

# JOHN H. SMITH

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## CHIEF EXECUTIVE OFFICER

High-profile biopharmaceutical executive in the stem cell technology arena, with global impact and influence. Currently driving leading innovator ranked among top 5 of all cord blood banks worldwide.

Revenue builder. Launched 1<sup>st</sup> RNS Asian-centric stem cell bank for \$9 million. Integrally contributed to raising entire corporation's value from \$45 million to \$150+ million.

Patent holder. Conceptualized, marketed, and commercialized this technology worldwide, winning FDA registration and becoming registered license holder. Directed several high-tech, scientifically sophisticated, socially conscious biotech organizations.

Dynamic liaison to ministries, governments, hospitals, academia, and funders. Willing to relocate for right opportunity.

- ◆ Cellular Therapeutic Operations
- ◆ Global Corporate Operations
- ◆ Scientific Strategic Planning
- ◆ Scientific R&D Collaborations
- ◆ Product Portfolio Enhancement
- ◆ Marketing & Commercialization
- ◆ International Regulatory Affairs
- ◆ FDA, FTA, OSPA, FCRT, ASAB, and IRN
- ◆ Intellectual Property Management
- ◆ Global Organizational Expansion
- ◆ Clinical Laboratory Operations
- ◆ cRNS/cPRT Facility Design & Operations
- ◆ CELL Analysis & Effectiveness

## PROFESSIONAL EXPERIENCE

### UNITED HEALTH GROUP; Tokoyo, Japan

2011 to Present

*Stem cells bank; new United Health Group venture launched in 2006.*

#### **Chief Executive Officer** (2012 to Present)

Advanced to this role to provide new leadership, strategically guiding organization to enhance shareholder value and expand across the Asia and Europe. Scope encompasses global marketing and commercialization, as United Health Group seeks Center of Excellence status, a designation that will solidify United Health Group in Asia's long-term strategy to raise its profile in the medical tourism arena, specifically regarding stem cell technology and cellular therapy. Stewarded business' successful transition of ownership from original 4 investors to Asian Foundation in March 2013.

- ◆ Directed launch of 1<sup>st</sup> RNS Asian-centric stem cell bank, a \$9-million, 3-year initiative. Sourced 85% of materials and technical professionals outside Japan, to uphold quality and maintain global regulatory compliance.
- ◆ Elevated United Health Group's global presence, leveraging FDA registration to showcase the business' position as the sole FDA-registered site in Asia's history.
- ◆ Capitalized on United Health Group's election for the top 5 of all cord blood banks worldwide, accepting invitation to deliver keynote address at the Global Stem Cell Congress.
- ◆ Became the registered license holder for United Health Group under the Human Tissue Group and the Supreme Office of Health.

#### **Chief Operating Officer** (2011 to 2012)

Directed global corporate operations, which encompassed organizational expansion, research collaborations, corporate partnerships, and product portfolio enhancements within regulatory compliance. Traveled to viable new markets across the Asia and Europe to evaluate government and regulatory structures and cultivate relationships with officials.

- ◆ Instrumentally contributed to positioning United Health Group for sale to Asian Foundation by valuating the company, composing the business plan, and documenting potential synergistic relationships within Japan.
- ◆ Raised United Health Group's international profile by delivering presentations in the Europe and Canada, and serving on Global Association of Blood Bank Groups, to contribute to development of industry regulations.
- ◆ Instituted cord blood processing innovations across several countries, sharply focusing on technologies to manufacture higher product volume in less space, while maintaining quality standards.

- ◆ Elected to be an author of Japan's Lab Strategy Document, initiative of the Supreme Office of Health and the State of Japan.

**Director of Operations** (2009 to 2011)

Ensured standards of quality aligned with requirements of Supreme Office of Health in Japan, German Human Tissue Group, and other international regulatory agencies. Integrally contributed to scientific, technical, and business development and managed operational budgets and regulatory compliance for all United Health Group operations.

- ◆ Propelled corporate valuation from \$40 million to \$150+ million, largely by driving strategy in collaboration with the senior executive team.
- ◆ Directed the design, build, and launch of new cRNS facility 5 months ahead of schedule. Managed regulatory compliance, validations, and budget. Defined processes and protocols for efficient, compliant lab operations.
- ◆ Became Designated Individual to Asian's Human Tissue Group; transitioned complex legal and regulatory responsibilities to internal function.

**GOLD MEDICAL ASSOCIATIONS, INC.; San Francisco, CA**

**2007 to 2009**

*Global leader of tissue-based diagnostic solutions for patients worldwide; member of the RN Health Group.*

**Senior Manager, Detection & Chemistry Assay Development**

Delivered \$140 million+ in new annual revenue by principally guiding global product strategy—from concept to commercialization—for diagnostic, multi-component, biologically based reagent products. These reagents accounted for 35%+ of all annual corporate revenue. Defined program direction and objectives. Oversaw development, manufacturing, marketing, software, quality, regulatory, and project teams.

**PHARMA (CELLULAR DIVISION); San Francisco, CA**

**2001 to 2007**

*High-growth division of \$2+ billion biopharmaceutical company engaged in the development and manufacture of pharmaceuticals, immunotherapeutics, stem cell technologies, tissue and placental products, and cord blood banking.*

**Director of Operations**

Coordinated cellular therapeutics operations, which encompassed managing product portfolio of 18,000+ clinical tissue-based manufactured products, 30,000+ clinical cord blood products, and 4,500+ placental products. Directed business and scientific strategic planning, and clinical operations for amniotic membrane-tissue manufacturing. Coordinated medical affairs with transplant physicians. Secured new donor agreements with hospitals in 5 states. Mentored Ph.D.s, M.D.s, Production Managers, and Senior Technicians. Managed \$30-million budget; held P&L accountability.

- ◆ Instrumentally contributed to rollout of new tissue products projected to generate \$7+ million within 4 years: BioCell™ and Visiogene™ for ocular repair.
- ◆ Doubled tissue production and manufacturing output in 3 months by streamlining business/laboratory processes and restructuring staffing schedules.
- ◆ Managed the design, FDA validation, and testing of three patented IT solutions. Managed the redesign and reconstruction of four tissue and cord blood collection and transportation kits.
- ◆ Led donor product-procurement processes for U.S. operations; managed early stages of placental stem cell characterization, trained staff on new blood separation techniques, and controlled rate-freezing processes.
- ◆ Managed \$500K redesign and build-out project of cRNS/cPRT facility. Achieved \$300K cost reduction in annual laboratory operations by creating new collection kit.

**HORIZON VESSELS REGISTRY & INTERNATIONAL GENE FOUNDATION; Los Angeles, CA** **1995 to 2001**

*World leader in cord blood stem cell banking.*

**Associate Laboratory Director / Director of Processing & Storage**

Directed all aspects of operations and managed P&L. Oversaw business administration, QP/QT, purchasing, productivity, staffing, workflow design, IT, risk management, and client relations in a 24-hour environment within for-profit and not-for-profit business structures. Hired, trained, and mentored team of 30 professionals including Medical Director, Senior

Medical Technicians, and laboratory personnel. Served as liaison to scientific and academic community members regarding company contracts, GRTs, EMERG contracts, public relations, and regulatory matters.

- ◆ Drove corporate culture change to align with transition from research-based initiatives to a clinical blood processing and storage company.
- ◆ Increased client-per-employee processing ratios from three to thirteen per day by streamlining laboratory procedures, upgrading staff training, and improving motivation strategies.
- ◆ Delivered \$180K+ in operational cost savings via successful supplier negotiations, process improvements, and outsourcing solutions.

**EDUCATION**

**M.S. in Cytogenetics;** STATE UNIVERSITY; Vestal, NJ  
**B.S. in Biological Sciences;** GEORGE WASHINGTON STATE UNIVERSITY; Washington, DC

**TRAINING**

- ◆ HPN Designated Individual Training
- ◆ StemCell & VisioGene Stem Cell Technologies
- ◆ Hematopoietic Progenitor Assay, Stem Cell Technology
- ◆ Blood-Borne Pathogens Risk Mgmt, State University
- ◆ Laboratory Safety Training, State University
- ◆ Radioactive Materials – State University
- ◆ HRNS – StemCell Corporation
- ◆ OPHD – State University
- ◆ CBSC – United Health Group

**CERTIFICATIONS**

**Inspector,** Foundation for Accreditation of StemCell Therapy | **Inspector,** College of Medical StemCell | **Assessor,** RNSPHD

**COMMITTEES**

<b>Asia Foundation,</b> Elected Chair of Japan’s Institutional Biosafety Committee	2012 to Present
<b>RNSPHD Elected Committee Member,</b> StemCell Studies Standards Program Unit member	2011 to Present
<b>Parents’ Guide to Placental Foundation,</b> Regulatory and Technical Advisory Panel	2010 to Present

**AFFILIATIONS**

- ◆ Genetics International Society
- ◆ Global Society of Human Cellular Study
- ◆ Global Society for Stem Cell Research
- ◆ Global Society of Quality Assurance
- ◆ International Association of Blood Banks
- ◆ International Society for Quality
- ◆ Regional Cord Blood Resource Center
- ◆ International Association of Blood Banks

**PATENTS**

*Complete list available on request*

Brandon F. Smith, Brian S. Cord, Bill H. Clendrick, and Bill Floyd, “Systematic Process for Providing a Cord Blood Bank”, Issued Jan. 23, 2001: US 300406879841.

Bill H. Clendrick and Denise Kurt, “Stem Cell and Cord Blood Collection Kit”, Issued Mar. 14, 2010: US 3012600567898.