KEVIN RAMBO

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**SKILLSET:**

Pragmatic manufacturing management professional with Six Sigma and Lean Manufacturing proficiency within the Pharmaceutical industry. Proven ability to successfully lead PAI and GMP FDA inspections, strategic tech transfer projects, develop a skilled workforce (both Union and non-Union roles), and produce tangible cost savings. Hands-on leadership style with the desire and ability to personally integrate with Union and Staff level workforce on a day-to-day basis.

**PROFESSIONAL EXPERIENCE:**

**WindTree Therapeutics (formally Discovery Laboratories), Totowa, NJ/Warrington, PA** Sept 2010 – present

Plant Manager / Director Manufacturing Operations

Full responsibility for launching a 50+ person commercial, aseptic formulation / fill manufacturing plant including all regulatory and safety compliance (FDA, OSHA, NJDEP, EPA, PVSC, RTK, DOT) and all cost centers for the plant. Hosted successful PAI and two follow up FDA inspections with zero 483 observations, multiple NJDEP inspections, investor due-diligence audits and led the commercial manufacturing launch of FDA approved product.

* Successfully managed the plant closure per NJ State DEP ISRA process, 8 weeks ahead of plan.
* Successfully transferred manufacturing formulation to Contract Manufacturer for new lyophilized product.
* Led cost savings initiative resulting in two recurring years of 6-figure cost savings projects.
* Successfully negotiated multiple Collective Bargaining Agreements with Union Workforce.
* Filed for NJDEP Stewardship Initiative 2015 – reduced plant Hazardous Waste status to CESQG via aggressive recycling program and lean manufacturing program.

**LifeCell – A KCI Company, Branchburg, NJ** April 2010 –Sept 2010 Manager – Production

Responsible for Human Tissue production and packaging operations across 2 shifts with 65 reports (3 supervisors, 1 tech specialist, 1 intern, 60 technicians). Responsible for AATB, FDA and EMEA compliance for human tissue processing, calibration / validation of production equipment, inventory control, staffing and change control.

* Site Safety Committee Co-Chairman and First Aid team member.
* Six Sigma production throughput core team member.

**Merck Inc., West Point, PA** Sept 2009 – April 2010

Sr. Manufacturing Facilitator – RotaVirus Vaccine Production

Responsible for all aspects of viral fluid filtration for RotaVirus manufacture including generating SOP’s, validation execution, inventory management, FMEA safety project and hiring / training of new hires to launch multi-shift vaccine manufacture in a Unionized labor environment.

**Discovery Laboratories (now WindTree Therapeutics), Totowa, NJ** Dec. 2005 – Sept. 2009

Manager, Manufacturing Operations

Managing manufacturing operation (inventory, dispensing, sterile formulation, sterile fill, vial inspection and utilities) in a Unionized labor environment, authoring change controls, investigating process deviations, CAPA closure, creating and maintaining SOP’s and master batch record files, trending and reporting metrics. Lead day-to-day manufacturing efforts for producing clinical, PV, and research supply of sterile product. Author for NDA manufacturing and controls module.

* Implemented DMAIC investigative principles for Deviation Quality system.
* Mfg lead for the transfer of actives dispensing and finished product vial inspection in house from CMO. MBR creation, qualification, Tech Transfer risk assessment, generating specifications and environmental monitoring plans, training operators and securing equipment.
* Mfg. lead for installation and qualification of new primary sterile liquid filler.
* Led batch record reengineering project based on FDA recommendations.

##### **Pfizer - Global Manufacturing, Parsippany, NJ** June 2003 – Dec. 2005

Manufacturing Team Coach

Overseeing manufacturing operations of sterile liquids, ointments & creams and non-sterile liquids with twenty direct reports. Responsible for daily operations, inventory control (MAPS), change control, QAR / OOS reports and associated CAPA closure, PO’s, batch record review and employee performance evaluations. Main contact for plant purified water system (Reverse Osmosis), waste treatment, Safety and CQA / FDA issues throughout manufacturing on 1st and 2nd shift.

*Kevin Rambo page 2.*

##### **Chiron Corp. (Biopharma), Annadale, NJ** Feb. 2002 – June 2003

Supervisor of Contract Manufacturing

Reporting to the Director of Manufacturing, primary responsibilities entail the overall management of contract manufacturers for aseptic blow-fill-seal liquid products, syringe filling and packaging acting as a “person in plant”. Duties include managing various 3rd party manufacturing sites to ensure compliance, evaluate new procedures and validations, quality audits, and oversee: formulation, in process testing, sterile filling, pouching and final packaging.

##### **Ortho Clinical Diagnostics (Johnson and Johnson), Raritan, NJ** January 1999 – Feb 2002

##### Sterile Filling and Labeling Supervisor - September 2001 – Feb. 2002

Supervised thirty employees within two departments over two shifts. Responsible for monthly production reports, fulfilling production schedule, FDA / compliance audits, timely completion of nonconformance reports / CAPA, controlling the departmental budget, SOP revisions and validations. Other duties involve conducting team meetings, employee performance reviews, project delegations, and compensation planning.

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2nd shift Biovue Inspection / Packaging Supervisor - May 2001 –Sept. 2001

Responsible for tracking employee performance, attendance and training. Other duties include defect classification, using Lean Manufacturing techniques to increase output, ensuring smooth workflow, meeting production schedule, culmination of batch paperwork and evaluating process metrics.

* Implemented 5S strategy resulting in reducing workspace footprint by 50%

Senior Technician - January 1999 – May 2001

Performed all aspects pertaining to the sterile filling of diagnostic serums and parenteral injectables. Duties include certification for workin an ISO 5/7 clean room, executing validations / engineering projects, training, batch record and SOP review / revisions, team building, completing corrective actions by due date, QA/FDA audits participation, safety team member, media fills, scheduling products/manpower over two shifts. Key player in the daily evaluation of line operations utilizing day by the hour charts, TPM metrics, and Process Capability indices.

* Lead technician in the implementation of "**Lean Manufacturing / Process Excellence”**.
* Utilized DMAIC methodology to increase liquid filler OEE by 20% (60 to 80+)

**INTERNSHIPS AND RELEVANT EXPERIENCE**

**M&M - Mars**, Elizabethtown, PA Spring-Fall 1997

**Research and Development Internship** – Cocoa Raw Material Group

**Moyer Packing Company (MOPAC)**, Souderton, PA Spring 1996 - Spring 1997

**Quality Assurance Internship** - Beef Division

**M&M - Mars**, Hackettstown, NJ Summer 1994 & 1995, 1997 - 1998

**Lead Material Handler/Operator** and **Maintenance Mechanic**

**EDUCATION:**

**Delaware Valley College of Science/Agriculture:** Bachelors of Science **(B.S.)**in***Food Science and Management***.

**CONTINUING EDUCTION / TRAINING:**

Pfizer courses:

Method One Six Sigma Green Belt training, Advanced Microsoft Excel, Kronos Administration, “Choose to Lead” – 5 day management course, Effective Communication in Business.

J&J courses:

Lean Systems and Development, Advanced Lean Manufacturing Techniques – Six Sigma, The Manager and the Law / salary administration, The Impact of Kaizen events - 2-day course, Project Management (FPX methodologies).

Professional Programs / courses:

ISPE – Pharmaceutical Manufacturing Seminar, Industrial Water Systems.

*The Writing Center -* Technical Writing

**Rutgers University, Center for Management Development** – Supervision and Management Development, certificate program.