

LOUIS A. MEEUWEN

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CAREER PROFILE

Experienced and entrepreneurial R&D leader with a track record of innovation, team building, and driving global business results. Broad technical, business, and collaboration skills have led to customer-focused innovation and growth in the field of critical care medical device and pharmaceutical products. Self-motivated team leader, big picture thinker, organized and creative with a focus on delivering revenue growth and profitability; leading the development of new products from concept to commercialization.

PROFESSIONAL EXPERIENCE

AMGEN INC., Thousand Oaks, CA 2016-2018
Oncology, R&D Senior Project Manager

Assigned to lead large cross-functional project teams through the development, registration and global launch of new immunotherapy drugs.

Critical Need: *Lead multi-disciplinary development teams in the development of new-to-world biologic medicines*

- Projects included phase 1 development for three bi-specific T-cell engager immunotherapies in the oncology space – leukemia and solid tumor cancers
- Manage high-level project teams consisting of function leaders from Drug Development, Medical Affairs, Clinical Operations, Regulatory Affairs, Quality Management, Pharmacovigilance/Safety, & Operations
- Project sub-teams executed development for all pre-clinical work, approval for clinical protocols and conduct of global clinical trials; multi-sites in the Americas, Asia, and Europe
- Led early stage governmental policy, market access, and marketing teams to identify and assess clinical need, obtain and evaluate patient and caregiver inputs, and guide target drug label development

BAXTER HEALTHCARE CORPORATION, Deerfield, IL 1986-2016
Medical Products Division, Deerfield, IL, R&D Senior Project Manager 2010-2016

Member of Fluid Systems Project Management Office for the Division. Assigned to lead large cross-functional project teams through development, registration and launch of new drugs and drug delivery products.

Critical Need: *Provide seasoned pharmaceutical project management experience to lead key project development efforts for major legacy product lines.*

- Project manager for large-scale drug container program. Product profile will set the global standard for flexible I.V. containers; SVP and LVP with manufacturing production targets at over a million units per day.
- Project manager for new amino acid product development in EU; supports the global pharmacy compounding strategy.
- Formed and led cross-functional team to develop an improved material profile I.V. solutions container. This life cycle management project spanned 4 countries including the U.S. market.
- Achieved clinical materials production for Phase IV studies of a legacy I.V. base electrolyte solution. Successfully led team to develop a unique double-blind product labeling scheme to ensure integrity of the studies.

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Pharmaceuticals & Technologies, Round Lake, IL, Innovation Lead 2006-2010

Reporting to the VP of Global R&D, provided leadership for a senior-level Innovation team consisting of top Directors and Baxter scientists in identifying new and improved pharmaceutical products for critical care therapies.

Critical Need: *Fill a dry product pipeline for a \$2.2B SBU with differentiated products and in so doing, distance Baxter from an increasingly price-oriented generic drug market.*

- Provided strategic and operational leadership for a Division-wide product innovation initiative. Built a culture of innovative thinking and developed organizational discipline to match new ideas with strategic plans.
- Developed full business proposals including: market value propositions, product development plans, clinical programs, regulatory strategies, IP assessments, risk maps, timelines and full financial plans.
- Interacted with and influenced senior internal and external stakeholders, managed the program prioritization process, and led the product portfolio development process.

International Operations, New Providence, NJ, Senior Manager 2003-2006

Executed country and region growth strategies for the Anesthesia & Critical Care global business that had acquired the critical care drug portfolio from ESI/Lederle.

Critical Need: *Coordinate a complex matrix organization; balance growth goals of the newly formed global business against country and region financial targets.*

- Executed a business and operational plan to implement country and region growth for a \$300MM global anesthesia critical care business.
- Planned and implemented a comprehensive portfolio of projects leading to the launch of a broad range of injectable and inhalation critical care drugs to meet country and region objectives.
- Built global project teams and project management capabilities and deployed these from portfolio evaluation through registration and product launch.

Oxygent™ Development, New Providence, NJ, Project Manager 2000-2003

Led a joint venture development team chartered to complete the development, regulatory approval, and commercialization of Oxygent™, a temporary intravascular oxygen carrier, in the U.S., Canadian, and European markets.

Critical need: *As soon as the JV agreement was signed, it was announced by the partner that the two pivotal Phase 3 trials had been halted due to adverse events. We needed pathways to restart clinical development and preserve the \$55M joint venture deal.*

- Created new plans for all phases of development in pre-clinical, clinical, CMC, and regulatory activities leading to registration in three major markets.
- Led European, Canadian, and U.S. commercialization team efforts through qualitative and quantitative market research, pharmaco-economic and clinical advisory board development, and implementation of market preparation activities.
- Accountable to the JV Board as well as Senior Management of both companies in securing and prioritizing resources to keep this large-scale (> \$250MM market value) drug development project on schedule.

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Anesthesia Product Engineering, Round Lake, IL, Group Manager 1995-2000

Established a product and manufacturing engineering department for a new \$80MM anesthesia medical device business. Directed engineering resources for medical device development and manufacturing in the U.S., Latin America, Caribbean, and Far East.

***Critical Need:** Immediately improve product quality and product service levels as well as establishing credibility of this new business with Senior Management of key functions including Regulatory, Quality, and Manufacturing.*

- Redesigned an intravenous drug reservoir bag to address quality problems and maintain sales of a \$20M infusion pump product line and \$2.1MM in disposable devices.
- Completed an inhalation anesthetic breathing mask manufacturing start-up in China, increasing gross profit by 215%.
- Developed & executed a \$1.6MM capital plan for the transfer of a manufacturing line, stabilizing manufacturing capability, achieving \$356,000 annual cost savings, and expanding capacity by 50%.

Process Technology, Round Lake, IL, Manager 1993-2000

Responsible for the validation of medical plastics processes including injection molding and component bonding processes involving ultrasonic welding, solvent and adhesive bonding for new and existing products.

***Critical Need:** Launch new products and improve manufacturing cost positions in an increasingly demanding global pricing environment and competitive landscape.*

- Developed and implemented tooling and manufacturing process for a ground breaking needle-less medical device line resulting in 1st year sales of \$60MM. This \$4.4MM capital project was completed in 18 months across three global manufacturing sites (Singapore, Puerto Rico, U.S.).
- Provided product engineering and manufacturing process improvements to allow re-start of a blood separation business.
- Introduced a high output injection molding program to revamp current molding technology reducing manufacturing costs by \$1.2MM over 3 year period.

Polymer Technology, Round Lake, IL, Manager 1986-1993

Achieved the successful application of a broad range of processing technologies including medical polymer materials engineering, joining technologies, production tooling, and process development for intravenous medical devices.

HOECHST-CELANESE CORPORATION, New York, New York 1980 to 1986

Design Technical Services, Chatham, NJ, Manager

Started up a new engineering department to support sales and market development and achieve 10-15% growth for a \$250 million engineered resins business.

CHRYSLER CORPORATION, Detroit, Michigan 1978 to 1980

Corporate Plastics Engineering, Materials Engineer

Designed, tested and developed new and unique automotive applications in high strength polymer materials including glass and mineral filled nylons, unidirectional fiberglass and carbon fiber composites, aluminum/polymer laminates, low density SMC and BMC molding compounds.

EDUCATION:

MBA, Lake Forest Graduate School of Management, Lake Forest, IL, 1994. Eugene Hotchkiss Scholar
BS, Chemical Engineering, University of Akron, Akron, OH, 1978.