Hesam Setayesh [↖]

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Professional Summary

Hesam is an honored USC master's graduate in Biomedical Engineering with a strong foundation in Mechanical Engineering, cardiovascular science, and cardiovascular anatomy. He brings over five years of experience, including hands-on expertise in medical device CAD software (SolidWorks, Fusion 360) and CAPA investigations. Hesam is skilled in root cause analysis (RCA), risk mitigation methods, FDA Class II and Class III guidelines, ISO 13485 compliance, statistical data analysis techniques (Excel, JMP, Minitab), and managing projects with several stakeholders.
Additionally, he has experience with medical device programming languages (Python, MATLAB), machine learning algorithms, and MATLAB image processing toolboxes. Hesam is seeking to leverage his skills in senior product / process development and senior R&D roles.

Professional Experience

Manufacturing Process Engineer – Quality Engineer, Abbott, Temecula – Full Time   March 2025 - Present
- Certified CAPA investigator, led root cause analysis, and completed 7 full CAPA investigations for catheter product lines.
- Proficient in Excel, JMP, and Minitab for statistical analysis, process monitoring, and risk management.
- Conducted equipment validations (IQ, OQ, PQ, PPQ), reliability tests, and out-of-tolerance calibration reviews.
- Mentored entry-level engineers on process troubleshooting and risk mitigation, aligning with division and leadership goals.
- Knowledge of engineering materials such as nitinol, coatings, and extrusion manufacturing
- Prepare and present monthly process control monitoring reports to directors and upper management

Manufacturing Process Engineer, Abbott, Temecula – Full Time   Oct 2023 - Present
- Improved manufacturing yield by $55K using Lean Sigma, A3, Kaizen, Ishikawa Diagram, and Gemba walks.
- Conducted and designed over 20 DOEs and statistical analyses (JMP, Excel) to address major production defects and optimize key processes.
- Led cross-functional team of 12 (operations, industrial, and quality engineers) to optimize layouts and conduct time studies.
- Collaborated with R&D for product development, troubleshooting coating failures, and improving catheters' manufacturability and materials.
- Designed and implemented technical solutions and fixtures (GD &T) to improve PFM efficiency and reduce manual touch time.
- Proficient in GMP, QSR, FDA guidelines, FMEA, PFMEA, supplier quality, and process control, defines technical requirements for experiments.
- Six Sigma Yellow & Green Belt certified; currently advancing in project management and problem-solving through internal talent development.
- Project manager for MDD to MDR transition of 2 vascular products, including software updates, labeling revisions, and supplier coordination.
- Engineering point of contact for technical support of endovascular products for external vendors and suppliers.

Regulatory Affair Consultant, DK Kim International Center for Regulatory Science, Los Angeles   Aug 2022 – Jul 2023
- Authored and compiled technical documentation supporting PMA submission for a Class III cardiovascular implantable device.
- Conducted predicate device research and regulatory landscape analysis using Open FDA APIs, supporting risk analysis and product positioning.

Lead Mechanical Engineer, University of Southern California (Brain & Body Dynamics Lab) [↖]   May 2023 - Nov 2023
- Designed and prototyped mechanical components for a 9 DOF robotic hand using Fusion360 and SolidWorks, supporting functional testing.
- Led 3D printing of custom fixtures Bio-inspired robot using PRUSA, supporting early-stage assembly and statistical evaluation processes
- Implemented a custom test setup for audio signal analysis and sensor validation using Raspberry Pi and microcontroller integration.

Mechanical Engineer, Taha Gostar Co., Tehran, Iran   Apr 2020 - May 2021
- Performed mechanical drawings using AutoCAD and SolidWorks based on regional standards for fabricating prototypes
- Conducted process monitoring, risk assessment, and project mapping, resulting in an annual cost reduction of over 15%.

Junior Mechanical Engineer, Taha Gostar Co., Tehran, Iran   Apr 2018 - Apr 2020
- Resolved real-time on-site problems as an onsite engineer, managing project phases based on stakeholder timeframes

Education

Master of Science - Biomedical Engineering, University of Southern California, Los Angeles, GPA:3.50   Aug 2021 - May 2023
- ➤ Viterbi School of Engineering – M.S. Award for Academic Excellence and Service - Class of 2023 [↖]   May 2023

Master of Science - Mechanical Engineering, Azad University Science & Research Branch, Tehran, GPA:3.50   Sep 2017
- ➤ Ranked 6th in nationwide entrance exam

University Professional Experience

Research Assistant, University of Southern California, Los Angeles   Aug 2022 - Nov 2023
- Led a FEA experimental research on cell deformation patterns under external ultrasound force employing Solid works for designing, Ansys CFX for computational simulation (Funded by Keck medicine of USC)
- Implemented simulations on atrial fibrillation databases, processing ECG signals using Random Forests, and SVM algorithms.
- Conducted 2D and 3D motion and noise analysis on CT Dicom images using MATLAB for radiomics analysis, ImageJ for data visualization

Publications

- Viscoelasticity in 3D cell culture and regenerative medicine: measurement techniques and biological relevance, ACS Material Au [↖]   Jun 2024
- The Effects of Geometric Factors on Power Generation Performance in Solar Chimney Power Plants, Journal of Energy [↖]   Jun 2024
- Image Perturbation Analysis to Study the Effect of Noise on Radiomics Metrics: Phantom Study, SIPAIM [↖]   Dec 2023
- Image perturbation analysis to study the effect of motion on CT images, Radiological Society of North America (RSNA)   Nov 2023

Skillset

Project design tools: Solid Works |Fusion 360 |AutoCAD |Microsoft Project Management | Microsoft Office (PowerPoint, Excel, Word) | Outlook
Project Skills: Lean Six Sigma Green Belt (DMAIC, PFMEA, DOE, RCA, FMEA) |ISO 13485| CAPA |SAP | Blueprint programming
Developed Skills: Statistical Data Analysis (Excel, JMP, Minitab) | Statistical tests (ANOVA, T-test, non-parametric) |Power Bi
Computational Tools: Ansys CFX |Ansys Fluent | 3D printing PRUSA slicer | Test Validation | Plastic molding (Extrusion, Injection)
Programming Languages and Machine Tools: Python |MATLAB |Simulink |NumPy |Pandas |ML algorithms (Regression, unsupervised)