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SUMMARY

BIOPHARMACEUTICAL R&D EXECUTIVE with a diverse, progressive career. Experience in Drug Substance Development, Formulation Development and Quality Assurance. Cross-functional leadership expertise spans strategic planning, change management, risk management, product strategy, and organizational effectiveness. Demonstrated excellence in managing departments of ~20 R&D personnel. Proven track record in the development, scale-up and technology transfer for commercialization of drug products.

- Depakote ER
- Kaletra
- Simcor
- Survanta
- Viekira Pak
- Product Development: Phase I to Launch
- Strategic Efficiency and Technology Improvements
- Global CMC Regulatory Submissions
- Business Excellence Black Belt Certified

PROFESSIONAL EXPERIENCE

AbbVie, Waukegan, IL **2012 - 2015**
Director: Quality Strategic Planning,

Led strategic improvements within Quality System including but not limited to documentation management optimization, change management, and quality risk management. Responsibilities included

- Implemented a Quality Risk Management process for R&D and across AbbVie. Program promoted awareness and helped establish training on tools and overall implementation. Program enhanced quality and improved efficiency
- Established a new Quality System positioning to support AbbVie as a new Biopharmaceutical company.
- Co-led adaptation of a new set of AbbVie policies; reducing the policy number from 136 to 23; structured in way to promote the highest quality and agility.
- Executed a new Change Management process that streamlined change management within R&D clinical manufacture.

Abbott Laboratories, Waukegan, IL **2007 - 2011**

Director: Global Formulation Development

Directed a highly talented group of scientist in the development and launch of drug products. Led strategic business improvement programs to enhance speed to market

- Executed numerous formulation development programs ranging from FIH to commercial launch.
- Designed, implemented, and maintained the Quality by Design program for both formulation and analytical sciences. Responsibilities included directing the global core quality by design implementation team, advancing risk assessment tools, training, and implementing quality by design principles for numerous projects.
- Managed multi-million dollar capital expenditure program and designed and implemented an improved resource management tool and provided global resource requirements for numerous development programs

Abbott Laboratories, Waukegan, IL **2005-2006**
Associate Director: Global Formulation Scientist

Directed acquisition of Kos Pharmaceutical's R&D site technologies and personnel into Abbott's Laboratories as well as launching new products and implementing process improvements

- Integrated development scientist into a new pharmaceutical development organization
- Led the global integration of Abbott's Ludwigheiven product development site into the global formulation development organization
- Managed multiple early development products ensuring all products met clinical supply and evaluation requriements
- Served as technical chairman for CAMP consortium and Co-Chairman for FDA/AAPS QbD focus group ensuring Abbott was connected with latest development technology and to establish a leadership role for Abbott in the larger pharmaceutical community.

Abbott Laboratories, Waukegan, IL **2002-2005**
Associate Director: Process Development

Established process development department overseeing the process development, scale-up, and launch of drug products.

- Successfully filed and launched a number of key products within Abbott Laboratories.
- Established a PAT strategy and platform and implemented PAT systems for blending, and drying.
- Implemented new manufacturing science technologies to improve science and efficiency.
- Implemented a pharmaceutical guidebook that improved knowledge management within the organization.

Early Career

Joined Monsanto as a Research Engineer supporting solid processing and scale-up of complex organic synthesis to support development of artificial sweeteners. Advanced to the manager of the chemical pilot plant. Later joined Abbott Laboratories as a Senior Research Engineer supporting the development of numerous products and processes including a novel bio-separation process.

EDUCATION

Masters Certificate, Applied Statistics, Texas A&M
MSc, **Chemical Engineering**, Michigan State University
BSc, *Microbiology*, Michigan State University

Professional Development courses or certifications

Business Excellence Green Belt Certified
Business Excellence Black Belt Certified
Project Management PMI Certification: Completion of program in 2016