



December 12, 2022

Design Outreach

Quality Engineer II, Quality—DO Medical

Organization:

In today's world, billions of people living in developing nations lack access to basic and life-saving healthcare technologies. Every year, medical equipment is donated by international donors, but it quickly falls into disrepair due to improper design, lack of supplies, and inadequate training. Without access to appropriate healthcare equipment billions of people around the world face dangerous conditions, disease, and even death.

Design Outreach (DO) exists to solve these global challenges through the development of innovative and appropriate technologies in the Medical Device and Water, Sanitation, Hygiene (WASH) sectors. We do this by engineering technologies that are appropriate for the context and communities in which they are used by providing a high level of quality in all our products. As a Christian humanitarian engineering organization, our vision is to see low-income and marginalized communities around the world transformed physically, economically, and spiritually. We have seen firsthand the transformation that happens in communities where appropriate technology has provided reliable, safe water for years without failure—evidence that appropriate and reliable technology solutions can break the cycle of poverty and provide bridges to share the Gospel. We now aim to achieve the same impact through appropriate medical device technology.

Design Outreach is a small team with global impact. At Design Outreach, you will have the opportunity to dive into a diverse set of projects, solve uniquely challenging engineering problems, have high-level ownership of your work, and make a direct impact on our mission. Our team has grown from 5 to over 30 staff members in under three years and continues to expand as we strive to be the global leader in appropriate technology development. DO's work environment is highly collaborative. Our staff work alongside and learn from volunteers within industry and academia, including the DO Fellows, a group of world-class subject matter experts that work with and mentor our staff. In the next three years, we are planning to deploy seven technologies in the Medical Device and WASH sectors.

What will your impact be? We invite you to find your purpose and live out your calling at Design Outreach. Join our team, and work alongside others who are committed to putting their faith into action!

Position:

Reporting to the Chief Technology Officer (CTO), the Quality Engineer II will assure product quality from the design process, through manufacturing, and continuing to the post-sale/placement of the products. This position includes: assuring compliance to design and development processes, assisting Project Engineers with Design History File documentation, developing Quality procedures, auditing internal processes, qualifying suppliers, coordinating product inspection methods with suppliers, developing inspection plans, inspecting purchased products using mechanical and optical gauging, maintaining the Device History Records, investigating product issues, assisting during FDA audits, and working with customers to resolve product issues. The Quality Engineer II position is a full-time permanent position with benefits and requires support raising.

Key Responsibilities:

- Support-raise launch funds and annual funds, while maintaining consistent and appropriate contact with ministry partners.
- Participate in design project teams and professionally represent Design Outreach while interfacing with various volunteer, industry, healthcare, and advisory partners.

- Assist Project Engineers in risk management and the design and verification process, per applicable standards, to assure that design outputs meet design inputs and user needs/intended uses.
- Assist Project Engineers in developing and maintaining Design History File documentation.
- Support 510(k) submissions.
- Assist in the initial development of a quality system compliant to the FDA Quality System Regulations (QSRs).
- Maintain the Device Master Record for all Design Outreach Medical products.
- Conduct supplier quality audits and maintain an Approved Supplier List.
- Develop Supplier Quality Control Plans with suppliers to assure consistent and accurate inspection methods.
- Develop internal, statistically-based inspection plans for purchased products and inspect products using mechanical and optical gauging methods.
- Coordinate and maintain gauge calibrations.
- Coordinate and maintain Device History Records with suppliers.
- Coordinate internal quality system audits to assure compliance to QSRs
- Conduct product investigations to identify root cause and corrective actions.
- Support on-site FDA audits.

Requirements:

- Understands and supports the mission of a Christ-centered organization dedicated to sharing the Gospel by word and deed.
- Passion and agreement with Design Outreach's vision and mission.
- Kingdom and abundance-minded when working with ministry partners.
- 1-3 years of experience within the medical device industry and knowledge of QSR requirements.
- Mechanically inclined with a basic understanding of blueprint reading and metrology.
- High capacity to be self-motivated for independent work and to be collaborative for work with teams, including volunteers.
- Strong communication in English (written, oral, and presentation) and interpersonal skills.
- Self-motivated and detail-oriented.
- Excellent verbal, grammar, computer, and Word/Excel/PowerPoint skills.
- Ability to provide presentations to coworkers and volunteers.
- High capacity to multitask, work independently, and problem solve.
- Ability to commit an average of 8 hours per day 5 days per week (40 hours total per week), with availability in evenings and weekends to support special events, accommodate volunteer/donor schedules, and ensure deadlines are achieved.
- Works from office in Columbus, Ohio or Warsaw, Indiana with ability to travel domestically and internationally to meet with staff and/or partners.
- Ability to work in a team-based collaborative environment.

Required:

- BS degree in a technical or science discipline.
- References.

Timeline:

- Position start date is negotiable, and interviews will be ongoing until position is filled.