

David Dychala

Materials and Process Development Engineer

Philadelphia, PA - Email me on Indeed: [indeed.com/r/David-Dychala/cc8c59d5c7dc4cd6](https://www.indeed.com/r/David-Dychala/cc8c59d5c7dc4cd6)

Authorized to work in the US for any employer

WORK EXPERIENCE

Senior Quality Engineer

TELEFLEX MEDICAL - July 2013 to March 2015

QA Engineer managing CAPA and NC projects across global facilities at product and quality system levels. Execution of Failure Investigations using Root Cause Analysis tools; develop Implementation Plans; preparation of Event Investigations for Field Corrective Actions.

Senior Quality Engineer - Arrow Products

- Manage cross facility CAPA and NC projects to resolve product/process compliance issues
 - o Create and maintain project binders to assure completeness of documentation
 - o Instituted the use of Summary Reports during the NC process
- Provide Regulatory Agency auditors readily available objective evidence
- Minimize the probability of drill down inspections by the auditors
 - o Provide technical recommendations during review and correction of drawings and procedures
- Develop and present technical rationales in support of documentation amendments
- Eliminates future risk of non-compliance of amended documentation
- Provide support to field correction actions
 - o Compile and analyze objective evidence to facilitate closure of recalls
- Support Regulatory Affairs in the closure of observations from Notified Body audits

Quality representative

TIMET - November 2012 to March 2013

Quality representative providing technical guidance and hands-on operational improvement support to existing powder metal manufacturing procedures, preparation of raw material specifications based on analysis of customer requirements, assess testing methods for compliance with ASTM standards.

Quality Engineer - TIMET Powder Metals

- Developed process improvements through collaboration with in-house business unit teams
 - o Oversaw process re-design efforts to assure compliance with HSE requirements.
 - o Refined existing manufacturing processes to resolve customer complaints
- Quality representative to product and process development teams
 - o Led PFMEA teams to mitigate customer supplied 'Hazard Reviews'
 - o Directed CAPA activities for resolution of customer complaints.

Materials and Process Consultant

ENRG, INC - October 2009 to October 2012

Rheology and film coating subject matter expert providing timely improvement to existing process methods, derive novel solutions for product development projects, establish robust manufacturing processes to reduce finished goods lot-to-lot variability.

Project Manager - Consultant

- Developed optimal process solutions collaborating with in-house teams and external resources
- o Defined critical customer requirements and established product attribute specifications
- o Established release specifications based on customer needs and production capability
- Led product and process development teams
- o Executed process audits to establish manufacturing cost and output baselines
- o Evaluated new methods for material processing and production operations
- Optimized manufacturing techniques for continuous production systems
- o Standardized material and process parameters to minimize batch-to-batch variability
- o Initial optimization efforts resulted in 15% direct labor and 25% material cost reductions
- Developed external vendors to assure minimization of quality and production costs
- o Defined minimum raw materials specifications and receiving documentation requirements
- o Initial system improvements reduced incoming inspection direct labor costs by 20%

Principal Process Development Engineer

ORTHOVITA - August 1998 to July 2009

Founding member of the R&D team; bio-ceramic subject matter expert delivering key contributions to product/process development programs, Patent Applications and FDA 510(k) filings. Co-author of intellectual property filings and technical representative for regulatory agency audits.

Provided technical management during product and process transfer from R&D to Production

- o Design of Experiments and data analysis supporting Design for Six Sigma initiatives
- o Identification and qualification of vendors to assure consistency of incoming materials
- Led inter-departmental FMEA teams to ensure product/process design capability
- Directed material, process and procedure development activities to support product launches
- o Established raw, intermediate and finished goods material specifications
- Provided technical leadership to the Operations group on process improvement projects
- o Developed and modified processes assuring product quality, and improved time to market
- Mentored and coached staff in the use of Six Sigma Methodologies
- Trained and developed Manufacturing personnel
- o 4X increase in manufacturing output over 3 years with 50% decrease in unit cost
- o Maintained schedule and first time good levels at 95%+ with constant staffing
- Identified, procured, installed and validated new and modified production equipment
- o Modified and validated existing equipment to improve manufacturing process efficiency
- Prepared and maintained capital and expense budgets per marketing demand forecasts
- Designed, developed and validated ISO and FDA cGMP compliant manufacturing systems
- o Ensured compliance of process methods to all applicable Health and Safety regulations
- Developed and maintained project schedules and deliverables
- o Managed in-house resources and external contractors assuring launch timelines were met

Manager - Special Projects

ELECTRO SCIENCE LABS - May 1986 to July 1998

Senior member of R&D staff; micron-sized materials processing and high solids film coating application subject matter expert providing novel solutions to product and process development programs and on-site support of customer projects. Negotiated contracts, managed new product development programs assuring delivery dates, product performance and price targets were achieved.

Technical and hands-on management during technology transfer from R&D to manufacturing

- o Resolved customer issues by identifying and implementing manufacturing improvements

- Prepared ROI assessments of customer requests and internal development programs
 - o Analyzed product designs against technical feasibility and manufacturing capability
- Prepared and executed customer site audits to support alternative technical solutions
 - o Provided process alternatives and technical rationale to management and customers
- Directed cross departmental project teams of engineers, line supervisors and operators
 - o Refined manufacturing procedures to reduce labor costs following ISO/QS methodology
 - o Reduced inventory and production costs through material and process standardization
- Developed materials databases and process systems knowledge bases
 - o Provided for rapid assessment of requisite chemical, electrical and mechanical properties
 - o Allowed continual correlation of manufacturing parameters to final product properties
- Prepared and presented technical product introduction packages
 - o Provided on-site process setup instructions to customers for new products
 - o Served as subject matter expert in support of Marketing

EDUCATION

Bachelor of Science in Ceramic Engineering

Pennsylvania State University

LINKS

<http://www.linkedin.com/in/ddychala>

CERTIFICATIONS

ASQ Certified Six Sigma Black Belt

October 2004 to December 2016

ASQ Certified Manager of Quality and Organizational Excellence

October 2013 to December 2016

GROUPS

American Ceramic Society

American Society for Quality

International Microelectronic and Packaging Society

ADDITIONAL INFORMATION

Refer to LinkedIn profile for a list of Patent and Publications.