



# Example of Senior Design Quality Engineer Job Description

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Our company is growing rapidly and is looking for a senior design quality engineer. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

## Responsibilities for senior design quality engineer

- Lead shelf life and biocompatibility testing and create associated test procedures and reports
- Create and update product risk analyses and risk management files
- Develop and implement new and improved quality/compliant pre-market engineering methods, techniques and processes
- Build stable relationships internally
- Apply statistical methods and process/design excellence tools to establish test plans evaluate test data and processes
- Provide leadership in all areas of the Quality System, including, but not limited to Corrective & Preventive Actions, Risk Management, Complaints, Post Market Surveillance, Nonconforming Materials
- Communicate effectively at all levels within Quality, cross functionally with departments such as Research & Development, Regulatory, Marketing and Manufacturing
- Serve as primary quality representative on project teams
- Communicate effectively at all levels within Quality, cross functionally with departments such as Research & Development, Regulatory, Manufacturing, Supply Chain, and Marketing
- Produce and review a wide range of quality documents including

## Qualifications for senior design quality engineer

- Familiar with quality processes and tools such as APQP, Control Plans, MSA, FMEA
- Strong understanding of industry expectations in the areas such as voice of customer, specification development, risk management, design verification and validation, stability studies, sterilization validation, biocompatibility, transportation testing
- Working knowledge of electro-mechanical devices, software validation methods, and/or plastics related manufacturing processes
- Familiar with gage and inspection techniques
- Fluid verbal and written communication skills
- 4-9 years progressive, seasoned design assurance engineering within the biopharma