# **Joseph Tay**

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#### **Skills**

Project Management, Work Breakdown Structure, Mindjet MindManager, Installation Qualifications, Operational Qualifications, Performance Qualifications, Statistical Process Control, Visio, Microsoft Project, MiniTab, Arena, Photoshop, AutoCAD, MySQL, SAP, HTML/CSS, R, SAS, C, Matlab

### **Experience**

## Medtronic, Santa Ana CA

Manufacturing Engineer II

Jan 2019 - Present

- > Project: Electronic Device History Record(e-DHR) and Electronic Batch Record(e-BR) Initiative
- Spearheaded design of product and information flow during implementation of e-DHR and e-BR initiative using parallel streams in Visio.
- Created work breakdown structure in collaboration with cross-functional team using Microsoft Project and Mindjet MindManager
- Organized and led sprint meetings with stakeholders to ensure Gantt timelines are maintained with effective resource management.
- Facilitated utilization of SAP Enterprise Resource Planning in test and production environments to implement efficient information transfer per regulatory requirements of quality records throughout entirety of process.
- > Project: Heartbeat 2.0 Cost reduction initiative
  - Assisted project manager with timeline creation and work breakdown structure planning for major labor reduction overhaul of assembly process (projected cost savings: 10 million dollars per year)
  - Collaborated with Microbiology to write and release protocols for microbiological testing and qualification of new tooling and fixtures.
  - Developed sub-project plan for new part number release for all products impacted by new process.
  - Co-ordinated vendor liaisons for sourcing of machined subassemblies for new tooling/fixtures.
  - Conducted DOEs during design review of tooling to determine root cause of deficiencies & identification of opportunities for improvement.

#### Associate Manufacturing Engineer

Jan 2018 - Jan 2019

- o Wrote protocols and reports for qualification and validation activities of process changes and new equipment introduction.
- o Investigated and dispositioned nonconforming product by evaluating root cause and designing corrective actions to prevent recurrence.
- Provided daily support to troubleshoot and resolve equipment and process issues on multiple value streams, reducing downtime and implementing one-piece flow processing in several production sequences.
- o Identified process improvement opportunities in the valve assembly process and led Lean-Six Sigma projects based on those opportunities for improvement, effectively improving manufacturing yield and optimizing material usage variance of production areas.
- o Designed manufacturing processes and sequence of operations in compliance with FDA and other regulatory bodies.
- o Champions Continuous Improvement projects, providing lean six sigma mentorship to team members starting their own initiatives.
- o Provides solutions to issues related to process, equipment, supply chain and Quality Management Systems.

#### ➤ Project: Yield improvement for valve assembly process

- Led a cross-functional team to determine scope and regulatory requirements for implementation of a new subassembly product
- Wrote and Performed Design Characterization protocol and report with assistance from design counterparts to investigate if a previously unacceptable characteristic can be characterized as acceptable under the right circumstances.
- Submitted report and findings to FDA with assistance from regulatory affairs counterpart to allow production and clinical use of subassemblies with new characteristics defined within certain geographies utilizing HDE 75-day submission for USA-based product.

#### FreshRealm LLC, Riverside CA

Process Quality Engineer

May 2017 – Jan 2018

- o Wrote, reviewed and maintained integrity of company-wide GMPs, SOPs and Quality Control Policies.
- Solved and mitigated process and product related non-conformances by owning and leading site-level CAPA projects by acquiring, cleaning and mining data for production-based root-cause analysis of quality issues.
- o Bolstered company efforts to obtain SQFII and ISO certification through the authoring and release of important quality systems policies.
- Drove continuous improvement within production facility to enhance productivity and profitability based on specific key performance indicators while adhering to food safety standards.

## > Project: West Coast retail program launch & Riverside facility start-up

- Facilitated launch of new retail program in freshly-acquired facility, including layout planning and scalability initiatives post-launch.
- Organized set-up of production lines and inventory locations utilizing Lean Six Sigma concepts like Kanban systems (a necessity for JIT fresh food inventory), Cell layouts for efficient product flow and 5S Methodology to minimize waste.
- Trained and managed a team of Quality Technicians to perform standardized work involving quality management system adherence.
- Oversaw line improvement and quality deficiency response projects to completion with the use of effective resource management tools like sprint planning and Gantt chart timelines to achieve major milestones.
- Supported fulfilment operations by implementing DMAIC problem-solving methodology to help production meet takt times consistently through production volume ramps.

#### **Education**