical Device Innovation Zone

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Zone Administrator

Bob Stowe, bob.stowe@bothellwa.gov

Chair of the Board

Matt Smith, matts@economicalliancesc.org

I. EXECUTIVE SUMMARY

The Biomedical Device Innovation Zone, located in Bothell, Washington, is one of 14 regional Innovation Partnership Zones (IPZs) in Washington State focused on stimulating the growth of the state's targeted industry clusters.

The organization received its designation in 2008 through a competitive process focused on regions with an existing concentration of industry (established and start-up) and a higher education institution within its purview.

The Innovation Zone physically encompasses Bothell's four privately owned science parks, and the University of Washington Bothell in addition to Lake Washington Institute of Technology in Kirkland, the site for the organization's Mercury Medical Device Technologies Incubator. The innovation zone is unique in that it spans both King and Snohomish Counties. Medical device companies located within the zone include Philips Healthcare, EKOS Corporation, Fujifilm SonoSite, and Mirabilis Medica.

II. MISSION & GOALS

Mission

The Biomedical Device Innovation Zone's mission is to accelerate the growth of the biomedical device industry in Washington State.

Goals

The organization focuses on programming and partnerships targeted at:

- Supporting new company formation and job creation through the commercialization of innovative medical technologies via the organization's Mercury Medical Technologies Incubator and rapid prototyping lab;
- Fostering industry interaction and partnerships to strengthen the regional biomedical device eco-system through the annual Washington State Biomedical Device Summit, CEO Roundtables, and incubator workshops and partnerships
- Monitoring, measuring, and reporting on the industry's progress and trends
- Strengthening workforce development through industry alignment with regional higher education institutions and workforce training organizations to meet the ever growing needs of the industry.

III. LEADERSHIP / GOVERNANCE

The Biomedical Device Innovation Zone is an extremely collaborative organization led by the organization's primary founding partners: the City of Bothell; University of Washington Bothell; the Washington Biotechnology & Biomedical Association (WBBA); the Economic Alliance Snohomish County; the Economic Development Council of Seattle & King County; and the

Washington State Department of Commerce. Working with a host of supporting partners, the organization serves as the lead convener of the biomedical device industry in the region.

Collaborative supporting partners include industry firms Philips Healthcare, Aqueduct Critical Care, EKOS Technologies and Mirabilis Medica, in addition to Lake Washington Institute of Technology and service firms including Moss Adams, Foster Pepper and Product Creation Studios

The Innovation Zone's non-profit officers and board members serve as the Management Team for the organization.

Chair: Matt Smith, Economic Alliance of Snohomish County
Vice-Chair: Jens Quistgaard, Mirabilis Medica | NaviSonics
Secretary: Bob Stowe, City of Bothell
Treasurer: Hovan Asdourian, Washington State Department of Commerce
Directors: Tom Clement, Aqueduct Critical Care
Dan Fowler, Moss Adams
Jary Krauser, EDC of Seattle & King County
Lori Melkerson, EKOS Corporation
Chris Rivera, Washington Biotechnology & Biomedical Association
Terry Sweeney, formerly with Philips Healthcare
Ex-Officio Director: Elaine Scott, University of Washington Bothell

Chair

Matt Smith

Matt Smith is a Vice President with the Economic Alliance Snohomish County (formerly the Economic Development Council for Snohomish County). In his role with the Economic Alliance, Smith is responsible for managing the organization's retention, expansion, and recruitment projects.

Vice Chair

Jens Quistgaard

Jens Quistgaard is the CEO of Mirabilis Medica, a women's healthcare company dedicated to improving the treatment of symptomatic uterine fibroids using its proprietary high-intensity focused ultrasound (HIFU) technology. Prior to Mirabilis, Quistgaard held senior level positions at several leading medical device companies in the region including Liposonix, SonoSite and ATL Ultrasound (new part of Philips).

Secretary

Bob Stowe

Bob Stowe has held the position of City Manager for the City of Bothell since January 2005. He is responsible for carrying out the policy established by the city council and acts as business manager for the City, recommending and advising the council on a broad array of issues. Before arriving in Bothell, Stowe was the City Manager for the City of Mill Creek, WA for nine years and held other top administrator positions for two other Washington cities for an additional 10 years.

Treasurer

Hovan Asdourian

Hovan Asdourian is the Life Sciences & Global Health Business Development Manager with the Washington State Department of Commerce. Prior to joining the Commerce Department in June 2012, Asdourian provided consulting services in commercialization, business development and analytics to the biopharmaceutical and medical device sectors. Addourian has held management positions with global responsibilities at Rhone Poulenc Rorer (Sanofi-Aventis), CuraGen, Centocor, and Eli Lilly & Company. He spent some time in Saudi Arabia establishing a new medical school and a teaching hospital and is fluent in Arabic.

Directors

Tom Clement

Tom Clement is the Chief Executive Officer at Aqueduct Critical Care, a company focused on improving the treatment of neurological disorders related to the production and regulation of cerebral spinal fluid (CSF). Clement is a seasoned medical device veteran with 30+ years' experience in the industry including CEO of start-ups Pathway Medical Technologies and Cardiac Insight.

Dan Fowler

Dan Fowler is a Senior Manager at Moss Adams, a nationwide firm with headquarters in Washington state which focuses on assurance, tax, consulting, risk management, transaction and private client services. Fowler has been in public accounting since 1997. He provides audit, review, and consulting services to companies in the technology, life sciences, and manufacturing industries, and has significant experience working with startup organizations, venture backed and angel-financed companies. Fowler also has significant experience working with mid-size manufacturing companies and customers in medical device, aerospace, and heavy machinery industries.

Jary Krauser

Jary Krauser is the Business Development Manager for Life Sciences & Health at the Economic Development Council of Seattle & King County in addition to serving as CEO of StratusG Consulting, a business and technology consulting firm with over two decades of experience with clients in the pharmaceutical, biotechnology, and medical device industries. Krauser has worked extensively throughout all phases of the product development pipeline, from concept through research, development, commercialization, and beyond.

Lori Melkerson

Lori Melkerson is the Vice President of Operations at EKOS Corporation. Melkerson has worked in Manufacturing Engineering and Operations in the medical device industry for 25 years with experience in moving products from concept to commercialization. Prior to joining EKOS, she worked for Abbott Laboratories, Heart Technology, and Boston Scientific. Melkerson has a Bachelor of Science degree in Chemical Engineering from Queen's University in Kingston, Ontario.

Chris Rivera

Chris Rivera is the President of the Washington Biotechnology & Biomedical Association (WBBA). Prior to joining the WBBA, Rivera was the founder and CEO of Hyperion

Therapeutics, a specialty biopharmaceutical company focused on the development and commercialization of therapies for gastroenterology and hepatology diseases.

Elaine Scott

Dr. Elaine Scott is the dean of the School of Science, Technology, Engineering and Math at the University of Washington Bothell. Scott has served on the faculty at Seattle Pacific University, Virginia Tech, the University of Utah and Michigan State University. Since joining the UW Bothell, science and technology education at the campus has risen to regional and national prominence. The School of STEM has introduced nine new degree programs since 2013 further supported by the opening of Discovery Hall, the new Science and Academic Building in the fall of 2014.

Terrence (Terry) J. Sweeney

Terry Sweeney is the former Vice President Global Clinical Affairs at Philips Healthcare worldwide. Sweeney’s career in regulatory affairs began in 1974 and he has directed regulatory affairs departments for Johnson and Johnson, Quantum Medical Systems, Advanced Technology Laboratories, and Philips Healthcare.

IV. STRENGTHS OF THE INNOVATION ZONE

Washington State has long been recognized as a world-class epicenter for the life sciences. The state has been ranked as the fifth-largest Life Sciences cluster in the US by the Milken Institute. The Seattle metro area has been the focus of much of this attention, as a well-established and recognized center for biotechnology and life sciences activity. However, that activity has historically favored the pharmaceutical sector. The medical device sector makes up over a third of the regional life science industry in Washington state, medical device companies have historically been, unintentionally, overlooked. Establishment of the Biomedical Device Innovation Zone, in part, remedied this situation by giving device firms an entity and regional industry cluster around which they could network and rally.

An economic impact study of the medical device cluster completed in 2008, as one of the organization’s initial initiatives, indicated that 48% of the Greater Seattle region’s medical device jobs and 72% of the industry’s gross business revenues are based within the IPZ boundaries.

Washington State Biomedical Device Industry Study, May 2008		
	<u>Bothell IPZ</u>	<u>Greater Seattle Region</u>
Number of Jobs	2800	5800
Number of Companies	18	108
Gross Revenues (2007)	\$1.8B	\$2.5B
Average wage/employee	\$84K	\$84k

Currently medical device companies make up 34% of Washington State’s life science industry with 301 companies in 64 cities. Washington’s medical device innovation ecosystem has produced a myriad of medical advances, ranging from advanced imaging technologies such as

ultrasound, tomography and MRI; to incredibly sophisticated implants. These technologies have shortened hospital stays, reduced the economic burden of disease, and saved and improved millions of lives.

V. BIOMEDICAL DEVICE MARKET OPPORTUNITY

The global medical devices industry is large, intensely competitive and highly innovative, with 2014 global sales hitting \$375.2 billion, a 4.1% annual growth rate over 2013, and worldwide sales forecasted to reach \$477.5 billion by 2020.

The United States remains the largest medical device market in the world with a market size of nearly \$110 billion, and it is expected to reach \$133 billion by 2016. The U.S. market value represented about 38 percent of the global medical device market in 2012.

There are more than 6,500 medical device companies in the U.S., mostly small and medium-sized enterprises (SMEs). More than 80 percent of medical device companies have fewer than 50 employees. Medical device companies are located throughout the country, but are mainly concentrated in regions known for other high-technology industries, such as microelectronics and biotechnology. The states with the highest number of medical device companies include California, Massachusetts, Minnesota, Georgia, Washington, and Texas.

U.S. medical device companies are highly regarded globally for their innovations and high technology products. Investment in medical device research and development more than doubled during the 1990s, and research and development investment in the domestic sector remains more than twice the average for all U.S. manufacturers.

The United States continues to command a leadership role in the global medical devices space, and an aging population and increased availability of healthcare as a result of the Affordable Care Act (ACA) should continue to keep the U.S. well positioned in the medtech space going forward.

With several growth constraints in the legacy markets, medical device companies will be aiming to expand into lucrative new markets. Expansion in the emerging markets, especially those with double-digit annual growth rates, represents one of the best potential avenues for growth in 2016 and beyond.

The biomedical device industry is unique among manufacturing industries because it is known for smaller quantities of individual products, but a wide range of product lines. Smaller companies generally develop individual products and devices, while larger companies remain competitive by using their core and proprietary technology to develop a complete range of products in various sectors to negotiate favorable deals with group purchasing organizations (GPOs).

Top-tier devices makers are expected to continue their merger/acquisition trend in 2016, especially as a means to enter new markets and diversify their portfolio. In 2015, total medtech

M&A deal values rose 166% to \$84 billion the first half of 2015 - characterized by mega-mergers.

VI. COMMERCIALIZATION OPPORTUNITIES

The Biomedical Device Innovation Zone is seeing a confluence of commercialization resources for the industry. For years the organization's providing these resources have been collaborating informally, to support individual small businesses.

In 2012 the IPZ, with the support of an Innovation Partnership Zones grant and a grant from the University of Washington, launched the Mercury Medical Technologies Incubator at the Lake Washington Institute of Technology in Kirkland. Since its founding, Mercury has hosted four startup clients: Aqueduct Critical Care, Monitor Mask, NaviSonics, and OtoNexus Medical Technologies. To date, these organizations have raised over \$7.5 million in funding. Three of the startups have graduated from the incubator and are now continuing to move forward with their commercialization efforts.

The entrepreneurial climate within the zone continues to strengthen and grow. The Biomedical Device Innovation Zone's Mercury Medical Technologies incubator has served as a catalyst to raise the formal cooperation amongst the various entrepreneurial support organizations for the medical device sector, and the opportunities for new partnerships continue to flourish. In addition, this has also attracted new program offerings to the region such as Bothell Startup Weekend HEALTH, the first Startup Weekend globally to focus on health including medical devices, healthcare IT, wearables, contract research organizations, health data and business intelligence innovations, pharma, payer-insurer technology, consumer health applications and nutrition.

The Biomedical Device Innovation Zone has nurtured interactions within the cluster, accumulating successful experiences and collaborations that provide the foundation for supporting future programs. Through Mercury and its ever expanding program offerings, the Innovation Zone hopes to raise the formal cooperation amongst various support organizations, in order to provide a more efficient and seamless experience for the entrepreneurs in the sector including partnership with:

- Lake Washington Institute of Technology's Design, Innovation, Research, and Technology (DIRT) Lab and Machine Technology Program;
- Washington Biotechnology & Biomedical Association's Washington Innovation Network (WIN) for Life Sciences Entrepreneur Mentoring Program;
- WINGS - The Washington Medical Technology Angel Network and its network of angel investors;
- University of Washington Bothell's Electrical and Mechanical Engineering student capstone projects;
- University of Washington's Master of Science in Biomedical Regulatory Affairs program practicum which requires students shepherd a new medical product through aspects of the regulatory affairs process;

- University of Washington's CoMotion Incubator programming,
- the Bothell Startup Weekend HEALTH organizer's future startup workshops, and
- the regional Society for Physician Entrepreneurs (SoPE).

With the state's strong public and nonprofit research Institutions, regional entrepreneurial spirit and deep industry executive experience, we have the potential to grow the medical device cluster through new company formation.

VII. ACCOMPLISHMENTS & FUTURE PROGRAMMING

The Biomedical Device Innovation Zone and its partners continue to meet regularly to promote cluster development through programs focused on improving industry branding, funding, networking, education/development and secondary industry support.

The Innovation Zone has conducted a number of industry studies including the Washington State Biomedical Device Industry Study in September 2008 that served to determine the economic impact of the industry on the broader community; a Machine Shop Survey in November 2008 that helped to identify organizations in the region that had either done prototype development work with the industry or were interested in doing so; and an annual Industry Outlook Survey focused on benchmarking regional industry trends including sales and hiring.

The Innovation Zone has also hosted a number of industry events including its annual Washington State Biomedical Device Summit. The event, which annual draws over 200+ registrants, is recognized as the premier regional forum highlighting trends and opportunities specific to the medical device industry. The organization also hosts a quarterly C-Level Roundtable that provides a medium for device executives to meet and discuss their business challenges, successes, and opportunities. Participants include executives from startup or small new-to-market firms, in addition to serial entrepreneurs.

In 2012 the IPZ launched the Mercury Medical Technologies Incubator featuring a rapid prototyping lab at Lake Washington Institute of Technology. Since its founding, Mercury has hosted four startup clients: Aqueduct Critical Care, Monitor Mask, NaviSonics, and OtoNexus Medical Technologies. Three of the startups have graduated from the incubator and are now continuing to move forward with their commercialization efforts.

Going forward the IPZ will continue to support Mercury's current incubator activities, while consolidating existing IPZ programming and events into the incubator and expanding programming to include:

- a web-based portal that will allow entrepreneurs and researchers statewide the opportunity to access streamed and archived content from future workshops, as well as partner resources including information on regional University engineering and regulatory capstone programs and internships;

- a SBIR applicant workshop series and supporting programming targeted at assisting medtech researchers and entrepreneurs with the application process to access the \$780 million in NIH SBIR/STTR grants available annually;
- a medtech entrepreneurship 101 workshop series based upon Stanford's proven BioDesign Medical Device Innovation Process and utilizing an experiential learning approach delivered by people who have been there in the marketplace as entrepreneurs and business leaders; and
- A robust fellowship program to include mentors, advisors and prospective investors to provide input and support for each of Mercury's current and future offerings.

In addition to expanded program content the Innovation Zone will review expanding Mercury's current revenue streams to include virtual incubator memberships, tiered workshop admissions, program sponsorships, and external grant funding to cover the ongoing cost for staffing and support.

These updates will serve to expand the support network and connection point for Washington's medical device companies throughout the state, resulting in a grow in number of startups, funds raised, and jobs created for the companies within the medical device industry.