# RAGHBIR SINGH (RAVI) BHULLAR

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**Quality Executive • Global Program Manager • Process Improvement Executive • Consultant • Product & Process Development Executive • Business Development Executive • Technology Executive**

## PROFILE

Talented and accomplished technology, quality and business management professional with special expertise in product and process design and implementation, product manufacturing, supplier quality, purchasing controls, device complaint handling process and project management. Proven ability to facilitate corporate growth through the effective leadership of business and technology initiatives. Adept at strategy development, best practices, process performance improvement, organizational change management, and streamlining. Consistent record of success in delivering innovative new products and intellectual property for employers, with over 115 patent applications and 30+ US patents granted. Excellent leadership, communication, and problem-solving skills.

Technology Management • Product Design • Manufacturing • Research & Development • Process Design & Performance Improvement •Intellectual Property Management • Process Automation • FDA QS Regulation • Supplier Quality Management • Lean Initiatives • Supply Chain Operations • Best Practices • Project Management Road-mapping • Purchasing Controls • Negotiations • Technology Implementation Cost/Budget Control • Leadership • Strategic Planning & Execution • Streamlining • Benchmarking

## PROFESSIONAL EXPERIENCE

RAVIBHULLAR, Indianapolis, IN — Feb 2009 – Present

**Founder and Principal Consultant**

Founder and principal consultant of this consultancy specializing in project roles for medical device manufacturer and pharmaceutical companies in the following areas:

- FDA compliant Non-Conformance management, Deviations, purchasing controls, global supplier quality & development including quality assurance (extensive experience in managing and executing remediation or work stream activities related to 483 citation, Recall or Consent Decree)
- CAPA/SCAR system management per FDA's QSR requirements
- FDA (QSR) compliant medical device complaint handling business process
- Process Performance Improvement (business & technical)
- Supply chain improvements (diagnostic, analysis and recommendations)
- Biosensor (disposable strip) technology manufacturing resolution, development & transfer
- Manufacturing process & technology development, qualification and validations per cGMP (IQ, OQ and PQ)
- Risk Management initiatives for medical devices (Hazard Analysis, Use FMEA, DFMEA, PFMEA, Risk Controls)
- Due-diligence (product, process & supply chain)

Currently assigned to Consent Decree remediation activities in Production & Process controls, Purchasing Controls and Supplier Quality for Terumo Medical (Cardiovascular Systems), Ann Arbor, MI. Terumo products are used in cardiac surgeries in over 160 countries.

ROCHE DIAGNOSTICS, Indianapolis, IN — 1992 – 30 Jan 2009

**Manager, Strategic Business Initiatives** (2007-30 Jan 2009)

Internal consultant at $4B+ medical diagnostics manufacturer, reporting directly to President. Charged with evaluating existing supply chain processes and industry supply chain trends and leaders. Member of Supply Chain Transformation team responsible for developing & delivering best practices, associated technologies, including lean supply chain roadmap.

- Saved $600,000 per year in shipping of products manufactured in Puerto Rico by eliminating shipping to, and storage at, US warehouse. Migrated process to direct shipping from manufacturing site to customers, to manage finished goods inventory without additional touches or movements.
- Delivered recommendation projected to save >$3.1M in less than 2 years by implementing centralized transportation planning function for domestic and international shipping.

Tasked to deliver FDA complaint, most cost effective, end-to-end device complaint handling business process.

- Led and created "to-be Future State" end-to-end device complaint handling process introducing RFID in cross-functional team per 21 CFR 820.198.

Tasked to co-ordinate and transfer a novel technology base low cost blood analyzer from a start-up company in Finland to well established Roche Instrumentation group in Rotkreuz, Switzerland.

- Led a multi-disciplinary executive team of Finish and Swiss expert to delivered (tech transfer) product platform plan on novel technology to launch low cost, decentralized blood analyzer with the goal to expand revenue stream and market share.

**Manager, Supplier Quality & Development (Supply Chain)** (2005-2007)

Promoted to oversee resolution of supplier quality issues and obtain FDA compliance for purchasing controls (21 CFR 820.50), including procurement, supplier selection, evaluation, and supplier quality including Corrective And Preventive Action (CAPA) and SCAR management (21 CFR 820.100). Managed procurement process, procurement and supplier quality records management, supplier audits, and Lean & 6 Sigma initiatives. Supervised 5 source development engineers and 3 source compliance consultants across 2 teams.

- Led successful supplier remediation project that eliminated pre-existing 483 FDA citations and remediated 80% of all supplier records, including 100% of high-risk records. Supervised 8-person team.
- Directed project to create electronic database of all supplier records. Coordinated file location, scanning, and labeling effort that saved company $80,000 per year in costs caused by delays in finding files.
- Reduced time required for purchase requisition approval from 1 week to 2 days, and eliminated backlog of approvals, by migrating Purchasing requisition categorization process to centralized team.
- Assumed control of Supplier Quality Board and implemented changes that resulted in shorter times required for company to make decisions regarding ongoing supplier issues. Managed outstanding CAPAs to bring closure.
- Proposed and lead supplier quality improvement initiatives for critical component suppliers across the globe.
- Improved productivity and performance levels by initiating group evaluations of new hires. Also increased productivity and quality by implementing cross-training of personnel.

**Principal Engineer, Discovery, Process R&D** (1998-2004)

Coordinated multi-disciplinary, international teams in developing, discovering, and enabling innovative technologies to improve company's competitive edge. Investigated and resolved issues for scientists. Performed physical and structural analyses of competitors' products. Developed new process technologies. Worked closely with technical and scientific partners in academia, industry, and institutions worldwide. Administered $250,000 - $1.2M in annual R&D budgets. Created significant intellectual property. Supported cGMP regulation 21 CFR 820.30 for Design Controls.

- Directed team of US and German scientists and engineers (tech development & transfer) in revolutionizing company's manufacturing platform for diabetes test strips by introducing patented laser ablation manufacturing technology. Product launched with 6 Sigma Quality internationally in 2005 and has facilitated over $1B in sales.
- Provided company with potential to save up to $20M per year by replacing adhesive based sealing with patent-pending laser sealing technology.
- Delivered patented organic light emitting diode-based biosensor, giving Roche competitive edge.
- Filed numerous patents and assisted patent attorneys in patent prosecutions.
- Recommended building prototype pilot facility to rapidly test biosensors, eliminating months of testing.

**Principal Engineer, Product & Manufacturing Process Design & Development** (1994-1997)

Coordinated multi-disciplinary teams in conceiving, developing, and enabling innovative production technologies to fulfill company's new product commercial launch criterion. Conducted process validations (IQ, OQ and PQ). Worked closely with technical and scientific partners in academia, industry, and institutions worldwide to understand & solve manufacturing problems. Administered $10 M in project budgets.

- Directed team of internal and external resources to design, develop, test, qualify and validate various production technologies (converting) for successful commercial launch of disposable bio-sensor. For example:
    - Hot melt adhesive dispensing, coating and slitting (Lean & 6 Sigma Project)
    - High speed sensor punch and packing (6 Sigma Project)
    - High speed labeling technology (Lean & 6 Sigma Project)
    - High speed mesh slitting technology (Lean & 6 Sigma Project)
    - High speed dispensing technology (6 Sigma Project)

**CAREER NOTES:** Previous positions with Roche include **Principal Engineer, Product & Process Design and Development** (1994-1997) and **Machine Design Engineer, Production System Design and Development** (1992-1993). Led internal and external (global) teams to design and develop numerous innovative products, along with production systems that led to major costs savings and process improvements while meeting launch criterion.

## EDUCATION

- **Executive Certificate in Technology & Innovation Management**, California Institute of Technology (Caltech), Pasadena, CA
- **Executive Certificate in Technology, Operations & Value Chain Management**, Massachusetts Institute of Technology (MIT), Cambridge, MA
- **Masters of Business Administration (MBA)**, Purdue University (PU), West Lafayette, IN
- **BS in Mechanical Engineering (BSME)**, University of Southern California (USC), Los Angeles, CA

## PROFESSIONAL DEVELOPMENT

GMP Compliance, Strategic Decision Making (Harvard), Managing Complex Product Development (MIT), Developing a Leading Edge Operations Strategy (MIT), Supply Chain Strategy & Management (MIT), Lead Auditor Training-FDA Regulated Industries, Quality System Regulation (**QSR**) for the Medical Device Industries (2005), FDA 101, Roche Leadership Academy, Engineering Management Program (Purdue University), Streamlining the New Product Development (Caltech), Project-Cost Estimation (Caltech), Effective Complaint Handling, IP for Technology and Business Development (Caltech), Management of Technology & Innovation (Caltech), PMP Training, Legal Deposition Training, FDA **Quality System Regulation** (2012 by AAMI) and many others.

## ADDITIONAL INFORMATION

**Patents:** 115 patent publications, with 30+ US patents.
**Publications:** Complete list of peer-reviewed publications available on my website.
**Computer Skills:** MS Office (PC & MAC), Visio, SAP R/3, Product Data Management (Matrix), EtQ System
**Website**: www.ravibhullar.com
**LinkedIN**: Raghbir (Ravi) Bhullar
**Affiliations:** Council of Supply Chain Management Professionals (CSCMP), Project Management Institute (PMP Trained), American Society of Quality (ASQ), Association for the Advancement of Medical Instrumentation (AAMI).