Dr. Ediuska Laurens, EngD; M.S.

Biomedical Engineer. Medical Device Product Dev., Regulatory & Quality Compliance

Details

Phone

716-228-0465

Email

ediuska@geniusshield.io

Skills

FDA 21 CFR 820 Quality System Regulation

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ISO 13485:2016 Quality System Medical Devices

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510(k), Technical File Regulatory Submission

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Leadership Skills

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Excellent Communication Skills

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Adaptability

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Microsoft Office

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Links

LinkedIn

Languages

English

Spanish

Profile

Biomedical Engineer Consultant and Expert Witness in Medical Device Product Development, Regulatory Compliance, and Quality Assurance. Accomplishments include the development and regulatory clearance of bioresorbables, bone cements, and distraction technologies in the USA and EU. Inventor and patent holder of two craniomaxillofacial technologies. Experienced with pediatric implants and hydrogel biomaterials for tissue engineering and orthopedics (spine, cartilage repair). Developer and investor of emerging medical technologies that serve vulnerable populations (e.g., women's health, pediatric, etc.). Published author and frequent speaker.

Education

Doctor of Engineering, Cleveland Clinic Foundation - Cleveland State

May 2009

Biomedical Engineering - Biomaterials

Master of Science, State University of New York (SUNY) at Buffalo

May 2005

Mechanical Engineering - Biomaterials

Bachelor of Science, State University of New York (SUNY) at Buffalo

May 2003

Aerospace Engineering

Professional Experience

Founder & CEO, Genius Shield LLC

Nov 2018 — Present

Genius Shield is the neurotransmitter between SCIENCE and INDUSTRY, translating ideas into viable, compliant, global medical solutions. We shield early stage medical device companies from the risks and liabilities of the compliance process, through product development, quality, and regulatory expertise, which are essential to get to market. We also perform technical and regulatory due diligence on medical device innovations for investors (VC's, Angels, Incubators, Accelerators) educating and advising on the viability of a potential investment.

- Successfully helped clients to get their medical devices to market through Regulatory and Quality compliance services: FDA Q- Submissions, Regulatory Plan & Strategy, Regulatory Submissions (510(k), De Novo, Technical File etc.), Product Registrations, Quality Management System implementation (ISO 13485:2016, QSR 21 CFR Part 820), Design Specifications, Risk Management, Clinical Evaluation.
- Managed team of five Regulatory/Quality/ Product Development experts that come from the top Fortune 500 medical device companies.
- Subject Matter Expert: craniomaxillofacial and neural implants & instruments, biomaterials, hydrogel biomaterials, tissue engineering and regeneration, orthopedics, spine, FDA & EU regulation, medical device quality assurance.
- Provide Expert Witness services to both plaintiff and defense counsel in biomedical engineering, FDA regulations, product manufacturing and safety, medical devices, medical device regulations, quality management systems.
- Genius Shield is a Women Owned Certified business.

Senior R&D Project Manager , Stryker Craniomaxillofacial

Jan 2011 — Oct 2018

Stryker is one of the world's leading medical technology and Fortune 100 companies, which offer innovative products and services in Orthopedics, Medical and Surgical, and Neurotechnology and Spine that help improve patient and hospital outcomes

- Advanced from Biomaterials Project Engineer to Project Manager to Senior Project Manager.
- Led a global cross-functional team focused on customer centered design principles, regulatory, quality, operations and marketing to drive high quality Bioresorbables, Distraction, and Bone Cements medical solutions to market.
- Successfully managed, developed, acquired regulatory clearance, and globally commercialized:
- ***The Stryker DirectInject Bone Cement, which won the Stryker Innovation Award and generated over $3 M revenue right after launch.***
- ***The Stryker Delta Bioresorbable System that immediately contributed to the system's growth from $500K to $6-7M yearly.***
- ***The first Stryker Pediatric Mandibular Distractor, fulfilling a great need for Cranioplastic surgeons and their patients.***
- ***The Stryker Pediatric Mandibular Distractor 2 that is the second generation of this technology with an anti-reverse mechanism and as a sterile version to fulfill global and regulatory market needs.***
- Successfully innovated and acquired two patents in bioresorbable and distraction technologies, respectively.
- Received the Stryker Patent - Innovation Award 2017 as inventor of the Stryker Pediatric Mandibular Distractor.

Research Engineer - Post Doctoral Fellow, Cleveland Clinic Foundation Lerner Research Institute

Sep 2005 — Dec 2010

The ***Cleveland Clinic Foundation*** is the No. 2 Hospital in the nation and the Lerner Research Institute is home to all laboratory-based, translational and clinical research at Cleveland

Clinic with the mission of understanding the underlying causes of human diseases and developing new treatments and cures.

- Assessed the mechanical properties of Tyramine Crosslinked Hydrogel Biomaterials as a potential implant to replace the nucleus pulposus in the spine to treat degenerative diseases of the spine.
- Contributed to the development of a biocompatible tyramine- substituted hyluronan hydrogel technology, licensed by Lifecore Biomedical, for a wide range of clinical applications such as knee cartilage and spine repair, dura sealants, derma fillers, opthalmic, tissue engineering, etc.
- Contributed to the MRI field by using T1 & T2 mapping and creating a hyaluronan and collagen hydrogel phantom system that allow accurate monitoring of the changes in concentration induced by loss of glycosaminoglycans and collagen in cartilage, which are critical osteoarthritis treatment.

Research Assistant, State University of New York (SUNY) at Buffalo

May 2002 — Aug 2005

Center of Biosurfaces

- Developed a method for photo-crosslinking Human Wharton's gel in the presence of Eosin Y dye as a novel potential tissue engineering system.
- Assessed the viscoelastic properties of polyvinyl alcohol (PVA) hydrogels and their suitability as spinal intervertebral disc replacement.

Toshiba Stroke Research Center

- Designed laser induced fluorescence system that enabled monitoring blood flow and measuring the flow field effect of placing a stent in the aneurysmal portion of a curved vessel.

Oral Diagnostics

- Developed a method for early detection of calcified carotid arteries using panoramic dental x-rays that could help providing on time treatment to patients.

Inventions

Issued Patent US2014/0148812A1

"Pediatric Internal Mandibular Distractor" Inventors: Ediuska Laurens, Stephen Harris, Nathan Gorentz.

Issued Patent US2015/0297273A1

"Delta Panels with Countersink" Inventors: Stephen Harris, Ediuska Laurens, and Julia Zelenkova.

Invention Disclosure R-5941

"Method of Wet Bonding of Tissue to Mineral, and Resultant Prostheses– filed on July 8th 2004. Inventors: Ediuska Laurens and Robert Baier.

Publications

Laurens, E; Schneider, E; Vinalski, CS; Calabro, A. **A Synthetic Cartilage Extracellular Matrix Model: Hyaluronan and Collagen Hydrogel Relaxivity, Impact of Macromolecular Concentration on dGEMRIC**. Skeletal Radiology. 41(2) 209-17, 2012.

Laurens, E; Darr, A; Dave, N; Calabro, A. **Analysis and Biomechanics of Tyramine Cross-Linked Hyaluronan Hydrogels.** Journal of Biomechanics. 41: S235, 2008.

Laurens, E; Kayanja, M; Darr, A; Mills, R; Lieberman, I; Calabro, A. **Mechanical Testing of Crosslinked hydrogels for Nucleus Pulposus Replacement.** Journal of Biomechanics. 40:S272, 2007.

Laurens, E; Holand, K; Baier, R; Spernyak, J; Muzurchuk, R. **Customized Spinal Disc Prosthesis with Glass- Ceramic Annulus and Human Wharton's Gel Nucleus Pulposus.** Proceedings, 24th Canadian Biomaterials Society Conference (May 26-28, 2005; Waterloo, ON) pp 129-130, 2005.

Conferences Presentations

Cracking the Code: The Four Critical Questions for Breaking into the US Market in the Age of Artificial Intelligence. Laurens, E. **Maryland Technology Council's CRTC & BRC Healthcare Technology Forum: An evening at Johns Hopkins Hospital MISTIC (Surgey).** September 2024, Baltimore, Maryland.

Femtech Regulatory Landscape. Laurens, E. **Femtech & Consumer Innovation Summit 2024.** May 2024, Hasbrouck Heights, New Jersey.

MedTech and the Future of Medicine Panel. Laurens, E. **Maryland Tech Council - Chesapeake Regional Chapter**. August 2023, Annapolis, Maryland.

Medical Device Product Development. Laurens. E, **Swissnex Fostering Equity in Women's Health**. November 2021, New York, New York.

Thera-NOS. Laurens. E, **Fem Tech Focus Summit**. May 2021, New York, New York.

Medical Device Product Development. Laurens. E, **Fem Tech Focus Summit**. May 2021, New York, New York.

Biomechanics of Tyramine-Crosslinked Hydrogels. Laurens, E; Darr, A; Dave, N; Calabro, A. **The International Society of Biomechanics Congress (ISB) 2009**. July 5th - 9th 2009, Cape Town, South Africa.

Tyramine-based Hyaluronan Hydrogels for Nucleus Pulposus Replacement Characterization by Magnetic Resonance Imaging. Laurens, E; Montgomery, V; Vinalski, C; Schneider, E; Vasanji, A; Gilbertson, L; Darr, A; Calabro, A. T**he North American Congress of Biomechanics (NACOB) 2008**. August 5th - 9th 2008, Ann Arbor, Michigan.

Analysis and Biomechanics of Tyramine-Crosslinked Hyaluronan Hydrogels. Laurens, E; Darr, A; Dave, N; Calabro, A. **The European Society of Biomechanics (ESB) Congress 2008**. July 6th - 9th, 2008, Lucerne, Switzerland.

Mechanical Testing of Crosslinked Hydrogels for Nucleus Pulposus Replacement. Laurens, E; Kayanja, M; Darr, A; Mills, R; Lieberman, I; Calabro, A. **The International Society of Biomechanics (ISB) Congress 2007**. July 1st - 5th, 2007, Taipei, Taiwan.

Mechanical Testing of Dityramine Crosslinked Hydrogels for Nucleus Pulposus Replacement. **53rd Annual Meeting of the Orthopedic Research Society (ORS).** February 11th - 13th, 2007, San Diego, California.

Customized Spinal Disc Prosthesis with Glass-Ceramic Annulus and Human Wharton's Gel Nucleus Pulposus. Laurens, E; Holand, K; Baier, R; Spernyak, J; Muzurchuk, R. **The 24th Canadian Biomaterials Society Conference.** May 26th - 28th, 2005, Waterloo, Canada.

Mechanical Properties of a Hydrogel Based Prosthetic Intervertebral Disc. Laurens, E; Baier, R. **The Hulbert Conference "Bioengineering with Glass-Ceramics"**. July 23rd - 24th, 2004, Buffalo, New York.

Affiliations

Regulatory Affairs Professional Society (RAPS)

International Society of Biomechanics (ISB)

Served as Economically Developing Countries Champion

Corporate Member, Women's Health Innovation Coalition

May 2020

Women's Health Innovation Coalition helps drive innovation, investment, and research in women's health. We are a coalition of innovators, investors, clinicians, analysts, and executives with the shared goal of advancing innovation in women's health.

Advisor , Springboard Enterprise

May 2019

Springboard is an expert network of innovators, investors and influencers who are dedicated to building high-growth technology-oriented companies led by women. Our programs and initiatives are how we source, qualify, advise, showcase and support the most promising businesses seeking capital or partnerships for product development and expansion.

Venture Fellow Partner, FundRX

Apr 2018 — Mar 2021

FundRX is an early stage venture capital firm exclusively focused on health, which backs entrepreneurs inventing novel therapeutics, designing the next generation of medical devices, pioneering new technology for providers and risk bearers, and bringing new clinical care models and wellness products to consumers.

Awards & Honors & Accomplishments

Created Clinical Gait Analysis Laboratory in Venezeula

Established the second Clinical Gait Analysis Laboratory in my home country of Venezuela, aimed at benefiting patients and advancing biomechanics within the region.

First Latina Elected as Student Rep. to International Society of Biomechanics

First Latina elected as the Student Representative to serve on the board of the International Society of Biomechanics following a global vote.

2020 STEM Women in a S.T.E.M. World Award

Women's History Month at Cleveland State University

Women and Girls in Science Assembly at the United Nations

Invited Guest Only Assembly

Guest Lecturer at Columbia University Department of Biomedical Engineering

"Medical Device Product Development and Regulatory Compliance"

Stryker Patent Innovation Award 2017

Panelist at ISPE –Women in Pharma Infuencing Change and Promoting Growth

Sponsored by Johnson & Johnson

Med In Ireland Conference

International Leader Guest at the invite-only Ireland's largest medical technologies event sponsored by Enterprise Ireland in Dublin, Ireland

Forum on Women's Leadership and Panel Discussion

Invited guest-only. Sponsored by the Irish Consulate in New York, New York.

Scientific Reviewer of "Biomaterials and Medical Devices"

International Society of Biomechanics (ISB) Congress in Brussels, Belgium.

"Zero Power Smart Fashion Wearable Sensors and Green Energy" Symposium

Invited guest to Zero Power Smart Systems Initiative EPFL and ETH Zurich and Swissnex Boston in New York, New York.

Travel Grant Award The International Society of Biomechanics

Doctoral Dissertation Research Award Cleveland State University

Graduate Student Travel Award Cleveland Clinic

National Honor Society Award Phi Eta Sigma

Dean's List University at Buffalo