LETICIA HERNANDEZ

Addison, IL 60101 | (312) 576-4419 | Lhgarcia76@hotmail.com

Project Management · Relationship Management · Project Delivery · Leadership · Vendor Management

I am a forward-thinking leader with 20 years of experience in project management, project delivery, relationship management, and vendor management in the pharmaceutical industry. I specialize in successfully delivering large-scale technology projects by collaborating and making effective decisions. I thrive in fast-paced environments where I can think innovatively to tackle challenges and resolve problems.

CORE COMPETENCIES

Project Management Regulatory Requirements Relationship Management

·Adaptability ·Project Delivery ·Motivator

•Team Leadership •Risk Analysis/Mitigation •Data Management

·CAPA Plans ·Innovator ·Strategic Planning/Execution ·Vendor Management ·Problem Solving ·Software Development ·Interactive Response Technology (IRT) ·CFR 21 Part 11 ·Drug Development

PROFESSIONAL EXPERIENCE

Pfizer, New York, NY Sr. Manager, IRT Lead

Jan 2020 - Feb 2024

Pfizer Inc. is a global biopharmaceutical company, one of the world's largest pharmaceutical companies, known for its research, development, and manufacturing of medicines and vaccines across various therapeutic areas.

- Mentored project managers, using proven coaching techniques to foster individual growth and development.
- Directed studies between clinical teams and vendors, ensuring requirement specifications adhered to company standards and regulatory requirements.
- Served as the subject matter expert, designing complex clinical supply and randomization studies.
- Designed and executed complex test plans, ensuring comprehensive validation of system functionality, compliance, and traceability before deployment.
- Managed multiple vendor relationships, ensuring service quality, contract adherence, and issue resolution.
- Led escalation processes, proactively addressing critical vendor issues to mitigate risk and maintain project timelines.
- Established governance frameworks and communication strategies with vendors to enhance accountability and performance, resulting in collaborative relationships.
- Developed and presented vendor KPIs to senior leadership, ensuring the implementation of actionable plans.
- Led corrective and preventive action plans, utilizing root cause analysis methodologies like the 5 Whys and Fishbone to ensure accurate issue identification and the implementation of measurable action plans.
- Spearheaded department-wide initiatives to optimize processes, enhance operational efficiency, and drive strategic alignment, resulting in improved performance and measurable business impact.

Bioclinica, Princeton, NJ Nov 2013 – Jan 2020

A global clinical trial technology company offering end-to-end solutions for decentralized and hybrid trials and a clinical outsourcing model where a pharmaceutical or biotech company contracts specific functions or roles to an external provider rather than outsourcing an entire study or project.

Group Lead – Vendor Management (embedded with Pfizer)

- Managed complex studies in collaboration with clinical teams and vendors, ensuring compliance with company standards and regulatory requirements while aligning with specified study requirements.
- Served as the subject matter expert for complex system designs, providing strategic guidance on regulatory requirements, functionality, and implementation best practices.

- Collaborated with cross-functional teams to translate the protocol into scalable and compliant system solutions.
- Led design reviews, identified potential risks, and recommended optimizations to enhance system efficiency, usability, and regulatory adherence.
- Drove departmental productivity and identified opportunities for improved efficiency and quality by strategically
 assigning projects, evaluating and monitoring staff workload, ensuring timely project completion, and
 implementing necessary changes.
- Led departmental initiatives and special complex technology projects in collaboration with senior management to enhance operational effectiveness.
- Managed the successful implementation of new technologies by managing end-to-end deployment, coordinating cross-functional collaboration, and ensuring seamless integration.
 - Developed and executed comprehensive training programs to equip teams with the necessary skills, foster user adoption, and optimize system utilization.
- Fostered strong internal and vendor relationships by maintaining open communication, collaborating with
 internal and external stakeholders, and ensuring successful project execution while proactively addressing and
 resolving client concerns.
- Supervise and develop staff by setting clear expectations, monitoring performance, providing coaching and mentorship, and enforcing policies and procedures to maintain a high-functioning team.

ADDITIONAL EXPERIENCE

- Tourtellotte Solutions, Vendor Management Analyst
- Sigma Systems, Vendor Management Analyst
- BLC Consulting, Vendor Management Analyst
- Kay and Associates, Business Analyst
- Hewitt Associates, Business Analyst

TECHNICAL SUMMARY

- **Methodologies:** Proficient in waterfall and scrum methodologies for efficient project delivery. Proficient in root cause analysis utilizing the five whys and fishbone methodologies.
- Risk Management: Adept at identifying, assessing, and mitigating project risks to ensure smooth project execution.
- **Team Collaboration**: Strong leadership experience in remote, global cross-functional team environments, promoting successful collaborations through tools like Microsoft Teams.
- System Knowledge: QMS, GDMS, IRT, TMF, CDMS, SharePoint, Microsoft Suite

EDUCATION

- Bachelor of Science (BS), Business Administration | DePaul University, Chicago, IL
 - Graduated with honors