

# Mihir P. Sheth

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## PROFILE

**Leadership Qualities:** Highly regarded mission-focused, flexible, cross-functional technical and business leader possessing a high degree of emotional intelligence required to lead complex, global teams in a matrix environment. Exceptionally collaborative, excellent communicator, team player, effective decision maker, inclusive, result-oriented and change agent known for outstanding problem solving, strategic planning, precise execution, and developing trust-based partnerships globally.

**Organizational and Cross Functional Leadership:** Recognized for building and leading high performing teams by hiring and developing top talent. In-depth knowledge and solid experience in Medical Device R&D, Project Management, Business Development, CMC, Pre-clinical, Clinical, Clinical Operations, Safety, Regulatory, Manufacturing, Marketing, Medical Affairs, Quality, Finance, Procurement, and Legal.

**New Product Innovation:** An expert with a proven track record of creating strategies, developing and commercializing a broad range of novel drug delivery devices for drug/device combination products such as pen injectors, auto injectors with connectivity, pre-filled syringes, transdermal patch and drug eluting stents. Solid experience in developing and commercializing diagnostic devices, and Class II and Class III medical devices such as balloon catheters, and platelet/plasma separation and purification kits.

**Business Development:** Led evaluation of more than 15 deals including strategic partnerships and acquisitions in the range of \$40M to \$300M. Led target company identification, due diligence, term sheets, agreements, post-deal execution, and integration.

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## CORE COMPETENCIES

Strategic Planning | Strong Business and Financial Acumen | Budget Creation and Management | Cross Functional Stakeholder Management | Drug/Biologics/Device Combination Product Development and Commercialization | Diagnostic Device Development and Commercialization | Digital Health | Project & Portfolio Management | Talent Recruiting & Development | Strategic Partnerships | Design Control and Risk Management | Human Factors and User Research | Regulatory Submissions and Approvals | Speed-to-Market Initiatives | Product Development Process Improvements | On-Market Product Support | Post Market Surveillance, Audit Support and Compliance | Manufacturing Scale-up & Process Validations | Supplier Management

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## PROFESSIONAL EXPERIENCE

**ABBVIE (formerly Allergan) - Executive Director, Device R&D, Irvine, California**

**08/18 – 06/22**

### ***Job responsibilities***

- Accountable for strategy, development and commercialization of primary drug containers and drug delivery devices for the portfolio of drug/biologic/device combination programs in Eye Care, Gastroenterology and Medical Aesthetics therapeutic areas.
- Lead and manage a multi-site organization comprised of R&D Directors, Device Sub-Team Leaders, Managers, engineers and scientists.
- Responsible for execution of ~15 development programs with R&D operating and capital budget in excess of \$100M, strategic partnerships, due diligence, acquisitions and integrations of companies.
- Develop and commercialize medical devices through collaboration with external partners and multiple internal functions such as Medical Device R&D, Project Management, CMC, Pre-clinical, Clinical, Clinical Operations, Safety, Regulatory, Manufacturing, Medical Affairs, Quality, Finance, Procurement, and Legal.
- Partner with consulting firms (e.g., McKinsey, PwC) to improve business systems and processes to accelerate product launch timelines.
- Provide program updates to Senior and Executive Leadership Team

### ***Key Achievements***

- Developed and commercialized drug delivery device for first intracameral, biodegradable sustained-release drug/device combination product (DURYSTA) in the US for treating open angle glaucoma.
- Developed delivery device with connectivity and diagnostic device for a biologic/device combination product for treating Ulcerative Colitis and Crohn's disease.
- Developed a new drug delivery technology platform for delivery of dermal fillers and neurotoxins.
- Developed a new drug delivery device through strategic partnership for diabetic gastroparesis.

**ALLERGAN - Director, Device R&D, Irvine, California****03/14 – 07/18****Job responsibilities**

- Accountable for strategy, development and commercialization of primary drug containers and drug delivery devices for the portfolio of drug/device combination programs in Eye Care therapeutic area.
- Lead and manage a multi-site organization comprised of R&D Directors, Device Sub-Team Leaders, Managers, engineers and scientists.
- Responsible for execution of ~5 development programs with R&D operating and capital budget in excess of \$35M, strategic partnerships, due diligence, acquisitions and integrations of companies.
- Accountable for all aspects of programs such as budget, schedule, quality, resources, risk mitigation and issue resolution. Build, lead and direct cross-functional teams to achieve program milestones and product launch dates.
- Collaborate with external partners and multiple internal functions such as Medical Device R&D, Project Management, CMC, Pre-clinical, Clinical, Clinical Operations, Medical Safety, Regulatory, Manufacturing, Medical Affairs, Quality, Finance, Procurement, and Legal.
- Communicate project status, cost and schedule changes, risks, and issues to the Sr. Leadership.

**Key Achievements**

- Led development of a new delivery device platform to support multiple indications of drug/device combination product.
- Led drug delivery device development for a drug/device combination product development program and completed all deliverables 5 months ahead of schedule within total program budget of \$8M.

**BOSTON SCIENTIFIC - Sr. Program Manager, Maple Grove, Minnesota****01/06 – 03/14****Job responsibilities**

- Responsible for major internal development programs and strategic alliances for Peripheral Intervention and Interventional Cardiology businesses
- Lead all the activities from Proposal through Commercialization phases of the program. Lead cross-functional teams comprised of Marketing, R&D, Quality, Operations, Regulatory, Packaging, Pre-Clinical, Clinical, and Finance.
- Communicate project status, cost and schedule changes, risks, and issues to the Executive Management.
- Lead due diligence activities for target acquisitions and integration activities for the acquired company.

**Key Achievements**

- Successful commercialization of innovative device for treating Chronic Total Occlusions (CTO) for Peripheral applications. Commercialization achieved within the budget and timeline.
- Achieved commercialization of a multi-site platform program for the development of a next generation coronary stent with the total program budget of \$45M and a cross-functional team of 48 personnel. Product launched 4 months ahead of schedule and within budget.
- Successfully led and completed a multi-site Carotid Stent program within the total program budget of \$20M and a cross-functional team of 53 personnel. Achieved higher gross margins than the plan.
- Led the acquisition of EndoTex Interventional Systems from the initial due diligence through acquisition and integration into Boston Scientific.
- Successful leadership and management of a balloon catheter development program to launch a novel Polarcath™ Cryoplasty balloon catheter. Actual sales of the product exceeded the forecast.
- Led the acquisition of Cryovascular Systems, Inc., a novel balloon catheter company from initial due diligence through acquisition and integration into Boston Scientific.

**BOSTON SCIENTIFIC - Project Manager, Maple Grove, Minnesota****01/04 – 01/06****Job responsibilities**

- Responsible for all the elements of the project such as cost, schedule, resources and quality.
- Direct all the activities from Proposal through Commercialization phases of the program.
- Lead cross-functional teams comprised of Marketing, R & D, Quality, Operations, Regulatory, Packaging, Pre-Clinical and Clinical

**Key Achievements**

- Successfully led a multi-site, cross-functional team of 30 personnel to launch a guide wire for renal applications. Project completed three weeks ahead of schedule and 1.5% below the budget.
- Led the acquisition of Rubicon Medical, Inc., an embolic protection device company from initial due diligence through acquisition and integration into Boston Scientific.

**BAXTER HEALTHCARE - Sr. Principal Engineer, Round Lake, Illinois****04/01 – 01/04****Job responsibilities**

- Responsible for the development of disposable devices from concept through production for INTERCEPT® Plasma program. Lead cross-functional teams comprised of R & D, Marketing, quality, manufacturing and regulatory representatives to develop disposable devices.
- Establish budget, project milestones and schedules. Communicate project updates to the Senior Management of Baxter and external partner Cerus Corporation.

**Key Achievements**

- Successfully led cross-functional teams of Baxter Healthcare and Cerus Corporation to commercialize the disposable device for INTERCEPT® Plasma.

**BAXTER HEALTHCARE - Principal Engineer, Irvine, California****09/99 – 04/01****Job responsibilities**

- Lead the development of drug delivery devices for chemotherapy and pain management.
- Interface with Marketing to identify opportunities for the new product development based on the customer input. Develop project milestones and timelines.
- Identify cost reduction and quality improvement projects by developing new components and processes. Manage the R & D Lab to support the testing of new products.

**Key Achievements**

- Development and commercialization of a complex drug delivery infusion device for chemotherapy

**BAXTER HEALTHCARE - Senior Engineer, Irvine, California****01/97 – 09/99****Job responsibilities**

- Identify and implement cost and quality improvement projects for the elastomeric reservoir used in Infusor® and Intermate® drug delivery devices through unique material selection and innovative process development.
- Establish project milestones, schedules and budgets.

**Key Achievements**

- Achieved annual cost savings of \$1.5M by developing a novel material and manufacturing process.
- Lead the development of redesigned Infusor® device to reduce the customer complaint by 50%.

**BAXTER HEALTHCARE - Quality Engineer, Mt. Home, Arkansas****04/95 - 12/96****Job responsibilities**

- Evaluate and validate changes to PVC formulations, PVC blending and film extrusion processes that affect product quality.
- Identify and solve the sources of defects in IV solution bags and the manufacturing process. Support the development of new products and processes through validations, statistical analysis and testing.

**Key Achievements**

- Validated MARQ container (Non-PVC container) and its manufacturing process in 20% less time
- Validated the changes made by supplier in PVC resin used in manufacturing Vialflex® container.

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**HONORS AND AWARDS**

- **AbbVie** - President's Award for FDA Approval of DURYSTA drug/device combination product **10/2020**
- **Allergan** – Award for Successful Acquisition and Integration of Aline Inc (by Tautona Group) **03/2014**
- **Boston Scientific** - Award for Successful Acquisition and Integration of Vessix Vascular **11/2012**
- **Boston Scientific** - Award for Successful Acquisition and Integration of Revascular Therapeutics **02/2011**
- **Baxter Healthcare** – Outstanding Technical Achievement Award for novel formulation **06/2000**
- **Baxter Healthcare** – Outstanding Corporate Achievement Award for novel mfg. process **05/1999**

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**EDUCATION AND PROFESSIONAL DEVELOPMENT****M.S. Plastics Engineering, University of Massachusetts Lowell, Lowell, MA****01/1993 - 12/1994****B.S. Rubber Technology, Gujarat University, India****06/1988 - 06/1992****Project Management Professional (PMP) Certification, Project Management Institute 2004**