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## Summary

Founder and leader of Merck's Device Development Group for 22 years. Strategically focused drug delivery device and packaging development professional with an excellent track record in determining optimal product strategy, innovation, product development, people, technology and project management with successful regulatory submissions. 30+ years of experience directing/mentoring technical groups in successfully addressing strategic market needs for medical devices and combination products. Areas of technical focus include pen injectors, auto injectors, on body injectors, inhalation and nasal delivery devices as well as manufacturing/assembly systems and process development. Very experienced in bringing products from concept development to successful manufacture and launch.

Specific technical skills and experience include:

- Device and combination product strategy
- Parenteral and respiratory device and combination product development
- Engineering management
- People management
- Marketing focus group study design and execution
- Concept generation and engineering feasibility analysis
- Smart devices
- Design and process failure modes and effects analysis
- Design for manufacture
- Design controls and regulations
- Human Factors Engineering
- Manufacturing line development and start up
- Technical troubleshooting
- Technology due diligence
- Packaging development
- Regulatory strategy and submissions

## Education

**M.S. in Engineering Management**, New Jersey Institute of Technology.
**B.S. in Mechanical Engineering**, California State University, Sacramento, CA.
**B.S. in Psychology**, College of New Jersey.

## Professional Experience

### Princeton Device Solutions

***Principal and Owner*** ***March 2021 - present***
Device development consultant

### Merck

***Executive Director - Device Development***
**Global Leader of Merck's Device Development Group** ***November 2009 – March 2021***

Responsible for the strategic and technical management of all Device Development programs at Merck. In addition to managing 28 device development staff, specific roles include:

- Development of global delivery device strategy, supporting organizational structure and operational plans with input from key stakeholders to ensure strategic alignment and continuity across the organization
- Serve as the top company authority in delivery device selection, development and commercialization and lead our Delivery Device Center of Excellence to ensure timely execution of operational plans in support of clinical studies and product launches
- Develop and deliver on short and long term objectives that are globally aligned to the organizations current and future drug delivery needs.
- Scan the environment for delivery device trends, new technologies, IP and potential opportunities that could have a positive impact on the organization's short and long term objectives. Formulate plans for timely response to these changes as needed
- Provide post launch technical support to production sites as needed.

## Schering Plough Research Institute

***Director - Delivery Device, Packaging and Development Engineering May 2005 – November 2009***

**Leader of SPRI's Device Development, Package Development and Lab Automation Development Groups.** This represents a consolidation of 3 separate groups with 32 staff and 6 management level direct reports. Specific responsibilities include:

- Strategic and technical oversight of all delivery device development with focus on parenteral and inhalation products
- Strategic and technical oversight of all package development with emphasis on innovative packaging
- Strategic and technical oversight of all custom laboratory automation development
- Expense center management
- Responsible for verbal and written correspondence with regulatory agencies

***Associate Director - Device Development October 2002 - May 2005***

**Leader of SPRI's Device Development group.** Responsible for market assessment and the development of inhalation and parenteral delivery devices including mold tooling and assembly automation. Scope includes internal development programs and the management of outside resources for co-developed and purchased delivery devices. 8 total reports with 3 project manager direct reports leading groups focused upon product design, tooling development and assembly automation. I personally recruited and built this group from scratch to address significant delivery device shortcomings within Schering Plough's infrastructure.

***Manager - Device and Package Development November 1998-October 2002***

Responsible for project management and design optimization of drug delivery devices, manufacturing equipment, and the development of new pharmaceutical entities. Specific responsibilities include:

- Management of Drug Delivery Device and Package Development engineering group (6 direct reports). Areas of focus include dry powder inhalers, multi dose inhalers and injection devices.
- Technical evaluation of business opportunities related to delivery devices including insulin delivery using novel technologies.
- Management of a device manufacturing project with a budget of $18MM. This includes initial financial analysis, staffing, vendor selection, site selection and layout, procurement of injection mold tooling and automated assembly equipment, validation planning, tooling and equipment design reviews and all other related engineering management activities through validation and initial manufacturing start up.
- Chairman of Development Operations Working Group responsible for the development of two new inhaler based pharmaceutical products.
- Responsible for verbal and written communications with the FDA.
- Expense Center Manager responsible for employee and financial management including individual projects as well as my own group's annual operating budget.

## Therics

***Manager - Mechanical Systems Group*** ***July 1996 – November 1998***

Responsible for project management as well as managing engineering, design and technician level staff in Therics Mechanical Systems Group. Therics was a start-up company based upon a 3 dimensional printing/fabrication technology licensed from MIT for medical product development. They are currently a much larger company with marketed products. Achievements include:

- Design of three-dimensional printing based manufacturing processes and equipment for the production of pharmaceutical and tissue engineering products including oral dose forms and bone implants.
- Design of several synthetic and tissue based implants. Patent and publication issued.

## PA Consulting Group, Hightstown NJ

***Engineering Consultant & Technical Group Manager*** ***October 1993 – July 1996***

Responsible for selling, staffing, managing and operating medical device product development assignments as well as the management of Prototype Lab and Testing Lab personnel (4 reports).

- Specific responsibilities included marketing and sales, cost estimation, proposal writing, and project management.

***Senior Project Engineer*** ***January 1990 – October 1993***

Responsible for lead engineering and project management, including budget and manpower, on a variety of fast paced technical programs involving multiple disciplines. Representative examples include:

**Development**

- Developed a needleless injector for intramuscular drug delivery for a large pharmaceutical company. Project responsibilities included project management, market analysis with focus groups, developing a gelatin-based tissue model for parametric studies, injector design, design and execution of cadaver experiments using radio opaque substance for real time observation of injection performance.
- Developed a home use, disposable blood diagnostic cholesterol testing device for Johnson and Johnson.
- Development of a laparoscopic knot tying device for use with sutures and a single bladed surgical scissor with a compound motion cam mechanism that enables improved tactile feedback, cutting performance, and lower manufacturing costs than current models. Patents issued.
- Development and Design of a tissue simulation model for life cycle testing of an electromechanical sinus polyp cutting tool and a new type of autoclavable syringe and proprietary autoclave cycle for use with terminal sterilization. Two patents issued.
- Development of a new type of surgical stapler for gastrointestinal and thoracic procedures for Ethicon. Performed finite element analysis for design verification and managed manufacturing implementation.

**Technology Assessment**

- Performed technical assessments of all needle-based and needleless, personal drug delivery devices for several large pharmaceutical companies. Conducted focus group studies to identify and rank patient needs and preferences.
- Performed technology due diligence evaluation and subsequent design analysis for a low cost IV infusion device.
- Engaged in preliminary evaluation of modeling design parameters for empirical testing the minimization of pain in an auto-lancet device for diabetes patients.

## Special Training & Experience

- Clinical training in anatomy and surgical procedures, including tissue lab training and surgical observations.

- GAMP validation of computer systems
- Statistical tolerance analysis

## Professional associations, patents and significant Awards

2016 Thomas Edison Patent Award in Medical Device category
Merck Presidential Fellowship Award 2012
Schering Plough Research Institute Excellence Award 2007
Schering Plough Research Institute Presidents Award for Development 2003
Tau Beta Pi National Engineering Honor Society

**Granted patents:**
EP0758255B1 – Low drag syringe
WO1995030444A1 – Low drag syringe and cartridge
WO1995010230A1 – Endoscopic surgical instrument
WO2015187471A1 – Dry powder inhaler with dose counter
US20150020806A1 – Dry Powder inhaler
US9174012B2 – Dry powder inhaler with poly flux collider
US5431674A – Endoscopic scissor with compound motion blade
US5413563A – Syringe with leak proof seal and low drag
CA2173998A1 – Endoscopic instrument with adjustable handle
US5423836A – Endoscopic suture knot tying tool
USD4122065 – Syringe with detachable plunger rod
USD774641S – auto injector design
US6454811B1 – Composite tissue implant

## Launched and Marketed Products

1. Laptop pacemaker programmer*
2. Imaging agent, easy push syringe with proprietary sterilization cycle *
3. Inductive test tube rack for diagnostics machine*
4. Analytical reagent container*
5. Temperature controlled hair curler **
6. Motorized knee surgical instrument **
7. Motorized nasal surgical instrument **
8. Automotive wiring harness**
9. Lawnmower drive system**
10. Dry powder inhaler *
11. Dual chamber injector**
12. Metered dose inhaler*
13. Dual chamber auto injector*
14. Syringe based auto injector**
15. Sensor equipped catheter and manufacturing line*
16. Electro-optical connector and circuitry*
17. Surgical stapler (for open stomach procedures) **
18. Surgical stapler (for laparoscopic colon procedures) *
19. Compound motion laparoscopic surgical scissor *

* = Developed from scratch
** = Design and development to improve launched product