

Matthew Appel

Project Engineer in the Pharmaceutical Industry

Huntingdon Valley, PA - Email me on Indeed: indeed.com/r/Matthew-Appel/9524c846cddc2282

Talented, multi-faceted Master's Level Mechanical Engineer with diverse engineering experiences including design and development, manufacturing/production, real-world applications of theoretical research, electrical/mechanical overhaul, maintenance, and testing, educational aspects/teaching. Aiming to acquire a Mechanical Engineer or Project Engineer position (2-5 years experience) in Research and Development (R&D), Process Engineering, Facilities, Operations, Manufacturing/Production, Quality Assurance/Quality Control (QA/QC), or Sales Engineering. Progressive responsibility and proven expertise with:

- Demonstrated experience in R&D, Manufacturing, Assembly, Testing, and Process environments
- Familiarity with PM SOP's and IQ/OQ/PQ authoring and execution.
- Project management
- Problem-solving, organizational, and communication (written and verbal) skills
- Data Analysis
- Exposure to Original Equipment Manufacturer (OEM) environment
- Various CAD programs
- Disciplined approach to troubleshooting
- Ability to read and interpret mechanical drawings

WORK EXPERIENCE

Process Validation Engineer

Zimmer Inc. TMT - Parsippany, NJ - 2014 to Present

Responsibilities

- Created Process Validation Protocols encompassing various items needed to qualify the Chemical Vapor Deposition (CVD) manufacturing process. Attended meetings almost daily resolving conflict and troubleshooting key items that a potential internal QA or FDA auditor could identify as difficult to manage. This included Product Requirements and Process Parameter Specifications.
- Involved with the generation of Technical Reports including work order review and statistical analysis and the review and approval associated with such a document.
- Initiated Engineering Change Requests (ECRs) in order to make way for the execution and approval of validations. These documents authorize the initiation of the related protocols within Zimmer's Change Management System.
- Important team member in group for Clean Room Renovation project involving compressed air, humidifier revisions, piping installations, and software upgrades.

Project Engineer

Jacobus Pharmaceutical - Plainsboro, NJ - 2013 to 2014

Responsibilities

- Composed, Routed, and/or Executed qualifications for a variety of equipment including a top-unload legacy centrifuge, a Hitachi 20HP reciprocating air compressor, a 30 CF Gemco dryer with custom vacuum pump assembly, the mapping of a Cool Storage Room maintained at $\leq 15^{\circ}\text{C}$, and multiple pneumatic and electrical pumps.

- Regularly supported progression of Gemco Validation project including revising a Sequence of Operations Document, participating in initial cleaning protocol, and drafting follow-up initial cleaning validation document. Also proposed preventive maintenance items to Director of Engineering.
- Frequently authored and routed Change Controls and Deviations through Engineering, Production/Manufacturing, Quality Control, and Quality Assurance.
- Scheduled, corresponded, and reviewed subsequent documentation for routine HEPA environmental monitoring and Compressed Air monitoring.
- Scheduled and maintained Calibration master file and certification documents.
- Created site map using MS Visio that was used for Official Site Master File for items such as site layout, pest control, product and raw material process flow, emergency exits/lights/extinguishers, etc.

Contract Project Engineer

URL Pharma (now Sun Pharma) - Philadelphia, PA - 2012 to 2013

Responsibilities

- Responsibilities include authoring and reviewing various Change Control Requests (CCR) to update existing or new Preventive Maintenance Standard Operating Procedures (PM SOP's) and also include writing and performing Installation, Operational, and Performance Qualifications (IQ/OQ/PQ).
- Equipment dealt with for PM SOP's includes Collette mixers, Blenders, Environmental Control Chambers, Tablet Presses, Coating Pans, Fitzmills, Glen Mixers, Ultima XIR LEL Sensors, Acetone Remediation System, among others.
- Equipment dealt with for IQ/OQ/PQ development and execution include Homogenizers/Mixers, Granulator, Comils, and Fluid Beds (all R&D scale units).
- Assisted in the completion of other projects concerning the following: higher-efficiency QC and warehouse lighting, compressed air surveying, HVAC, Safety items, and the installation of new employee lockers throughout the site.

Process Engineer

Jade Precision Medical Components - Southampton, PA - 2010 to 2012

- Responsibilities included administering job packages to the shop floor for the manufacture of screws and plates for spinal implants. These job packages, encompassing over \$250k/week in orders, included the engineering of job routers (via Vantage by Epicor and MS Query), inspection reports, drawings, and ancillary documentation. Facilitated management with ISO 13485:2003 and 9001:2000 audits as needed, including audit of Management Review process.
- Developed inspection reports by ballooning drawings and assigning inspection methods. Final versions of the inspections reports were formulated after the mediation of meetings with manufacturing and quality control personnel.
- First segment of employment period dealt with maintaining a 6-month in-house inventory (VMI), generating shipping paperwork including packing slips, copies of inspection reports, material certifications, non-conformance reports (NCRs), and certificates of conformance and training new employees to aid with shipping, receiving, and document control on a daily basis. Produced purchase orders as needed for supplies and for outside subcontract operations such as passivation / anodization of parts and grit blasting. Assisted in quality control department (inspection) when work load demand was high.

Product Development Engineer

Sonomedix, Inc., A Vasculab Company - Ambler, PA - 2006 to 2007

- Key player responsible for making transition of licensed technology from academic to commercial setting in start-up environment. Responsible for furnishing laboratory area, writing test protocols so that testing could commence to commercialize novel blood sensor coagulation technology.

- Critical results obtained, presentations organized to further investment opportunities. Conducted thorough analysis of current competing products on the market and corresponding patents. Researched publications of most up-to-date test methods and results to prepare for larger scale testing and develop techniques to help strengthen our position to the medical community. Prototype modeling.

Research Assistant / Teaching Assistant

Drexel University, Master's of Mechanical Engineering - Philadelphia, PA - 2004 to 2006

Thesis "Characterization of the Response of a Collagen-Coated Thickness Shear Mode Biosensor due to Platelet Activation and Aggregation", Drexel University, Dr. David Wootton, Philadelphia, PA 2004-2006

- Developed, tested, and implemented successful prototype of flow cell that was able to characterize the hemostatic condition of blood which aided in the development of a user-friendlier instrument than is currently available.
- Led all phases of testing including blood sample obtainment, sample preparation (centrifuging, drug dosaging), prototype testing, raw data and image analysis, parameterization and statistical analysis, conclusion and recommendations.
- Enabled quantification of parameters of blood flow, which were then correlated with images of biological processes via various acoustic, electrical, and fluid mechanics theoretical relationships and instrumentation.
- Research culminated in a very technical 80-page document being presented to university personnel.

Test Director

Norfolk Naval Shipyard - Portsmouth, VA - 2002 to 2004

Responsibilities

- Team player responsible for isolating/processing work on nuclear aircraft carriers and submarines to ensure worker safety and prevent damage by verifying that the numerous mechanical/electrical systems being worked are drained, depressurized, and de-energized; secondary was to be alertly aware of the areas affected by this isolation tagout; exposure to PFDs.
- USS Truman (CVN-75) Project Aircraft Carrier Availability '03, USS Washington (CVN-73) PIA-03: Regularly led small teams involved in isolating, testing, and releasing work for HVAC plants and associated piping, install of massive ship-wide fiber-optic alarm system, hot/cold potable water, firemain piping, JP-5 (jet fuel) pumping system, ventilation ducts, duct heaters, fans; conducted test on Primary Flight Command Center console that covered flight deck communications, lights, and catapult system.

EDUCATION

MSME in Mechanical Engineering

Drexel University - Philadelphia, PA

January 2004 to January 2006

BSME

Lehigh Univ - Bethlehem, PA

ADDITIONAL INFORMATION

Word, Excel, Query, Vantage by Epicor (Process MRP), ERP, Visio, Powerpoint, Outlook, Internet research, IQ/OQ/PQ, SOP's, cGMP, MAPICS, Ideas, LabView, Fluent (CFD), AutoCad, Solidworks, Solid Edge, PFDs, beginner machine shop skills, various imaging software programs, familiarity with databases (SQL), Access, GD&T (ASME Y14.5M), commonly used inspection equipment, 21CFR [...] ISO [...]