Change Control Owner – Thousand Oaks, CA
Compensation Range*
$30.00/hr - $50.00/hr
*Exact compensation may vary based on skills, experience and education.

Job Summary:

Gabe, Inc.® is looking for a Change Control Owner that will play a key role in ensuring change initiatives are implemented in a thorough and compliant manner as defined by the Change Control Process. The primary responsibility will be to provide an active lead of change control records to ensure the process remains compliant with client SOP, meets high quality standards and established timelines.

Position Responsibilities:

- Gather information from team members and SMEs on a project and understand the overall scope and project plan.
- Provide clear, complete and accurate description of the change and potential known touchpoints to facilitate assessors understanding of the change
- Lead and actively facilitate the client Change control process by working with client and project teams to develop a detailed plan of the impacts and activities needed to control the impacts.
- Work closely with quality assurance to ensure information received is follows guidelines
- Gather SME input and summarize into a specific format per client SOP
- Track tasks to completion, working with project management to ensure timelines are maintained
- Ensure that all stakeholders potentially impacted by the change are identified and informed about the change and, if needed, are consulted for advice on the proposed change including its risk profile
- Own, develop and manage the change implementation plan

Skills / Competencies

- A solid understanding of GMP and change control requirements
- Experience with Quality Management applications such as Trackwise
- Strong project management skills
- Demonstrate technical understanding in relation to the subject matter of the change
- Exceptional communication skills, both written and verbal
- Comfortable with leading meetings and presentations
- Comfortable “raising a hand” and taking charge when issues present
- Flexibility in adapting to a process which changes periodically
- Action oriented to ensure timely management of the change control activities
- Ability to manage a cross-functional team
- Ability to manage multiple projects simultaneously
- Ability to use rigorous logic and methods to solve difficult problems with effective solutions
- Ability to identify the important criteria to meet the desired results
- Ability to influence others and move toward a common vision or goal
- Flexible and adaptable; able to work in ambiguous situations
- Must be a team player and able to work collaboratively with and through others

Basic Qualification

- Have a minimum of 2-3 years of client facing pharmaceutical project management and/or Validation/Quality experience
- Knowledge of basic validation/ qualification workflows

Preferred Qualifications

- Working knowledge of automation, IS, and control systems such as DeltaV, PI, FactoryTalk Asset Centre, and SCADA, with a strong understanding of their integration with equipment systems and compliance with FDA 21 CFR Part 11 (data integrity and security).
- Working knowledge of critical manufacturing equipment and utilities such as: chromatography, CIP/COP systems, bottling/filling lines, autoclaves, bioreactors, filtration systems, cold rooms, WFI, process air, nitrogen, and CO2.
- Experience in QA or working with the quality unit
- Experience with regulatory guidelines

Why should you apply?

- We offer a competitive compensation and benefits package
- Pay is hourly with overtime and is commensurate with qualifications and experience

Position may be remote, depending on circumstances. Normal working hours are 8:00 a.m. to 5:00 p.m. Monday through Friday; however irregular working hours should be expected during project execution.