

Calibration Technician I, II, and Senior

Process Team | Metrology Lab Team | Analytical Team

The Calibration Technician (Tech I, Tech II, Tech SR) reports directly to the Team Leader, Manager, or Director depending on the organizational structure. These positions are non-exempt. This job description is applicable to Calibration Technicians on the Process, Analytical, and Metrology Lab Teams, levels I, II, and Senior. Twenty five to Fifty percent travel may be required based on project and client needs.

Expectations:

Calibration Technicians complete calibrations, qualifications, and PMS with accurate and timely GxP documentation, following PCI and/or client specific policies and procedures. They are expected to take a proactive role in supporting the Team and in providing client support and are expected to build a high level of trust with internal and client personnel. This trust is developed through consistently upholding PCI Values and demonstrating Honesty, Integrity, Pride, Accountability, Teamwork, and Commitment.

In addition to the above expectations, the Tech II is expected to identify and execute tasks that enhance the ability of PCI to provide an 'added value' service for clients and provide guidance and direction on technical issues. Tech II's have a higher level of technical experience and expertise to troubleshoot issues, as well as assist in providing innovative, creative, effective, and long-term solutions.

In addition to the above expectations, the Tech SR is expected to build a high level of interaction with the Client, Project, and PCI to provide strategic direction. This high level of interaction is developed through consistently being a subject matter expert by providing high level direction, tactical thoroughness, reliability, strategic initiative and consistent follow-through. The Tech SR works closely with clients to evaluate, demonstrate, and initiate value-added solutions and services.

Responsibilities/Assignments:

- Calibration Technician I
- o Completes calibrations and qualifications in a safe, timely, and accurate manner, following PCI and client specific policies and proposals.
 - o Responsible for proper handling and maintenance of PCI and client equipment, including testing and standards equipment.
 - o Identifies project supply and equipment needs and conveys to the appropriate resource to ensure availability.
 - o Works to understand client needs and requirements through effective communication and develops client relationships through excellent customer service. Ensures client requests are conveyed to the appropriate PCI management resource and met in accordance with management direction.
 - o On average, 90 - 95% of work time will be utilized completing calibration and maintenance events.
 - o Timesheets and expense reports are completed weekly with accurate labor and expense codes.
 - o Maintains a neat and professional PCI work area and projects a professional image at all times.
 - o Always considers safety when executing tasks and projects. Ensures that PCI work areas are safe, neatly organized and professional on-site and in an office environment.
 - o Is attune to potential new opportunities for PCI when at a client site or interacting with a client and relays this lead back to Leader/Manager.
- Calibration Technician II (in addition to those listed above)
- o Without direct supervision, completes calibrations, qualifications, and PMS with accurate and timely GxP documentation, following PCI or client specific policies and procedures, and in a safe manner.
 - o Provides effective solutions to client needs and requirements, effectively communicates with clients, and develops client relationships through excellent customer service

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- Identifies potential value-added business opportunities at client sites and shares with appropriate PCI Team Manager.
- Develops basic quotes or proposals; assists with development of complex proposals.
- Professional, diplomatic, and tactful with potentially sensitive issues; has a good understanding of the business case. Comfortable dealing with all levels of management and clients, respected by peers and clients.
- Handles PCI and client owned equipment and test equipment with care and trains other Associates on proper use and handling.
- Ensures safe work practices are followed by other PCI Associates.
- Plans and makes sure project supplies and equipment are ready and available. Works with appropriate company resources in advance to ensure all project needs are met.
- Completes timesheets with correct labor code charges (weekly) and assists other PCI Associates in proper coding of time and expenses.
- May assist in PCI onboarding process and serves as a role model and mentor to other technicians through professional actions/ethics and technical skills.
- Is familiar with all PCI service offerings and is comfortable exploring potential leads while at client sites.

Senior Calibration Technician (in addition to those listed above)

- Oversees and supervises calibrations, qualifications, and PMS with accurate and timely GxP documentation, ensuring all Team members follow PCI or client specific policies and procedures, and in a safe manner.
- Provides guidance, direction and effective solutions to clients and PCI technical resources.
- Upholds, mentors, and is a role model to other PCI Associates on the PCI philosophy and values through honesty, integrity, self motivation, teamwork, pride and commitment.
- Proactively takes steps to ensure PCI and client owned equipment is handled and maintained properly, as well as trains other Associates on proper use and handling.
- Develops client quotes and proposals.
- Provides oversight and project planning including time codes, schedules, test equipment, documentation, and ensures client requirements are met. Also responsible for ensuring accurate and timely scheduling, resource allocation, proposal and quotation development, Labor Utilization Reports (LURs), fixed cost and T&E project management for profitability. Must have the ability to identify scope changes and communicate to client, as well as, process the scope change request documentation ensuring that time coding and billing are accurate in regard to the scope change.
- Proactively assesses project safety concerns and ensures PCI Team members are in compliance with any and all client and/or PCI site safety requirements.
- Strategically assesses client environments, needs, and requirements to develop and initiate effective solutions and through established solid relationships with clients, delivers successful execution.
- Takes client relations initiative and proactively seeks to expand PCI services. A Tech SR may lead projects and serve as "Account Manager" for select clients based on strong client ties and business needs.

Skills Required:

Calibration Technician I

- Basic understanding of Traceability, Substitution of Standards, and Test Accuracy and Uncertainty Ratios.

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- > Skilled with pneumatic, mechanical, and electrical instrumentation; as well as manual and computer-based process control loops and systems; understands and applies basic concepts of calibration and requirements including accuracy testing.
- Basic understanding and application of instrument, equipment, and loop calibrations of various parameters in manufacturing, utilities, and laboratory environments.



- Ability to climb stairs; climb on equipment such as tanks. Moderate to heavy lifting.
- Understanding and awareness of safety requirements and safe practices.
- General electrical panel knowledge and electrical safety procedures.
- Working knowledge of MS Office suite.
- Must have a valid driver's license and good driving record.
- Reliable, confident, eager to learn, and enjoy working with people.
- > Able to make independent decisions within defined scope of work, seeks clarification and directions when needed. Must be self-driven and demonstrate ability to work with little direction.
- Listens well and asks questions to learn more.
- Displays good organizational skills.
- Basic understanding and familiarity with incubators, centrifuges, balances, refrigerators and freezers, stability chambers, chromatography (HPLC or GC), spectrophotometers, other general laboratory equipment as needed per clients. (Analytical Team Only)
- Dependent upon client needs, may require familiarity with RT-PCR, bio analyzers, gel imagers, scintillation counters, and cytometers; familiarity with Histology Equipment, such as microtomes, slide strainers, tissue processors, harvesters, homogenizers, and microscopes; and/or familiarity with Liquid Automation / Robotics / HTS, such as liquid handlers, plate stackers, plate readers, and plate washers. (Analytical Team Only)
- Basic understanding of Traceability, Substitution of Standards, and Test Accuracy and Uncertainty Ratios as part of ISO 17025 requirements. (Metrology Lab Team Only)
- Follow the first-in-first-out principle in choosing work, be aware of expedited calibration requirements, help maintain a turnaround time of less than 10 days, and assist in maintaining supplies for laboratory day to day operations, such as batteries, fuses and other consumables. (Metrology Lab Team Only)

Calibration Technician II (in addition to those listed above)

- > Thorough understanding of calibration concepts and requirements including accuracy testing requirements.
- Thorough understanding and application of GMPs and Life Science industry regulations.
- > Thorough understanding and application of instrument, equipment, and loop calibrations of various parameters in manufacturing, utilities, and laboratory environments.
- Effective communication and problem solving skills with clients and coworkers.
- > Thorough understanding and troubleshooting capability with incubators, centrifuges, balances, refrigerators and freezers, stability chambers, chromatography (HPLC or GC), spectrophotometers, other general laboratory equipment as needed per clients. (Analytical Team Only)
- Dependent upon client needs, may require thorough understanding and working capability with RTPCR, bio analyzers, gel imagers, scintillation counters, and cytometers; Histology Equipment, such as microtomes, slide strainers, tissue processors, harvesters, homogenizers, and microscopes; and/or Liquid Automation / Robotics / HTS, such as liquid handlers, plate stackers, plate readers, and plate washers. (Analytical Team Only)

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- Thorough understanding and high level working knowledge of Traceability, Substitution of Standards, and Test Accuracy and Uncertainty Ratios as part of ISO 17025 requirements. (Metrology Lab Team Only)

Senior Calibration Technician (in addition to those listed above)

- Expert knowledge and application of instrument, equipment, and loop calibrations of various parameters in manufacturing, utilities, and laboratory environments. ➤ Exceptional Computer Maintenance Management Systems (CMMS) skills.
- Navigates and utilizes MAS500 Pivot Table and project KPI module to support team leaders and project managers effectively manage LUR & project expenses.
- Develops and updates PCI Policies and Procedures, understands and interprets Government Regulations and instrumentation/calibration principles and provides training and guidance to Tech I and Tech II resources. Assists clients with development and revision of policies and procedures as necessary.
- Excellent communication and problem solving skills with clients and coworkers.



- Thorough electrical panel knowledge and safety practices.
- Excellent negotiation skills with direct identification, development, and implementation of negotiation policies and processes in accordance with PCI objectives. Develops negotiation strategy on complex issues. Significant ability to effectively influence and guide others.
- Understands the business case and has an appreciation of financial issues and profit and loss implications. Excellent analytical skills with attention to detail while keeping strategic company goals in focus.
- PCI Trained Mentor. Sought after by technical staff for advice in technical or proposal issues, diplomacy, and ethical practices. Active in PCI onboarding process. Provides both on the job and specialized technical training. Strong applied and working knowledge of FDA; GMP; GLP; compliance and NIST traceability. Expert knowledge of test equipment and capabilities such as tolerance requirements and 4:1 TAR.
- Actively involved with an external professional organization (ISPE, ASQ, PDA, etc.). External certification preferred (ISA, ASQ, etc.).
- Expert level knowledge and capability with incubators, centrifuges, balances, refrigerators and freezers, stability chambers, chromatography (HPLC or GC), spectrophotometers, other general laboratory equipment as needed per clients. (Analytical Team Only)
- Dependent upon client needs, may require an expert level knowledge and working capability with RT-PCR, bio analyzers, gel imagers, scintillation counters, and cytometers; Histology Equipment, such as microtomes, slide strainers, tissue processors, harvesters, homogenizers, and microscopes; and/or Liquid Automation / Robotics / I-ITS, such as liquid handlers, plate stackers, plate readers, and plate washers. (Analytical Team Only)
- Expert level knowledge and applicability of Traceability, Substitution of Standards, and Test Accuracy and Uncertainty Ratios as part of ISO 17025 requirements. (Metrology Team Only)

Experience & Education Required for the Calibration Technician I :

A two-year degree in Engineering, Life Sciences, other related technical field or equivalent military training and two years of applicable (Metrology, Instrumentation, Calibration) experience or the equivalent combination of education and experience.

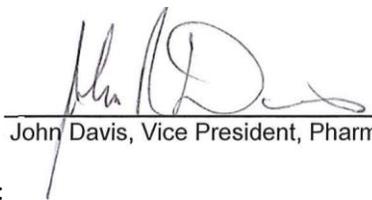
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Experience & Education Required for the Calibration Technician II:

A four-year degree in Life Sciences, Engineering, Electronics, other related technical field or equivalent military training and two years of applicable (Metrology, Instrumentation, Calibration) experience or the equivalent combination of education and experience. Quality System/Pharmaceutical experience is preferred.

Experience & Education Required for Senior Calibration Technician:

A four-year degree in Life Sciences, Engineering, Electronics, other related technical field or equivalent military training and four plus years of applicable (Metrology, Instrumentation, Calibration) experience or the equivalent combination of education and experience. Quality System/Pharmaceutical experience is required.

 Date: 5 Jun 2014
John Davis, Vice President, Pharmaceutical Calibrations and Instrumentation, LLC

Approval: