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Alessio Giuliani

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PRESENTAZIONE

Senior level innovator and adaptive leader with over fifteen years of experience maximizing sales and revenues through agile development invention and bringing innovative, next-generation and prosthetic medical devices and products to market. Transforms ideas into projects and innovative products by leading Regulatory Affairs and R&D efforts in the fields of MedTech, Orthopaedics, and Nanomedicine. Transforms new ideas into net income growth opportunities by leveraging team, expertise in R&D, project management, and product innovation. Quickly achieves marketplace dominance by delivering industry-breaking solutions and wellness to patients across the globe.

Serves as a trusted advisor and technical liaison to executives, management teams, organizational partners, and relevant staff. Cultivates strong relationships with doctors and clinical staff. Transforms underperforming individuals into dedicated teams focused on aggressive goals by coaching employees and inspirational leadership. Consistently delivers successful outcomes during times of rapid change, crisis, uncertainty, and unique challenges. Fluency in English and Italian. Additional Competencies include:
- Bold Product Innovator
- Ortho/MedTech Systems Expert
- Medical Device Development
- Competitive Insight Analysis
- Quality Management Improvements
- Product Management & Marketing
- Stakeholders Management
- Scientific Marketing & Communications

ESPERIENZA LAVORATIVA

ATTUALE Milano, Italia

DIRECTOR - REGULATORY AFFAIRS CLOVER ORTHOPEDICS

Clover Orthopedics, Milan, ITA 2020-Present
Director - Regulatory Affairs | Head of Transition MDR – European Union (2020-Present)
Reporting directly to the CEO, leads and oversees a team of direct reports including regulatory affairs, post-market clinical surveillance employees and consultants. Holds full responsibility for regulatory affairs, compliance, and accreditation of all biological and mechanical testing efforts, both internally and through external supplier partnerships. Holds full accountabilities for all clinical studies and post-market follow-up and surveillance in support of the MDR transition. Designs and implements strategic plans for securing CE mark, thus leading product innovation programs within the company

- Mitigated significant “at-risk” revenue loss by serving leading the development and strategic plan execution to overcome regulatory, political, government and healthcare related challenges pertaining to the global Steril Milano fraud crisis.
- Achieved a €4.5 million turnover during the above timeframe by leading a successful certification initiative of a portfolio of 10 products.

2012 – 2020 Milano , Italia

DIRECTOR - REGULATORY AFFAIRS AND PMO SINTEA FACTORY SRL

Directs a team of five people, while leading large-scale, multimillion-Euro projects and programs. Provides strategic leadership to achieve R&D objectives. Directs regulatory affairs efforts to ensure that all products are produced and marketed legally, in-country and internationally. Manages three to five critical development projects each year, bringing innovative new concepts in spine and orthopedic products to market. Serves as liaison between R&D teams, doctors, and other clinical professionals. Consistently achieves on-time and on-budget results by prioritizing workflow while empowering team members and leading to a successful launch of 7 new products onto the market. Reported to CEO.

- Saved €90k by achieving a 50% duration reduction while directing eight new medical devices through a CE certification project. Successfully led a team through the uncertainties of the COVID lockdown period.

- Delivered a 40% duration reduction. Obtained 100% certification of special medical device manufacturing processes in six months.
- Achieved a smooth transition, from Sintea Plustek to Sintea Factory, by handling CE and FDA products certification transfers.

Initiated, planned, executed, monitored, and controlled the development of an innovative shoulder prosthesis, large scale EU-funded projects, and nanomaterials-based products. Managed relationships with key clinical opinion leaders and crucial stakeholders. Covered functions of Regulatory Affairs Director. Served as liaison between all the company's functions, suppliers, clinical opinion leaders, and customers, leading a group of 20 people. Reported to CEO.

- Achieved €6 million in new commercial contract business, growing shoulder product sales 42%, by heading development of a patented mini-invasive anatomical shoulder prosthetic system.
- Created €1 million in potential revenue by cultivating a clinical group of surgeons to endorse a newly developed shoulder prosthesis.
- Influenced approval of a €1.5 million regional research fund by leveraging personal network partners, collaborating and identifying unfulfilled needs in the MedTech sector, setting goals and coordinating stakeholders' efforts to prepare and submit the proposal.
- Successfully coordinated a €7.3 million large-scale project: *"Symbionica, a reconfigurable machine for the new additive and subtractive manufacturing of the next-generation fully personalized bionics and smart prosthetics".*
- Invented and patented a "*Multifunctional Prosthesis with Multilayer Covering and Method of Producing Thereof"* valued at $1 million.
- Grew shoulder prosthesis revenues to €150,000 in just one year by enabling 40% cut in surgery time through inventing and patenting "*Guide for the anatomical resection of a humeral head, resection kit and method of resection of a humeral head"* in EC.
- Produced an internal rate of return of 32% and approximately €1.2 million through a 35% reduction of surgery time by researching and developing an inverse/reverse shoulder prosthetic system.

2005 – 2012 Milano, Italia

R&D MANAGER, PRODUCT MANAGER SINTEA PLUSTEK

Manager - R&D - Sintea Plustek **(2009-12**); ***Product Manager - Shoulder Prostheses, Sintea Plustek*** **(2005-08)**
As R&D Manager, led and directed all aspects of projects and programs for a medical device manufacturer, providing strategic leadership in achieving R&D objectives and compliance with regulatory affairs. Leveraged expertise in mechanical engineering to manage three to five new development projects each year, bringing innovative new concepts in orthopedic products to market. Reported to CEO. As Product Manager, served as liaison between R&D teams, doctors, and other clinical professionals. Promoted shoulder products by educating company's customers on the features that make them stand out from the competitors. Reported to Marketing & Sales Director.

2004 – 2005

PROJECT MANAGER TEXO GROUP

TEXO Group, Pescara, ITA 2004
Provides industry-leading lifting systems solutions to the automotive sector.
Project Manager
Led the development of a new car lifting system. Bridged the gap between engineering, marketing, and sales departments, working directly with customers to bring new products to market. Coordinated a group of eight in identifying customers' needs, creating relevant technical specifications for marketing and technical office, and collaborating with customers on project progress and support during and after lift installation. Reported to Marketing Director.

- Enabled a €500,000 sale to BMW by launching an innovative car lifting system, quickly establishing a proficient relationship, identifying client needs, and delivering product specifications to the internal technical department.
- Secured €800,000 in US Rotary orders, a hydraulic vehicle lifting systems company, through very attentive customer service during the pre- and post-development phases of the product development.

2003 – 2003 Merate, Italia

PRODUCT MANAGER PERMEDICA

Permedica SPA, Merate, ITA 2003
Medical device manufacture including orthopedic implants and instruments.
Product Manager

Led scientific and technical training for a knee replacement system while serving as a liaison between clinical opinion leaders and the engineering division of a medical device manufacturer. Notable responsibilities: presenting product features to doctors and distributors; assisting doctors in the operating room; organizing technical workshops at major medical conferences; responding to public tender; keeping product technical documentation up to date; scouting for new market opportunities; and identifying gaps and implementing solutions related to competitors' products. Reported to Marketing & Sales Director.

- Generated approximately €100,000 in revenues by ideating and developing a new unicompartmental knee system.
- Grew revenue another €600,000 by successfully assisting a targeted group of doctors.

ISTRUZIONE E FORMAZIONE

Durham, UK, Regno Unito
MASTER OF BUSINESS ADMINISTRATION – MBA DEGREE Durham University

Cranfield Bedfordshire, UK, Regno Unito
MASTER OF SCIENCE DEGREE IN NANOMEDICINE Cranfield University

Kaiserslautern, DEU, Germania
POSTGRADUATE STUDIES IN NANOBIOTECHNOLOGY Technische Universitat Kaiserslautern

Ancona, Italia
MASTER OF SCIENCE DEGREE IN MECHANICAL ENGINEERING BACHELOR OF SCIENCE DEGREE IN MECHANICAL ENGINEERING Università Politecnica Delle Marche

ULTERIORI INFORMAZIONI

PUBBLICAZIONI

"The Impact of Nanomedicine on Rotator Cuff Lesions: A Future Outlook – 2016
The Impact of Nanomedicine on Rotator Cuff Lesions: A Future Outlook. In: Gumina, S. (eds) Rotator Cuff Tear. Springer, Cham.

Giuliani, A., Chianella, I., Gumina, S. (2017)

1D Nanostructures for Sensing Purposes, Smart Nanomaterials for Sensor Application – 2012

Alessio Giuliani, Yi Ge

Biomeccanica di Spalla e Gomito nel Paziente in Carrozzina – 2011
Timeo

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