Steven Malecha

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SUMMARY

I am a resourceful, dynamic and quality-focused team player with over thirty years of experience in analytical chemistry, in pharmaceutical industry. Solid knowledge and experience in the areas of spectroscopic and chromatographic techniques and associated analytical instrumentation. Lead teams and had responsibility for analytical method development and validation, trace organic and inorganic analyses, extractable & leachable assessments, product stability testing, computer system validation, compendia particle analysis and metrology. Proven ability to use technical knowledge, expertise and experience to develop new products and drive problem solving teams to resolve manufacturing, product complaint and regulatory issues. Lead analytical chemistry department of more than 60 technical employees with responsibilities for all aspects of performance, budget and project management.

CORE COMPETENCIES

- Practical and critical thinker for rapid resolution of technical issues.
- Alignment of business needs with the technical arena.
- Implementation of regulatory expectations and requirements to laboratory practices.
- Knowledge and experience with trace level analysis, including extractable and leachable determinations.
- Analytical instrumentation and associated techniques, including mass spectrometry, gas and liquid chromatography, atomic spectrometry and general analytical instruments.

ACHIEVMENTS

- Responsible for resolution of regulatory issues, including the FDA warning letter observations associated with metrology and validation of physical test methods.
- Lead extractive and leachables initiative in the development of the PL2401 Clarity film, which represents the first plastic container system for storage of IV lipid emulsion. This product line continues to deliver strong sales and revenue streams. Efforts included development of the strategic approach and novel analytical techniques.
- Lead relocation and associated laboratory space design efforts for the R&D analytical team supporting the anesthesia product line.
- Resolution of numerous product and manufacturing issues, including the analytical assessments to keep heart valves on the market following a tragic incident at a Baxter manufacturing site in California.

WORK EXPERIENCE

Baxter Healthcare, Round Lake, IL **October 1984 to October 2018**

Technical Laboratory Lead **(Mar 2017 – Oct 2018)**

- Standardization of laboratory processes, practices and procedures
- Technical direction for deployment of LIMS deployment
- Successful preparation of both manufacturing and R&D sites for FDA and Medical Device Single Audit Program (MDSAP) inspections through the assembly, critical review of supporting materials and audit role play activities.

Principal Scientist **(Jan 2015 – Mar 2017)**

- Utilize recognized technical knowledge and leadership skills to focus on the compliance issues associated with FDA warning letter observations associated with a gap in evidence of validation for physical test methods and metrology calibration practices.
- Provided technical review and guidance to CAPA's
- Assisted with the development and assessments associated with a Quality maturity model to drive continuous improvement at manufacturing sites

Research Director **(Feb 2000 - Jan 2015)**

- Responsible for technical leadership of analytical chemistry group supporting new product development and marketed projects including compliance activities and resolution of customer complaints and manufacturing issues.
- Lead groups specializing in method development and validation, stability testing, trace analysis, extractable/leachable testing, reference standards, compendia particle analysis, computer system validation of laboratory instruments and metrology
- Responsible for transitioning the R&D analytical group supporting Baxter's anesthesia product line from New Jersey to Round Lake.
- Responsible for lab space remodel project, including coordination of lab design of multiple lab areas used by particulate matter, chromatography and spectroscopy teams. Development and execution of department overhead spending and capital budgets, resource loading and project oversight activities.

Research Associate/Research Scientist **(Oct 1984 — Feb 2000)**

- Responsible for conducting analytical laboratory work supporting, including gas chromatography, high performance liquid chromatography, mass spectrometry, infrared and wet chemical techniques.
- Served as study director, which include responsibility for the study design and execution of protocols for identification of unknowns, extractable and leachables assessments, method development and validation activities for both new product development initiatives and in support of marketed products

Medi+Physics, Arlington Heights, IL **November 1981 to October 1984**

Production Chemist

- Responsible for recovering isotopically enriched material that was used as the starting materials for production of radiopharmaceuticals. Used the recovered material to prepare targets for future cyclotron bombardment.

EDUCATION

MBA — Roosevelt University, Chicago, IL, 1989
BA, Chemistry — Knox College, Galesburg, IL, 1981