BreakThrough Life Science Consulting

THE BRAVEHEART GROUP INC

AMERICAN CHAMBER OF COMMERCE IN POLAND

AMERICAN INVESTOR DESK

POLMED
OGÓLNOPOLSKA IZBA GOSPODARCZA WYROBÓW MEDYCZNYCH

Invites you to participate in our meeting entitled:

Establishing your medical devices through the FDA in the USA

The meeting will be held on June 22, 2021 at 3:00 p.m.

Participation is free of charge, registration available at the link below:

Register here

Topic of the meeting: Highlight the navigation process of the most challenging medical devices/areas on the U.S. marketplace (i.e., software, apps, LDTs).

Registration deadline: June 21, 2021, 4:00 p.m.

Event format: online meeting via the Webex platform. Link to the meeting will be forwarded to all registrants after the registration deadline in June 21.

Organizer: The meeting will be hosted by AmCham Poland's American Investor Desk program and POLMED in collaboration with BreakThrough Life Science Consulting, and The Braveheart Group, Inc.

Meeting scope: During the meeting, we would like to familiarize you with a brief overview of traditional U.S. pathways, software as a medical device (SaMD), mobile medical applications, laboratory developed tests (LDTs), quality systems, intellectual property issues, government contracting, and promotional claims and practices.

Meeting agenda

The following topics will be covered during the meeting:

01| **Brief Overview of Traditional U.S. Pathways**
- Classes I,II, II
- De Novo
- Examples of devices for each category

02| **Software as a Medical Device (SaMD)**
- Definition statement
- Risk characterization
- Regulatory pathway
- Machine learning / artificial intelligence
- Examples

03| **Mobile Medical Applications**
- What are mobile medical apps?
- Device software functions that are the focus of FDA oversight
- Software functions for which the FDA intends to exercise “enforcement discretion”

04| **Laboratory Developed Tests (LDTs)**
- LDTs defined
- Risk-based classification
- The impact of 23 & me
- Examples

05| **Quality Systems**
- FDA vs ISO 13485

06| **Intellectual Property Issues**
- Software
- Artificial intelligence

07| **Government Contracting**
- Registration requirements
- Access to contracts

08| **Promotional Claims and Practices**
- Impact on regulatory pathway

Speakers

Rick Proctor – Managing Partner

Rick Proctor has 30 years of experience in pharma, biotech, and medtech. Rick was a marketing and business development executive for GlaxoSmithKline, then became CEO of Glenveigh Medical, an obstetric company developing novel therapeutics (for severe preeclampsia) and devices (post-partum hemorrhage, vaginal repairs).

After selling the major assets of Glenveigh, Rick started a consulting firm, Breakthrough Life Sciences LLC, providing strategic, financial, and operating guidance to start-ups and emerging growth firms. His clients have included physician inventors, as well as companies in women's health, oncology, digital health, and consumer products.

Rick also serves as the Chief Strategic Officer of Nixxi, a company whose unique platform combines digital screening tools, remote patient monitoring, and telemedicine to revolutionize the identification and care of women at risk for pregnancy complications.

Rick earned his undergraduate degree from Emory University and has an MBA from Wake Forest. He has also completed professional development programs at the University of Michigan, Duke University, and The Wharton School. Rick was elected Treasurer and to the Board of Directors of the Preeclampsia Foundation for 3 consecutive terms.

Jeff L. Smith – President & CEO

Jeff Smith is the CEO and owner of The Braveheart Group, Inc., a consulting business focussed on the medical device industry. Jeff is a seasoned expert with over 30 years of global medical device experience in project management, product development, mergers/acquisitions, business integration, process improvement, quality/regulatory, start ups, business rescue and bankruptcy.

Prior to starting The Braveheart Group, Mr. Smith has previously held numerous operational positions with Baxter Healthcare, C.R. Bard, InterVascular Inc., Horizon Medical Products, Graham-Field, Windstone Medical, Norwood EyeCare and Glenveigh Medical. Jeff formed The Braveheart Group in 2004 and has since been leveraging his vast experience for the benefit of global clients.

Jeff is a former officer in the United States Air Force where he served as a navigator and radar navigator in B-52 aircraft. Mr. Smith received a Bachelor of Science degree in Economics and a Bachelor of Science degree in Business Administration from the University of North Carolina at Greensboro.

Application process to participate in the meeting

We kindly ask you to register via the Glue Up platform available at the link below:

*Your personal data will be processed under article 6.1.a, b or f of GDPR. Full details available at the following link: https://amcham.pl/american-chamber-commerce-poland-privacy-policy-information

*AmCham Poland's legitimate interest for the processing of your personal data is to maintain or establish business relations with you and to inform you about activities or other products or services that may be of interest to you.