AbbVie Inc.
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Steven L. Laurenz

Experience

2015-Present AbbVie Inc. Abbott Park, IL

Director: Combination Product Risk Management Development

- Responsible for directing the risk management program for a new combination product involving a complex pumping technology and novel drug.
- Managing mature risk management integration into the combination product development department.
- Responsible for designing a risk based program to support clinical studies.
- Executed enteral tube flushing studies for a combination product system.

2012-2014

Director: Quality Strategic Planning

- Responsible for leading strategic improvements to the Quality System including but not limited to document transition and optimization, change management, and quality risk management. Responsibilities included
    - Led implementation of a Quality Risk Management process for R&D and across AbbVie. Program promoted awareness and helped establish training on tools and overall implementation. Customized a special tool and process for clinical operations to promote risk management in the design and execution of a clinical study. Program will not only enhance quality but will significantly reduce study cost.
    - Established a new AbbVie Quality System that is positioned 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.
    - Lead role in enhancing the application of change management within R&D clinical manufacture.

2007-2011

Director: Global Formulation Development

- Manage the formulation development department focusing on developing formulations from FIH to commercial launch. Responsibilities include overseeing the development of numerous products, establishing and maintaining capital expenditures, forecasting resource demands, managing the development of formulation technologies, and managing the development of scientific staff.

- Designed, implemented, and maintained the Quality by Design program for both formulation and analytical sciences. Responsibilities include directing the global core quality by design implementation team, advancing risk assessment tools, training, and implementing quality by design principles for numerous projects.

2005-2006 Abbott Laboratories North Chicago, IL

Associate Director: Global Formulation Scientist

- Activity supported transition of personnel to new GPAS organization.
- Served as technical chairman for CAMP consortium and Co-Chairman for FDA/AAPS QbD focus group to ensure Abbott is connected with latest development technology and to establish a leadership role for Abbott in the larger community.
- Managed early development activities for multiple products.
- Supported global integration of LU GFSS through mentoring, capital plans, and project management.
- Continued to support implementation of GPAS's PAT strategy through modeling, AP39 implementation, and coordination of PAT systems across Abbott divisions.
- Provided leadership to implement LSS systems to evaluate of GPAS's technology development systems.
- Lead efforts to implement ICH Q8 and Q9 programs within GPAS.

2002–2005 Abbott Laboratories North Chicago, IL

Associate Director: Process Development

- Set-up and 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 systems for blending, drying, and AP39.
- Implemented new manufacturing science technologies to improve science and efficiency within PARD.
- Implemented a pharmaceutical guidebook that improved knowledge management within the organization.

1997–2002 Abbott Laboratories North Chicago, IL

Group Leader

- Supervised process scientist in developing drug products
- Successfully brought to market several drug products from early research phase to launch.
- Implemented an improved tablet coating scale-up program.

1994-1997 Abbott Laboratories North Chicago, IL

Senior Research Engineer

- Implemented Novel bio separation system for a neonatal drug product.
- Ensured technical production issues were rapidly addressed during manufacture of neonatal drug product.
- Implemented new database system to improve quality and production performance.

1985-1994 The Monsanto Company Mt. Prospect, IL

Chemical pilot plant supervisor.

- Developed and launch new coated NutraSweet product.
- Developed, scaled, and launched new bulk pharmaceutical intermediate.
- Developed new sweetner from lab scale to production.
- Developed an improved fermentation isolation process.

Education

Michigan State University E. Lansing, MI

- B.S., Microbiology
- M.S.,Chemical Engineering

Texas A&M

- Masters in Applied Statistics Certificate (Degree completed in 2015: 4.0/4.0)

AbbVie BeX Program

- Business Excellence Green Belt Certified
- Business Excellence Black Belt Certified