MANISH AHUJA

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Chief Executive Officer

22 years of experience in leading and managing the development and commercialization of devices in the fields of *in vitro* diagnostics, laboratory instruments, neurosurgery, gastroenterology, neuro and peripheral vasculature, OB/GYN, human anesthesia and analgesia, orthopedics, image guidance technology, bone biopsy, soft tissue biopsy, interventional pain management, and trauma. Knowledge and expertise of working under the regulatory framework of the FDA, Health Canada, MDR, ISO, and IEC standards. Proven track record scaling CDMO operations, launching incubated ventures, forming strategic partnerships, and improving EBITDA through operational excellence, quality leadership, and disciplined portfolio management. Trusted leader with board-facing presence, and a hands-on approach to culture, talent development, and customer outcomes.

- Team Building & Motivation
- Clinical Trials
- ISO 13485:2016
- IEC 60601-1
- Management & Leadership
- Project Management
- CE Marking
- IEC 61010-1
- Process Automation
- Regulatory Strategy
- Incubation/Acceleration, governance
- cGMP
- Risk Management

MS in Mechanical Engineering and Design – The University of Texas at Austin, Austin, Texas (2005)

BS in Mechanical Engineering – Indian Institute of Technology, Delhi, New Delhi, India (2001)

Professional Experience

Biotex, Inc. – Houston, TX August 2010 – Present

Chief Executive Officer (February 20125 – Present)

- Oversee the development and commercialization of over twenty electromechanical, software-driven, and optics-based medical and laboratory devices.
- Lead an integrated platform providing end-to-end MedTech services: design & engineering, prototyping, verification/validation, regulatory support, GMP manufacturing, packaging/labeling, warehousing, and global order fulfillment—while operating an internal incubator/accelerator for new ventures.

Chief Technology Officer (September 2018 – Present)

- Manage Engineering, Quality, Regulatory, Marketing, Testing Services, and Network Administration departments
- Management Representative and Lead Auditor of the company's operations
- Lead architect of highly customized cloud-based proprietary electronic Quality Management (eQMS) and Manufacturing Execution System (MES) to digitally transform the entire company's operations, including purchasing, invoicing, proposal management, project management, document control, training, inventory tracking, supplier control, manufacturing, warehousing, and order fulfillment.
- Developed Testing Services department from the ground up through hiring of personnel and acquisition of equipment

Director of Engineering and Product Development (May 2015 – August 2018)

- Leading and managing a team of twelve engineers to develop all the medical devices manufactured by Biotex.
- Overseeing the development of more than 10 medical devices in various franchise portfolios
- Designing an updated website and managing business development activities
- Architected second-generation Upper Esophageal Sphincter assist device for reducing acid reflux by adding telemetry functionality via Bluetooth Low Energy. Managed mechanical design, electronics hardware, firmware implementation, and iOS and Android application development.
- Spearheaded development of second-generation oropharyngeal and esophageal pH monitoring device and engineered cloud-based solution for real-time sensor data acquisition. Architected HIPAA compliant web application for clinician access.
- Drafted, prepared, filed and secured 510(k) premarket notification with the FDA for cranial drill

Product Development Manager (August 2010 – April 2015)

- Proposed, designed, and developed cost effective single-use cranial drill compatible with stereotactic guidance tools to broaden the company's portfolio in the neurosurgery domain

- Led the development of product family consisting of reusable and disposable manual neurosurgical guides
- Draft, prepared and filed 510(k) premarket notification for neurosurgical guides
- Architected, designed, and prototyped a laboratory device for the detection and screening of various disease markers based on the principle of backscattering interferometry.
- Designed, engineered, prototyped, and tested an innovative Bluetooth-enabled temperature gradient hybridizer for DNA microarray incubation. The device can be remotely controlled and monitored via a PC or Android mobile device, in addition to an onboard touch display.
- Developed an Android tablet-based solution for purification of proteins and nucleic acids by continuous-elution electrophoresis.
- Explored the integration of a peristaltic pump with a flow meter into Visualase, a laser-based tumor ablation system
- Engineered, developed, and prototyped a safe and effective non-invasive device that includes a catheter and an embedded controller to provide permanent female sterilization via tubal occlusion.
- Coordinated with NRTL to get EMC certification on multiple devices
- Interfaced with NRTL to get three medical devices successfully tested for electrical safety per IEC 60601-1 3rd edition
- Managed and coordinated sterilization, biocompatibility, packaging, and performance validations of various medical devices.

Ansh Labs LLC – Houston, TX February 2009 – July 2010

Director of Engineering

- Developed, produced, assembled, and demonstrated luminescence reader having Bluetooth and orbital shaking capabilities in a very low footprint
- Established a complete regulatory framework for compliance with FDA and other regulatory agencies
- Proposed, conceptualized, modeled, fabricated and tested four plate orbital shaker for providing uniform mixing of reagents
- Extended the designs of already developed products to create a novel orbital shaker having temperature control, Bluetooth and automation friendliness
- Investigated various partners to integrate standalone devices into an automation platform thus providing a complete immunoassay solution
- Cooperated and developed relationships with various Chinese suppliers to procure cost-effective device components, including but not limited to motors, printed circuit boards, membrane switches, injection molded, and CNC-machined parts

MINRAD Inc. (A Piramal Healthcare company) – Orchard Park, NY July 2006 – February 2009

Director, Device Engineering (April 2008 – February 2009)

Conscious Sedation, Laryngoscope, and Image Guidance products

- Promoted to lead multiple project teams to develop and support all medical devices manufactured and marketed by MINRAD
- Supervised the Conscious Sedation design team to develop a drug delivery system to provide pain relief without the loss of consciousness
- Prepared 510(K) application for Conscious Sedation and Light Sabre™ radiofrequency needles

Director, Image Guidance Engineering (July 2007 – March 2008)

SabreSource™ targeting system and Light Sabre™ products

- Led two SabreSource™ and three Light Sabre™ engineering teams to conceptualize, design, develop, and support single-use fully disposable products comprising surgical drill, liver tumor ablation, syringes, pain management, bone biopsy, and soft tissue biopsy needles
- Explored symbiotic partnership with a potential C-arm manufacturer for navigation integration with the fluoroscope
- Supported the regulatory department in clinical trial efforts on image guidance products
- Envisioned, designed, and developed Light Sabre™ Spinal Access Device for bone biopsy and percutaneous spine procedures
- Successfully filed Spinal Access Device 510(K) application with FDA

Director, Image Guidance Engineering (July 2006 – June 2007)

SabreSource™ laser guided targeting system

- Turnaround SabreSource™ product line by streamlining production, thereby dramatically improving performance, quality and reliability

- Enhanced marketability by redesigning key aspects of SabreSource™ and by adding innovative features, thereby infusing new life into complete image guidance product line
- Reduced SabreSource™ manufacturing costs by as much as 15%
- Managed and supervised two image guidance project teams of six engineers
- Supported real-time image guidance production by resolving engineering and quality issues
- Collaborated with key vendors to ensure timely delivery of quality components
- Designed, developed, tested and launched six SabreSource™ models to cover more than 80% global market share of C-arm fluoroscope models.

Beckman Coulter – Webster, TX May 2004 – June 2006

Project Manager (July 2005 – June 2006)

Temperature controlled orbital shaker for ELISA assays

- Managed and headed a team of three engineers for building prototype of standalone temperature controlled orbital shaker
- Performed theoretical and experimental analysis to determine design and technical requirements of incubator/shaker

Mechanical Engineer (May 2004 – June 2005)

Integration of Tecan automation platform with luminescence reader

- Developed scheduling algorithm for ELISA assays using Artificial Intelligence techniques and established its optimality over other commercially available schedulers
- Devised evaluation strategy and conducted thorough user testing of luminescence reader beta product
- Prepared integration framework for luminescence reader assembly with Tecan automation platform
- Created operations document for offshore projects
- Conceptualized robotic arm design for integrating standalone instruments

Sapient Corporation – New Delhi, India May 2001 – July 2003

Associate, Technology

Delivered business value to various clients using technology solutions

- Established testing strategy and testing cycles for Offender Information Management System (Client: Texas Department of Criminal Justice), a web based solution for tracking offenders on parole
- Built development and production infrastructure of **cingular.com** (now AT&T) refresh B2C site, which provided new solution architecture
- Elicited customer requirements while working at TDCJ and Cingular client locations for 6 months
- Developed framework and caching strategy for **bp.com,** a project to merge the then existing 32 websites into one consistent bp.com

Patents

- Ahuja, Manish; Houssiere, Charles; Gowda, Ashok; Patwardhan, Ravish, “Access Device”, **U.S. D874,648 S**
- Ahuja, Manish; Kheradpir, Leila; Dupont, Kyle Richard; Jankowski, Jakub; Phillips, Jessica; Houssiere, Charles; Gowda, Ashok, “Shunt Stylet”, **U.S. D870,271 S**
- Ahuja, Manish; Houssiere, Charles; Gowda, Ashok, “Surgical Drill”, **U.S. 10,383,640 B2**
- Ahuja, Manish; Gowda, Ashok; McNichols, Roger J; Houssiere, Charles; Patwardhan, Ravish, “Stereotactic access devices and methods”, **U.S. 10,219,873 B2**
- Ahuja, Manish; Gowda, Ashok; McNichols, Roger J; Houssiere, Charles; Patwardhan, Ravish, “Stereotactic access devices and methods”, **U.S. 9,901,400 B2**
- Ahuja, Manish; Houssiere, Charles; Gowda, Ashok, “Surgical Drill”, **U.S. D784,537 S**

Technical Skills

Programming Languages	C/C++, C#, Java, Python, JavaScript (Angular framework), Lisp
Hardware	Assembly Level Language Programming (Intel 8085, Motorola MC68HC11), PLC, Microchip PIC, PicoBlaze, Texas Instruments MSP430,
CAD Software	SolidWorks
3D Simulation Software	Roboworks
Business Intelligence	Tableau, Microsoft Power BI

Software Development	Atlassian JIRA, Bitbucket, Confluence, Bamboo
IDEs	Xilinx ISE, Microsoft Visual Studio 2019, Eclipse
Operating Systems	Windows 7, 8.1, 10, Mac, Android, iOS
Other Software	Microsoft Office, Project, Visio, Adobe CC (Photoshop, Illustrator, InDesign, Flash, AIR)