RONALD J. TEDESCO

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MEDICAL DEVICE TECHNOLOGY EXECUTIVE

High-energy, innovative and hands-on leader with a proven record of accomplishment in driving medical device development strategy & implementation, cultivating strong teams and realizing development programs for commercial successes

PROFESSIONAL EXPERIENCE

MICROBEDX, Inc., Palisades, CA [a privately-held startup borne from UCLA scientists and UCI engineers with disruptive molecular technology to 'Redefine Antibiotic Informatics'] **2018**

Chief Product Development Officer *(Product development halted due to lack of funding)*
R&D leadership role to outline and implement strategy for new product development:

- **Built core development team** and formed alliances with reliable partners for immediate launch of development
- **Drove molecular diagnostic RNA/DNA assay development** onto consumable for milestone investor funding
- **Developed commercialization profile** for instrument and consumable architecture
- **Established R&D teams with FDA compliance** goals for 21 CFR Part 820 and IEC 13485
- **Drafted Project Plan and Design Inputs** for compliant Design History File

BIT USA [formerly SOURCE SCIENTIFIC, LLC], Irvine, CA BIT Group, Schwalbach, Germany is a privately held OEM developer & manufacturer of medical devices worldwide [a division of Messer, Bad Soden, Germany] **2009 - 2018**

Vice President of U.S. R&D, [2016-2018]
Led PMO and five functional departments to architect, plan and execute OEM R&D projects for global med device companies:

- **Expanded Systems Engineering function 2.5x** to respond to US technology trend toward Molecular Diagnostics
- **Improved Business Development effectiveness 50%** by deploying systems engineering team to support BD
- **Chief Technology Officer & Primary Systems Architect** for client solutions and business development proposals
- **Invested in internal AR/VR technologies** to improve new client acceptance, visualize existing product development trade-offs and to develop recurring after-sale revenue model
- **100% improvement of project transparency** by internally developing electronic Scrum system with real-time population of LN project data to project teams

Vice President, Project Management & Systems Verification [2013-2016]
Implement development strategy for reliability testing, quality engineering, regulatory compliance, hardware & systems verification functions for large-scale projects:

- **Created 35% improvement to on-time phase gate reviews** by staffing highly-effective hardware & systems verification, test engineering and regulatory compliance departments
- **Improved project efficiency by 25%** by implementing Scrum metric dashboard for integration, verification & development FMEAs
- **Reduced design transfers to production by 35%** by integrating industrial engineering planning and streamlining test strategy within the development process
- **Achieved 200% expansion of new BIT Platform chemistry and immunochemistry systems** by pre-architecting existing "white label" designs for market growth offerings
- **Created PMO project transparency** by establishing global C-Level project reviews monthly
- **Decreased client escalations by 70%** by implementing monthly Executive Steering Committee reviews for all projects
- **Reduced resource conflicts on projects of 90%** by creating R&D Resource Allocation Table, employee metrics and establishing monthly management review process
- **Improved training compliance 100%** by created onboard training on R&D Process, Project Management Tools, FDA 21 CFR 820.30, Risk Management (ISO 13485) and Verification Processes in first 45 days

Vice President, Diagnostics Project Management [2012-2013]
Developed and directed Project Management Office for BIT USA, serve as system architect for client solutions, map new development programs:

- **Improved project portfolio P&L by 15%** by developing project performance index for US project portfolio
- **Improved software development transparency 100%** by implementing Agile Scrum dashboard for project portfolio
- **Improved Platform component reuse 50%** by developing and publishing roadmap for BIT Platform systems, Platform subsystems and technical library for strategic reuse
- **Improved regulatory compliance by 50%** by redefining product development processes, procedures and work instructions for mid- and large-scale device development and FDA QSR Part 820 Design Controls
- **Improved Risk Management by 40%** on projects by focus & training of project management & engineering leaders on IEC 13485 Risk Analysis and FDA Design Control 21 CFR 820.30

Project Manager, Diagnostics Development [2009-2012]
Directed, planned, managed and delivered bi-continental development project (US & Germany) for German client; first product developed for BIT's new Platform strategy:

- **Successful design transfer of all new IA/CC system** with unique hybrid assay scheduler for integrated chemistry & immunochemistry assays, including polynomial, linear, endpoint and kinetic math models
- **Delivered BIT's first full instrument development**; first full system internally-developed for manufacturing transfer and strategic reuse
- **Winner of 2014 Medical Device Excellence Award** (MDEA) for the client
- **Delivered 'BIT Platform' technologies (HW & SW) for strategic reuse**; platform technologies include: thermal, mechanical, electrical, software and optical subsystems designed for reuse and capitalized as BIT IP
- **Piloted Agile Scrum Process** for SW Development

BECKMAN COULTER, INC., Brea, CA [a $3B public company serving instrumentation, reagents and supplies to life science and clinical markets worldwide – currently a $7B+ division of DANAHER, Inc.] **Career start to 2009**

Global Director, Systems Technical Support, Systems Engineering and Current Business [2006-2009]
Directed global product support for Chemistry, Immunochemistry product portfolio for an $800M Diagnostics division:

- **Drove 27 product design improvements** on flagship Clinical Chemistry analyzers (LX20, DxC600/DxC800), improving system field performance, reduced after-sale costs and improved customer satisfaction
- **Eliminated 10% of US emergency calls** by developing and implementing 45 remote applications and trigger thresholds for ProService™ remote diagnostics initiative
- **Successfully root caused 5 global fielded CAPAs** by developing unique diagnostic tools for field: fiber optic tester, STAT chemistry video capture designed to identify early warning evidence of fielded quality issues

Associate Director, Sustaining Engineering - Clinical Chemistry and Immunochemistry Platforms
Senior Manager, Technical Support & Technical Applications Groups - Lab Automation
Manager, Sustaining Engineering - Clinical Chemistry' Immunochemistry, Gel & Capillary Electrophoresis Platforms
Project Engineer - Clinical Chemistry, Immunochemistry & Capillary Electrophoresis Platforms
Sr. Systems Development Engineer, Chemistry Systems – Spectrophotometry & Electrochemistry
Field Service Engineering National Specialist – Clinical Chemistry Systems

EDUCATION / TRAINING / MEMBERSHIP

Master of Business Administration, Keller Graduate School of Management, Chicago, IL
Master of Project Management, Keller Graduate School of Management, Pomona, CA
Bachelor of Science, Electronic Engineering, DeVry University, Chicago, IL
Member Board of Advisors, California State University, College of Engineering, Biomedical Engineering, Fullerton, CA
Breakthrough Leaders, Executive Leadership & Management training program, Beckman Coulter

ADDITIONAL TECHNICAL FEATURES

Medical Device Development | Project Management | In-Vitro Diagnostics | Molecular Diagnostics | FDA Design Control
Agile Scrum | Chemistry & Immunochemistry | Clinical Lab Automation | Technical Support | After-Sale Service | CLIA
ELISA | Fluorometry | Nephelometry | Chemiluminescence | Turbidity | ISE | Photometry | Capillary Electrophoresis