John Tracy

Senior Engineer - MERCK

King of Prussia, PA - Email me on Indeed: indeed.com/r/John-Tracy/c6ed7158d5822b1f

WORK EXPERIENCE

Senior Engineer

MERCK - West Point, PA - 2009 to Present

· Worked with Quality Approver to author high quality GMP investigations within the Varicella Manufacturing Operations, while adhering to safety and compliance practices.
· Performed investigations on equipment failures to determine causation: either human or mechanical. Implemented viable corrective actions, including, but not limited to new equipment or increased maintenance.
· During a recurring failure investigation of end caps, I determined the causation to be a slight variation of grove width amongst different manufacturers, which had gone unnoticed for quite some time. When a cap failed, the entire batch was lost. I recommended and implemented revised specifications for the end caps. When the end caps not within the revised specifications were discarded or no longer purchased, the failure rate dramatically dropped.
· Investigated major processing equipment failure such as process vessels, valves, heat exchangers, pumps, tubing, process filters, flow meters, temperature probes, sonicators and gaskets. Used Root Cause Failure Analysis and Failure Mode & Effects Analysis and appropriate specification (ASME, ASNI) to determine causation of failures and worked with internal and external experts in developing proper corrective actions.

Chemical Process & Coatings Manager

ALLIED TUBE AND CONDUIT - Philadelphia, PA - 2006 to 2009

· Managed a three-shift operation of fifteen employees including two supervisors in a union ISO environment.
· Maintained accuracy and ordering of departmental inventory of $6,000,000.
· Implemented in-process improvements to: increase productivity, reduce material losses and decrease downtime.
· Researched, specified and purchased new processing equipment to reduce the process variation of the chemical tanks and increase productivity by decreasing out of spec items.
· Coordinated with engineering department to update process for efficiency and to evaluate new equipment.
· Managed production, with the mill-manufacturing department, to reduce downtime by ensuring the department was set up to produce new product without interruption.
· Coordinated all departmental maintenance issues with the maintenance department and engineering to ensure equipment was working adequately and designed equipment to create efficiencies.
· Managed all HR issues including counseling with union associates to ensure policies were met.
· Recognized, through troubleshooting, that bellows were cracking at an unusually higher rate. Worked with the manufacturer to determine the issue, which was a specification change on their end. With the manufacturer, I also worked for my company to receive compensation for the issue that arose due to miscommunication on their end.
· Investigated major processing equipment failure such as positive transfer pumps freezing, tank mixers, blowers, vacuum systems, transfer lines, process filters clogging, tank heaters, and air dryers. Used Root Cause Failure Analysis and Failure Mode & Effects Analysis and appropriate specification (ASME, ASNI) to determine causation of failures and worked with internal and external subject mater experts in developing and implementing corrective actions. Installed double redundant systems when it was deemed necessary based decreasing down time. Developed a preventive maintenance program for all processing equipment.

· Recommend modifying equipment for Single-Minute Exchange of Die (SMED) to reduce downtime and to eliminate the maintenance mechanic's required involment with changeovers and replacing equimpment that failed during processing.
· Recommended and implemented an increased preventative maintenance schedule due to the change in specifications.
· Recognized an issue with air quality causing pumps to freeze, performed investigation into the root cause and then researched and purchased an air dryer and pumps with new specifications, that I specified, which would eliminate the issue.

Supervisor, Downstream Purification Group

APPTEC - Philadelphia, PA - 2005 to 2006

Supervised 8 associates in daily purification duties and esured that personnel under supervision were properly trained in current Good Manufacturing Practices, procedures, documentation practices and regulatory matters
• Optimized the process including balancing workload versus man-hours and insured availability of correct processing equipment and materials.
• Worked with process development group to transfer technology from a lab scale operation to a pilot plant operation.
• Approved all batch records and SOPs to ensure technical validity and quality for revision and final review.

• Interviewed, hired and trained 4 associates to ensure department was adequately staffed and met department safety and regulatory standards.
• Managed 8 associates including disciplinary action, motivation, training, interviewing, hiring, and problem resolution for subordinates
• Coordinated production activities and requirements with three other departments to reduce down time and to make sure department was properly set up for optimum performance.
• Coordinated process development with clients and the process development group to ensure that the rigid production schedule was met.

Lead Biopharmaceutical Manufacturing Associate

GLAXO SMITH KLINE - King of Prussia, PA - 2001 to 2005

Supervised daily activities for a production suite consisting of seven employees on one shift.
• Supported Manufacturing as Automation specialist troubleshooting Proconex DCS, Delta, and RMNT process control systems.
• Developed and implemented SOPs for the start up of new processes and revised SOPs to reflect changes to the processes.
• Facilitated communication between three production suites to minimize lost production time.
• Provided recommendations for production schedule to production schedulers to reduce the amount of down time and to ensure adequate staffing for department.
• Initiated and monitored process operations using a computerized distributed control system.
• Performed in-process analyses from samples to ensure that all process parameters were within specification.
• Managed purification using: chromatography columns, UV detectors and flow meters.
• Conducted ultra-filtration and dia-filtration of biopharmaceutical proteins.
• Supervised the relabeling of all process and equipment in two production suites to ensure that all equipment was properly labeled and there were no discrepancies between SOPs and process diagrams.
• Member of safety committee and coordinated safety training.
• Recommended, developed and implemented numerous process and safety improvements. Including designing an improvement to the process transfer panels to increase the safety of employees.
• Reviewed and corrected all process instrumentation diagrams for the entire building.
• Worked with senior level engineers to modify and improve manufacturing process.

• Prepared reports for FDA pre-approval inspection.
• Trained several employees in process operations to ensure that personnel were properly trained in cGMPs, procedures, good documentation practices and regulatory matters.
• Coordinated preventative maintenance with maintenance department to reduce lost production time.

Chemical Operations Specialist

RHODIA, INC - Marcus Hook, PA - 1994 to 2001

· Supervised the training of twenty-five employees over four shifts on process operations and process chemical analysis in an ISO environment.
· Implemented process improvements to reduce cycle time of products and increase productivity.
· Worked in conjunction with production manager and maintenance department to coordinate annual shutdown. Determined which equipment would need to be evaluated. Recommended which equipment should be repaired and which should be replaced.
· Worked with production manager in identifying and creating a punch list and database for all plant equipment.
· Created a spare parts inventory, which was based on equipment failure rates and downtime.
· Developed a sample station on two reactors to increase the safety of the operators.
· Developed a laboratory safety program.
· Assisted in the development of calibration curves in the determination of hydroxyl values for Near-IR Analysis.
· Prepared statistical reports for internal and external review.
· Project leader of the team to reduce production cycle time and increase productivity and quality.
· Implemented Statistical Process Control in cooperation with plant and production manager.
· Investigated major processing equipment failure such as valves, heat exchangers, positive displacement and centrifugal pumps, pressure vessels, chemical storage tanks, piping, flow meters, temperature probes, pressure gauges, and level transmitter. Investigated all off line instrumentation failure. Used Root Cause Failure Analysis and Failure Mode & Effects Analysis and appropriate specification (ASME, API and ASNI) to determine causation of failures and worked with internal subject mater experts in developing robust corrective actions.

Draftsperson, Field Engineer

UNITED ENGINEERING AND CONSTRUCTORS - 1987 to 1994

Draftsperson

MOMENNE - KING ASSOCIATES - 1985 to 1987

EDUCATION

Villanova University - Villanova, PA

BS in Mechanical Engineering

Widener University - Chester, PA

Pennsylvania State University