Ediuska LAURENS

Ediuska Laurens M.S., Dr. Eng
Just your average Aerospace/Mechanical/Biomedical Engineer looking for ways to save humanity!

Demystifying the Regulatory System to Bring Visionary Medical Devices To Market

Want to wake up your audience with a speaker who has an infectious obsession with the tedious topic of the regulatory process?

"Ediuska is a very enthusiastic, unique, and inspirational speaker with high level insights. She is an excellent role model of women in the science/ engineering industry. She had the room hanging on her every word"

Shannah Falcone,
Director, Strategic Accounts CRB

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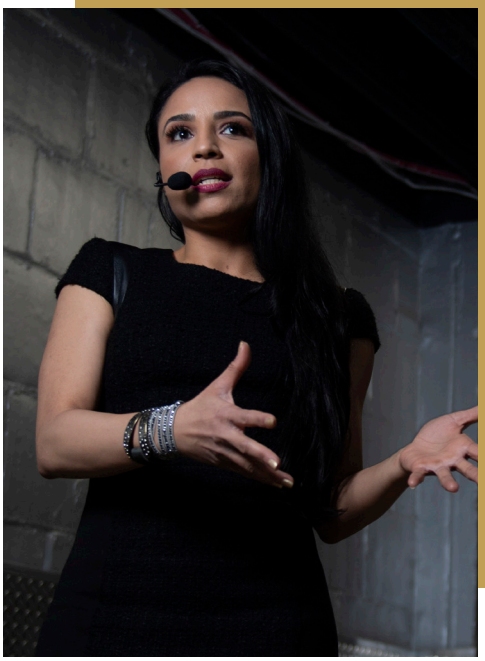

ABOUT

Ediuska Laurens brings her expertise of medical device product development/regulatory/quality to inventors, entrepreneurs and investors with big ideas and no clue what they are really in for when it comes to getting their inventions through FDA approval to market.

Ediuska Laurens is herself also an inventor and patent holder of 2 craniomaxillofacial technologies, and an expert in craniomaxillofacial reconstruction (bioresorbables, bone cements, distraction), pediatric implants, and hydrogel biomaterials for tissue engineering and orthopedics (spine, cartilage repair).

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Available for: Keynotes, Panel Discussions, Podcast Interviews

POPULAR TALK TOPICS

What Happens When You Don't Know What *They* Know

New entrepreneurs don't know what questions to ask, or how to even begin navigating regulation and medical device product development. How do you vet a regulatory plan? How will you assess suppliers? How likely is it that your Quality Management System will result in an FDA violation? (Answer: *extremely* likely!) Learn the essentials of what it takes to navigate this process the right way, the first time.

Theranos: Hay Dios Mio!

The signs were there all along, if only someone was watching. This talk takes you through the infamous product development and investment catastrophe, and what entrepreneurs and investors can learn from everything that they did wrong in their design-product development process.

The Sexiest Medical Device Product Development Presentation Ever

Learn from the Masters: Case Study of the product development of the Pediatric Mandibular Distractor and how you can use it to improve your own process.

Indications for Use: The Heart Of Everything!

The indication for use is critical and needs to be well crafted as it dictates the device's risk classification and therefore establishes all the regulatory requirements that you need to follow. Yet few entrepreneurs even know what it is. Learn what it takes to do this right.

Keep Your V's Straight If You Want FDA Approval: Verification vs. Validation*

People tend to get Verification and Validation (V&V) confused, especially if you are new. It is essential to have a strong V&V plan and execution as this is the information that will be submitted to FDA and evaluated for product approval. Gain clarity around these topics and what a strong V&V plan really takes.

Avoid The Recall: Design Specification & Risk Management*

75% of FDA recalls are due to design, in large part due to the confusion around user needs versus design inputs. This, plus an inadequate V&V, can not only lose you time and money, but can result in a business-crushing recall down the line. This talk breaks down the confusion and provides a road map to getting it right the first time.

Can be talk or workshop.

PRAISE

"Ediuska is a passionate, dynamic, and engaging speaker with high level insights which she translates into simple and easily understood ideas for an audience with a wide range of experience."

- Matthew Snyder, Project Manager | CRB

"Ediuska is the real deal: she brings a deep level of knowledge and understanding to the table yet is a master of simplifying the ideas for an audience with a wide range of experience."

- Loren Busby, Venture Capital & Private Equity Investor

"Ediuska gave a guest lecture in my course on product development and regulatory requirements for medical devices. The students appreciated her real-world experience and she shared key learnings for students interested in pursuing careers in the medical device industry."

- Katie Reuther, Senior Lecturer in Design, Innovation, and Entrepreneurship at Columbia University

CONTACT INFO

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