



Luciana Payne

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SUMMARY

Dynamic Principal Clinical Engineer offering over 12 years of experience in medical device development. Proven ability to lead diverse teams while managing project timelines, ensuring strict adherence to ISO 13485 compliance standards. Skilled at translating clinical needs into actionable design specifications, driving innovation in technology that significantly improves patient outcomes. A strong advocate for collaborative partnerships with clinicians and stakeholders to deliver comprehensive solutions tailored to real-world demands. Committed to advancing preclinical testing capabilities and employing evidence-based best practices to enhance product features and usability.

EXPERIENCE

Principal Clinical Engineer

January 2018 – Present

Innovative Medical Solutions

San Diego, CA

As the Principal Clinical Engineer, led advanced medical technology projects enhancing both user experience and clinical applicability. Drove design verification processes forward by collaborating with multi-disciplinary teams while adhering strictly to regulatory requirements.

- Spearheaded projects integrating intuitive designs based on clinician feedback, improving engagement and satisfaction.
- Set rigorous design parameters backed by preclinical studies ensuring product efficacy and safety within ethical standards.
- Actively oversaw budget allocations for resource optimization, resulting in enhanced internal testing capabilities.
- Communicated regularly with management regarding project status, facilitating timely interventions and decision-making.
- Diligently mentored less experienced engineers, nurturing a progressive environment focused on skill enhancement and innovation.
- Ensured compliance with global quality standards and regulations at all levels of product development and testing.

Senior Clinical Engineer

June 2014 – December 2017

NextGen Health Technologies

San Jose, CA

Oversaw product development and regulatory submissions as a Senior Clinical Engineer, fostering an environment of collaboration to meet fast-paced market needs. Focused on gathering insights from clinical users to ensure products remained relevant and competitively positioned.

- Developed testing plans aligned with international standards, seamlessly integrating design revisions post-feedback reviews.
- Enhanced efficiency of preclinical testing protocols, which directly reduced time-to-market for multiple devices.
- Facilitated meetings with regulatory entities leading to successful approvals of pivotal product advancements.
- Engaged systematically with end-users, collecting feedback that informed iterative enhancements of existing solutions.
- Managed project resources effectively, ensuring timelines were met while maintaining high-quality outputs.
- Hosted training seminars in regulatory compliance, elevating team knowledge and adherence to industry best practices.

Clinical Engineer

March 2012 – May 2014

HealthTech Innovations

Sacramento, CA

Acted as a Clinical Engineer to support product lifecycles and integral design assessments. Collaborated closely with engineering and clinical teams to ensure safety and effectiveness of innovative healthcare solutions.

- Conducted critical analyses of user feedback generating product improvement strategies to elevate client satisfaction.
- Participated actively in the preparation of regulatory submissions, maintaining adherence to ISO and other necessary standards.
- Engaged in risk assessment routines, enhancing safety awareness throughout the product design process.
- Worked alongside engineering units to refine manufacturing workflows to attain set quality expectations.
- Provided inputs creating clinical evaluation protocols vital for product validation during trials.
- Documented detailed findings from testing phases, influencing subsequent design iterations positively.

LEADERSHIP & AWARDS

- Recognized for Excellence in Clinical Innovation by Innovative Medical Solutions, 2021
- Outstanding Team Leadership Award, awarded by NextGen Health Technologies, 2016

EDUCATION

Bachelor of Science in Biomedical Engineering

2010

University of California, Los Angeles GPA: 3.8

Los Angeles, CA

Coursework: Biomedical Device Design, Regulatory Compliance, Quality Assurance, Medical Imaging Techniques

CERTIFICATIONS

- Certified Clinical Engineer (CCE) 📅 2016
- ISO 13485 Lead Auditor 📅 2018

TECHNICAL SKILLS

- **Design Tools:** SolidWorks, AutoCAD, CATIA
- **Testing Equipment:** Bioreactors, Analytical Microscopes, Mechanical Testing Machines
- **Quality Standards:** ISO 13485, FDA Regulations, GLP-compliance
- **Project Management Software:** JIRA, Microsoft Project, Trello
- **Statistical Analysis Software:** SPSS, R, Minitab
- **Collaboration Platforms:** Microsoft Teams, Slack, Zoom
- **Data Management Tools:** Excel, Access, Tableau
- **Clinical Evaluation Methodologies:** Randomized Trials, Usability Testing, Performance Benchmarks
- **Documentation Systems:** eQMS, Document Control Systems, SharePoint
- **Research Methodologies:** Literature Review, Meta-Analysis, Protocol Development

SKILLS

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|----------------------------------|-----------------------|------------------------|--------------------------|
| • Product Development | • Team Leadership | • Usability Studies | • Risk Analysis |
| • Clinical Testing | • Design Verification | • Quality Assurance | • Data Interpretation |
| • Regulatory Compliance | • Project Management | • Technical Writing | • Stakeholder Engagement |
| • Cross-functional Collaboration | • Budget Oversight | • Preclinical Research | • Ethics Compliance |

PROFESSIONAL AFFILIATIONS

- Active member of the Biomedical Engineering Society (BMES), contributing to peer discussions on industry trends.
- Volunteer Mentor for STEM Educational Programs aimed at inspiring future engineers.

LANGUAGES

- English (Native)
- Spanish (Proficient)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST