JOHN H. SMITH, Ph.D.

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EXECUTIVE MANAGEMENT: R&D, ACADEMIA BIOTECHNOLOGY, CELL & REGENERATIVE THERAPY

Visionary, driven, and skilled executive with core strengths in biotechnology R&D, business and market development, strategic planning, alliance building, and regulatory compliance. An accomplished scientist adept at developing communication channels and serving as SME on Cell and Regenerative Therapies at a global level. Holder of 3 patents for inventions related to cell biology and cell cultures. Highly skilled leader with extensive scientific background and outstanding communication, project management, and product development attributes. Multilingual: English, Russian, Ukrainian, and some French.

Results-focused analyst with the proven ability to align highly technical and complex scientific information with key corporate, revenue, and brand messaging goals. Capable and proficient mentor and instructor. Undeterred when faced with conflicts, challenges, or interruptions in operations, with the knowledge and skill to look beyond the obvious and solve difficult problems. Confidence to take a stand based on sound reasoning and thorough analysis. Easily builds affinity and trust with people from all backgrounds, age groups, and life circumstances. Follows code of ethics and protocol; highly accountable.

Core Competencies

Early Stage Discovery Research and Pre-Clinical R&D Programs • GMP (Good For Manufacturing)
 Regenerative Medicine • Cell Therapy • Market Research • Product Development • R&D • Business Planning
 Business/Product Valuation • Scientific Data Interpretation • Scientific Communication • Regulatory/Procedural Compliance
 Executive Presentations • Relationship Building • Alliance Management • Team Building • Mentoring • Reporting

PROFESSIONAL EXPERIENCE

MEDICINE CONSULTING LTD., Tampa, FL

2012-Present

Director, Founder

Spearhead all aspects of consultancy service, commercialisation, business development, regulatory compliance, and global business growth and development. Deliver expertise-based consultancy services for biotech companies; devise a go-to-market/commercialization strategy for biotechnology, biomedicine research, and products development. Acquire and cultivate relationships with business partners for R&D and product commercialisation initiatives. Integrate innovative biotechnologies through careful research and review. Strategize on working with fledgling departments, different governmental/regulatory systems, and resource optimization/allocation.

Key Accomplishments & Highlights:

- Serve as specialist of the Russian market, focusing on assessment of R&D product commercialization potential, developing of a commercialization strategy, coordinating clinical trials on xenotransplantation, cell and regenerative medicine therapies.
- Liaise with regulatory body to develop a strategy for a clinical trial registration, to source medical centers and registered CRO. Seamlessly navigate the Russian clinical trial market. Oversee clinical trial registration, their funding, processing and preparation of custom documents and visas..

ALIVE CELL HIGHLIGHTS, Tampa, FL

2001-2012

VP, Head of Research & Development (2011-2012)

Directed R&D operations related to regenerative medicine/cell therapy technologies, delivering expertise on product development and cell-based therapies for metabolic disorders, diabetes, haemophilia, acute liver failure, Parkinson's disease, and other neurodegenerative diseases. Led strategic planning, research goal development, and product safety management.

Key Accomplishments & Highlights:

- Successfully converted regenerative medicine/cell therapy/tissue engineering technologies from R&D to GMP.
- Finalized the preparation of the cell therapy products for dinical trials.

Regional Director, (2003-2011)

Quickly promoted from virology laboratory manager developing new molecular diagnostic methods for zoonotic pathogens to this role of increasing authority. Developed a Russian-based business providing regional support for company core technologies; outsourced medical bases for the clinical trial. Served as liaison to the Russian Ministry of Health representatives. **Key Accomplishments & Highlights:**

- Successfully established a daughter company—BIOBiomedical—supporting regional operations in Russia. Led product registration and technology certification.
- Championed a dinical trial on diabetes treatment with DIABECELL.
- Directed and led the application for residency in the prestigious President's Fund Skolkovo; applied for government grants within the Skolkovo Fund.

Head of Molecular Diagnostics (2001-2003)

Established and maintained the world's 1st registered xenotransplantation medical molecular diagnostic laboratory.

- Formulated microbiology risk assessment and risk management strategies for xenotransplantation.
- Represented the company in xeno-product safety matters in discussions with the regulatory bodies. Sourced a herd of pigs that were pathogen/virus free, attaining permission despite controversial regulatory environment.

SWISS HOSPITAL, Tampa, FL

1998-2001

Scientific Officer, Virology & Immunology Lab

Managed a project on pig endogenous retrovirus as a safety concern for xenotransplantation. Structured and developed new assays for molecular diagnostics. Devised screening processes for donors and recipients of xenografts.

EARLY CAREER:

ERLab, Swiss Hospital, Tampa, FL

Medical Laboratory Scientist, Virology & Immunology Lab

Histology Department, Swiss Hospital, Tampa, FL

Staff Technologist

Rehabilitation of Victims of the Chemobyl Disaster, London, England **Head of the Biomedical Research Department**

CD Research Institute, UK Academy of Science, London, England

Research Officer, Research Assistant

ADDITIONAL EXPERIENCE

SWISS LTD., Tampa, FL

2003-Present

Director, Founder

Conceptualised, developed, and launched a uniquely formulated skin care line. Designed several other skin care lines for clients in compliance with their specification including "all-natural" product concept. Chief leadership of all aspects of sales/marketing, business development, client relationship building, and online presence for this cosmetic company. Aligned business model with strategic plans to elevate and grow business from start-up to profitability. Delivered scientific expertise and interest in prolonging cell life to drive science and research.

Key Accomplishments & Highlights:

Integrated expertise and scientific acumen to deliver an original know-how to design cold preparation of emulsifier-free products for high-end skin care market

EDUCATION & CREDENTIALS

Ph.D., Oncology/Biochemistry

UK Academy of Science, CD Research Institute, London, England

Dissertation thesis: "Pathways of Protein Complexing and Its Change Associated With Tumour Growth"

The New Zealand Qualification Authority has assessed this qualification as an equivalent to a doctoral degree (Qualifications Assessment Report, 21 February 1996).

M.S., Biochemistry (Honours)

State University, London, England

Project. "Extraction, Purification, Characteristics of Double-Stranded RNA of Tumour Cells"; high marks.

Published peer-reviewed papers – full list available upon request

PROFESSIONAL AFFILIATIONS

American Microbiology Society Transplantation Society International Xenotransplantation Association