

Mary E. Garrity, B.S., MBA

Mobile: 330-241-9492

marygarritymba@gmail.com

www.linkedin.com/in/maryegarrity/

Executive business leader and peer-reviewed, published neuroscientist possessing more than 15 years of successful translational biomedical life science research and analysis. Experienced in commercialization and marketing in the pharmaceutical, gene therapy and medical device industries internationally. Extensive experience in all aspects of successfully leading and growing companies.

Vast experience in market research, clinical business development, management, budgeting, strategic planning, ensuring proper regulatory FDA compliance, international government regulatory compliance, oversight of safety and quality requirements, obtaining funding, working closely with investors, leading early and late stage companies, go to market strategies, creating and executing business and marketing plans, oversight of intellectual property, increasing profitability, procuring investment and structuring and executing deals.

SKILLS AND EXPERTISE:

Neurodegenerative Diseases - Amyotrophic Lateral Sclerosis - Retroviral Vectors -
Neuroprotection - Multiple Sclerosis - Neuropathology - Neuromuscular Disorders -
Demyelinating Diseases - Deep Brain Stimulation - All General Research Lab
Techniques - Leadership - Pharmaceuticals - Biologics - Medical Devices - Gene
Therapy - Translational Research - Biomedical Startups - Venture Capital Investing and
Funding – Clinical Trials - FDA Regulatory Compliance including Internationally -
Intellectual Property - Philanthropic Funding

EDUCATION:

PhD Student

Clinical Translational Research

Case Western Reserve University
School of Medicine
Cleveland, Ohio

Masters Degree Business Administration

Case Western Reserve University
Weatherhead
Cleveland, Ohio

Bachelors Degrees Chemistry and Biology

Graduated Summa cum Laude
Ursuline College
Pepper Pike, Ohio

FDA Regulatory Affairs

Lehigh University

EXPERIENCE:**Senior Director Biomedical and Translational Sciences**

Case Western Reserve University

School of Medicine

10/2022 - Present

Cleveland, Ohio

Executive Biomedical Analyst

Foresight Science and Technology

6/2008 – 10/2022

Providence, Rhode Island

Executive Director of Business Development for a biomedical technology transfer and marketing firm that assists non-profits, government agencies, and the medical industry in bringing innovations to market

- FDA regulatory compliance
- Lead advisement, growth, and business development of hundreds of companies and technologies
- Successfully led bench-to-bedside strategies including all aspects of clinical trials, regulatory affairs, and strategic advancement
- Market assessments, business plans, sales growth, management of teams, competitive analysis, patenting, strategic commercialization, leading all aspects of analysis and translation of novel biomedical life science technologies, gene and cell therapies, pharmaceuticals and medical devices to commercialization
- Lead mentor to recent graduate students

Director of Business Development

BioEnterprise Corporation

5/2016 - 5/2017

Cleveland, Ohio

- Manage a portfolio of pharmaceutical and regenerative medicine companies at various stages of development from concept to commercialization in gene/regenerative therapy, pharmaceuticals, medical devices and biologics
- Director of strategic growth, development and oversight of clinical trial advancement and marketing in all life science companies including FDA regulatory compliance
- Collaborate with banking and private equity firms in procuring investment
- Advise independent physicians and inventors in all areas of commercialization of novel medical innovations
- Mine new companies to add to the pipeline from various companies, industries, healthcare facilities and universities
- Successfully develop and maintain developing business relationships with C-level executives, Board of directors, attorneys, bankers, and relevant parties.
- Lead mentor to teams of graduate students and interns

Consultant

Executive Director of Business Development

Neuralstem, Inc.

9/2015 - 5/2016

Emory University, Atlanta, Georgia

- Strategize market entry for Neuralstem, Inc. for a novel cannula and stereotax to be used in delivering stem cell lines, biologics and pharmaceuticals to the human spinal cord. (Currently in phase II clinical trials).
- Responsible for all aspects of business development including budget forecasting, ensuring appropriate FDA and MFDS compliance and manufacturing good practice
- Develop SOPs, post approval strategy, audit vendors and oversight of quality management systems

VP Business Development and Interim CEO

Operadora Clinica AHI of the Americas

9/2014 - 9/2015

Isla Mujeres, Mexico

- Direct company in collaboration with multinational government officials and key stakeholders in all business development efforts for a US physician in establishing regenerative medicine facilities in Cancun and Isla Mujeres, Mexico
- Collaborate with banking and private equity firms in procuring investment
- Responsible for all aspects of business development including oversight of regulatory compliance through COFEPRIS, marketing strategy, collaborating with executives, physicians and potential investors

Director Translational Research Program Biomedical Engineering

Case Western Reserve University

4/2006 - 6/2008

Cleveland, Ohio

- Inaugural director in the development of a program supporting and propagating the commercialization of life science and biomedical research technologies
- Grew program from \$1 million to \$5 million in the first year
- Responsible for up to \$15 million in funding commitments
- Oversight of licensing deals
- Lead many start-up biomedical companies based on various biomedical engineering technologies
- Regulatory compliance, venture funding, safety oversight, quality compliance,
- Grant/proposal writing and submission across multiple biomedical areas
- Assess technologies for commercial potential and strategically foster their development
- Oversee resource allocation, process design and manage accomplishment of project deliverables
- Administrative and financial oversight of project and department budgets
- Lead mentor to graduate students and interns

Project Director of Neurosurgery and Neuroscience Research

The Cleveland Clinic

1/2000 - 4/2006

Cleveland, Ohio

- Development of start up company based on deep brain stimulation technology
- Grant writing and submission for successful funding support
- Full range of laboratory skills in techniques focused on neurorestoration and neuromodulation in models of ALS
- Manage the successful initialization and continued growth of new research laboratories
- Oversee daily project operations, ensure regulatory compliance, oversight of clinical trials, strategic planning, and project execution
- Write and develop business plans including medical device concept valuation
- Manage fund allocation and expenditures including budget/personnel
- Productive in academic peer-reviewed funded research; published
- Establish and maintain relationships with investors
- Extensive experience in writing and submitting grants and scientific publications
- Lead mentor to graduate students and interns

Clinical Manager

Cleveland Clinic

1994 - 2000

Cleveland, Ohio

- Key individual in business development and opening new satellite offices, initial preparation and set up of laboratories, training, and oversight of new employees
- Clinical/office management of multi-specialty healthcare offices; experience with multiple healthcare policies
- Experience with physician and payer contracting, member services, payer relations, and finance
- General patient care and transitions of care

Internship

Cuyahoga County Coroner

1999 - 2000

Cleveland, Ohio

- Genetics research thesis and oral presentation of dissertation topic: DNA Extraction and Forensic Analysis from Various Substrates
- Assist in human autopsies, forensic analysis of evidence relative to many aspects of the investigation of cause of death

AFFILIATIONS:

Panel Moderator

Case Western Reserve University

The Midwest Biomedical Engineering Conference (MBEC)

Showcasing the Future of Biomedical Engineering

Panel Moderator

Case Western Reserve University

Industrial Advisory Board Conference

Development of Academic Pathways for Bringing Scientific Research from the Laboratory into Clinical Practice

Licensing Executives Society (LES)

The LES, established in 1965, is a professional society with more than 6000 members engaged in the development, use, transfer, marketing, and management of intellectual property.

Association of University Technology Managers (AUTM)

AUTM's global network of members represent more than 350 universities, research institutions, teaching hospitals and government agencies as well as hundreds of companies involved with managing and licensing innovations derived from academic and nonprofit research.

The Regulatory Affairs Professionals Society (RAPS)

RAPS is the largest global organization for those involved with the regulation of healthcare and related products, including medical devices, pharmaceuticals, biologics and nutritional products.

Member of Promise Partners Case Western Reserve University (CWRU)

Organization supporting the entrepreneurial community in Northeast Ohio for nearly 30 years founded by CWRU Weatherhead Professor Richard Osborne. The primary focus is helping individuals acquire businesses through entrepreneurship.

SELECT PUBLICATIONS

Mary E Garrity, Q Teng, Krudy C, et al. XIAP gene-based neuroprotection for the peripheral nervous system. *Neurosurgery*, July 2006; 59(1):172-182

Mary E Garrity, Q Teng, Boulis NM. Neuroprotective Adeno-Associated Virus Bcl-xL transfer in models of Motor Neuron Disease. *Muscle and Nerve*, Dec 2005; 32(6): 734-44.

Jonathan Riley, **Mary E. Garrity**, et al. Targeted spinal cord therapeutics delivery, *Stereotactic Functional Neurosurgery*. Mar 2008; 86 (2):67-74

Teng Q, **ME Garrity**, N Mazarakis, et al. Trophic activity of Rabies G protein-pseudotyped equine infectious anemia viral vector-mediated IGF-I motor neuron gene transfer in Vitro. *Neurobiology Disease*. Dec 2005; 20(3): 694-700.

Q Teng, **ME Garrity**, MJ Imperiale, et al. A novel peptide defined through phage display for therapeutic protein and vector neuronal targeting. *Neurobiol Dis*, Aug 2005; 19(3): 407-18.

Q Teng, **Mary E. Garrity**, KB Baker, et al. Adenoviral clostridial light chain gene-based synaptic inhibition through neuronal synaptobrevin elimination. *Gene Therapy*, Jan 2005; 12(2): I08-I9.

K Tanase, Q Teng, **ME Garrity**, et al. Cervical spinal cord delivery of a rabies G protein pseudotyped lentiviral vector in the SOD-1 transgenic mouse. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. *Journal Neurosurgery Spine*, Jul 2004; 1(1): 128-36.

Mary E Garrity, et al. Book Chapter. Molecular biology and gene therapy in the treatment of chronic pain. *Neurosurgery Clinics of North America*. 2003 14(3): 419-35.

Yang, Jun, Teng, Qingshan, **Garrity, Mary E.**, et al. 2007. Reversible Unilateral Nigrostriatal Pathway Inhibition Induced Through Expression of Adenovirus-mediated Clostridial Light Chain Gene in the Substantia Nigra. *Neuromolecular medicine*. 9. 276-84.

Garrity, Mary E., Baker, Kenneth, Quingshan, Teng, et al. 2007. Targeted microinjection of cells into the ventral horn of the spinal cord using a novel delivery system in pigs. *Stereotactic and Functional Neurosurgery*. 85. 34-35.

Garrity, Mary E., Teng, Qingshan, Yang, Jun, et al. 2006. X-linked Inhibitor of Apoptosis Protein Gene-based Neuroprotection for the Peripheral Nervous System. *Neurosurgery*. 59. 172-82.

Teng, Qingshan, **Garrity, Mary E.**, Yang, Jun, et al. 2006. Neuronal affinity of a C7C loop peptide identified through phage display. *Journal of drug targeting*. 14. 263-71.

Yang, Jun, Teng, Qingshan, **Garrity, Mary E.**, McClelland, Shearwood, et al. 2006. 240. Hemiparkinsonism Induced through Unilateral Expression of Adenovirus-Mediated Clostridial Light Chain Gene in the Substantia Nigra. *Molecular Therapy*.

Garrity, Mary E., Teng, Qingshan, Yang, Jun, Subramanian, Thyagarajan, et al. 2005. 1050. Adenoviral Clostridial Light Chain Expression in the Medial Forebrain Bundle: A Reversible Model of Dopamine Depletion. *Molecular Therapy – Molecular Therapy*.

Boulis, Nicholas, Yang, Jun, Teng, Qingshan, Najm, Imad Chabardes, Stephan, Moffit, Michael, **Garrity, Mary E.**, 2005. 890 Light Chain Gene-based Control of Neocortical Epilepsy. *Neurosurgery*. 57. 426-427.

Yang, Jun & Teng, Qingshan & **Garrity, Mary E.**, & Najm, Imad, et al. 2005. 433. Gene Therapy of Epilepsy by Adenovirus-Mediated Tetanus Toxin Light Chain Gene Transfer. *Molecular Therapy*.

Teng, Qingshan, **Garrity, Mary E.** & Yang, Jun, Kutner, Robert, Tordo, Noël, Reiser, Jakob & Boulis, Nicholas. 2005. 482. Neuronal Gene Transfer with HIV-1-Based Lentiviral Vectors Pseudotyped with Lyssavirus Glycoproteins. *Molecular Therapy*. 11.

Noordmans, Aaron & Parent, Nicole & Bhatia, Vikas & **Garrity, Mary E.** & Boulis, Nicholas. (2003). Rigid Postoperative Fixation for Pedicled Cranial Flaps: A Case Comparison. Journal of Prosthetics and Orthotics. 15. 27-30.

Teng, Qinshan & **Garrity, Mary E.**, & Azzouz, Mimoun & Walmsley, Lucy & Mazarakis, Nicholas & Boulis, Nicholas, et al. 2004. 735. EIAV-IGF-I Gene Transfer to Motor Neurons Enhances Axonal Length In Vitro. Molecular Therapy

SELECT COMMERCIALIZATION AFFILIATIONS:

Case Western Reserve University - Coulter Translational Research Partnership

Inaugural director of the Translational Research Partnership between Case Western Reserve and the Wallace H. Coulter Foundation which fosters collaborations between clinicians and biomedical engineers to facilitate commercialization of novel medical technologies enhancing patient care.

NeuralStem, Inc. now Seneca, has a lead stem cell therapy candidate for chronic ischemic stroke in phase 2 clinical trials. It is also focused on therapy in the clinical development for major depressive disorder.¹

Intelect Medical. Boston Scientific acquired Cleveland Clinic neuromodulation spinoff Intelect Medical, an innovative technology designed to advance deep brain stimulation therapy. “The transaction values Intelect Medical at \$78 million”.²

Lobesity, Inc. A Cleveland based biopharmaceutical company utilizing anti-GIP, a monoclonal antibody to treat obesity and is being developed at The Metro General Health System.

Operadora AHI Medical Clinic of the Americas. A stem cell therapy clinic being formed in Isla Mujeres, Mexico by physicians focused on treating musculoskeletal maladies utilizing autologous stem cells.

¹ BizJournals: https://www.bizjournals.com/washington/news/2019/10/29/local-biopharma-rebrands-as-part-of.html?iana=cp_news_link

² Newswire: <https://news.bostonscientific.com/news-releases?item=59292>