

GMP Engineer

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Company: Pivot Workforce, LLC

Location: Indianapolis

Category: other-general

GMP Engineer
Department: Program Management/Quality Control
Reports to: Director of Program Management
Job Summary: Seeking a Commissioning and Qualification Specialist to ensure systems, equipment, and processes meet regulatory and quality standards. Join our team to plan and execute commissioning activities, develop qualification protocols, and maintain compliance with industry regulations.
Commissioning and Qualification: Plan and execute commissioning activities for new equipment or systems. Develop protocols and test plans for IQ, OQ, and PQ. Ensure correct installation and performance of equipment/systems.
Documentation and Reporting: Maintain detailed records of commissioning and qualification activities. Generate comprehensive qualification reports in compliance with regulatory requirements.
Regulatory Compliance: Stay updated on industry regulations (FDA, GMP, GAMP) and ensure compliance. Implement and maintain validation procedures per regulatory guidelines.
Collaboration: Work closely with cross-functional teams, engineers, and regulatory affairs personnel. Collaborate with vendors to ensure equipment meets specifications.
Troubleshooting: Identify and address issues during the commissioning and qualification process. Develop and implement corrective and preventive actions (CAPAs).
Risk Assessment: Perform risk assessments to identify potential issues affecting equipment/system performance. Mitigate risks through appropriate actions and documentation.
Training: Provide training on commissioning and qualification procedures. Ensure staff follows best practices.
Continuous Improvement: Participate in continuous improvement initiatives related to commissioning and qualification processes. Suggest and implement process improvements for efficiency and

compliance. Required Skills/Abilities: Excellent verbal and written communication skills. Proficiency in Microsoft Office (Excel, Visio, Outlook, Word, etc.). Strong understanding of industry regulatory requirements (FDA, GMP, GAMP). Experience with commissioning and qualification processes. Proficiency in generating and maintaining documentation. Strong problem-solving and troubleshooting skills. Effective communication and interpersonal skills. Attention to detail and commitment to quality. Ability to work in a team and independently. Education and Experience: Bachelor's Degree in Engineering, Science, Business, Management, or related field. Minimum five (5) years of experience in a commercial/industrial construction environment. At least five years of related experience (preferred).

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