

# Job Description



## Instrumentation Specialist I Senior Instrumentation Specialist

### Process Team I Analytical Team

The Instrumentation Specialist and Senior Instrumentation Specialist reports directly to the Team Lead, Team Manager or Director. These positions are non-exempt. Up to fifty percent travel may be required.

#### Expectations:

The Instrumentation Specialist provides high-level instrumentation field services for clients including calibration services, maintenance services, project services, and some consulting support. The Instrumentation Specialists may also support the development of or develop/provide internal and/or external technical training. The Instrumentation Specialist is expected to provide onsite process and/or analytical services as it relates to startup projects, installations, fixed-duration, and long term contracts for existing facilities. They consistently uphold PCI Values and demonstrate Honesty, Integrity, Pride, Accountability, Teamwork, and Commitment.

In addition to the above expectations, the Senior Instrumentation Specialist 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 being a subject matter expert by providing high level direction, tactical thoroughness, reliability, strategic initiative and consistent follow-through. The Senior Instrumentation Specialist works closely with clients to evaluate, demonstrate, and initiate value-added solutions and services. The Senior Instrumentation Specialist also develops and provides internal and external technical training.

#### Responsibilities/Assignments:

##### Instrumentation Specialist

- Conducts high level and technically complex repairs, calibrations, qualifications, and PM's with accurate and timely GxP documentation, following PCI or client specific policies and procedures, and in a safe manner.
- Provides guidance, direction and effective solutions to clients and PCI technical resources.
- 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.
- Development of client quotes and proposals.
- Identifies and initiates scope changes and communicates to client, as well as, processes the scope change request and uses proper documentation ensuring that time coding and billing are accurate with 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.

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- May lead projects and serve as "Account Manager" for select clients based on strong client ties and business needs.
- Understands and executes GMP and compliance practices as it relates to PCI clients and their instrumentation needs.
- Resource scheduling, account management and maintaining PCI client/project files in accordance with company procedures.
- Develops functional instrument requirements and procures instruments for clients.



- Performs and oversees equipment services and instrument procurement; partnering with and assisting third party technical services.

## Senior Instrumentation Specialist (in addition to those listed above)

- Self-directed; provides guidance and directs/manages other technicians on client sites.
- Project setup, management and turnover of technicians responsible for ongoing accounts.
- Independently initiates instrument specifications, purchasing, installation, calibration, maintenance, and troubleshooting.
- Mentors technicians and develops high level training related to new instrumentation and projects.
- Independently and with minimal oversight performs project management responsibilities including scope development, proposal development, budget and scope deliverables oversight, and monthly project reporting.
- Interacts with clients at a very high strategic level to build a foundation of trust, as well as has a thorough understanding of the specific details of client processes.
- Provides some consulting services with clients for new projects, additional instrumentation and resource needs.
- Takes client relations initiative and proactively seeks to expand PCI services. May lead projects and serve as "Account Manager" for select clients based on strong client ties and business needs.
- Is familiar with all PCI service offerings and is comfortable exploring potential leads while at client sites.

## Skills Required:

### Instrumentation Specialist

- Expert in-depth knowledge and application of a wide variety and type of instrumentation, equipment, and loop calibrations of various parameters in manufacturing, utilities, and laboratory environments.
- Exceptional Computer Maintenance Management Systems (CMMS) skills.

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- High attention to detail.
- Strong written skills, with the ability to develop and create quotes or proposals.
- 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.
- Sought after by technical industry for advice on technical issues. 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.
- Involved with an external professional organization (ISPE, ASQ, PDA, etc.).
- Ability to interpret proposals and coordinate activities to accomplish the approved scope.
- Extensive instrumentation and controls troubleshooting skills.
- Extensive experience with Microsoft Office Suite.
- Understanding of Validation principles and how it relates to calibrations.
- 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;

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and/or Liquid Automation / Robotics / HTS, such as liquid handlers, plate stackers, plate readers, and plate washers. (Analytical Team Only)

Senior Instrumentation Specialist (in addition to those listed above)

- Be considered a Subject Matter Expert (SME) in the fields of calibration and instrumentation within the process and/or analytical service fields and a technical advisor in various other life science industries.
- High level project management and customer service skills.
- > As an industry expert, be known and called upon as a valued and respected technical resource, be able to provide high level training both internally as well as externally to PCI, and at times, speak at engagements with other industry experts.
- Be a technical leader with a relevant professional organization (ie: ISPE, ASQ, PDA, etc).

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- > Ability to continually expand client relations, develop additional service scopes, and deliver successful client solutions through PCI services.
- External certification required [ISA, ASQ, etc.].
- Initiate consultative business development to include new, as well as expand existing client services.
- Continually expands client relations, develops additional service scopes, and delivers successful client solutions through PCI services.
- Expert level knowledge and capability with incubators, centrifuges, balances, refrigerators and freezers, stability chambers, chromatography (HPLC or CC), 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 / HTS, such as liquid handlers, plate stackers, plate readers, and plate washers. (Analytical Team Only)

## Experience & Education Required for Instrumentation Specialist:

A two-year or four-year degree in Engineering, Management, Life Sciences, or other related technical field (or equivalent military training) and four or more years of intense instrumentation experience in the Pharmaceutical/Quality industry or the equivalent combination of applicable education and experience.

## Experience & Education Required for Senior Instrumentation Specialist:

A four-year degree in Engineering, Management, Life Sciences, or other related technical field (or equivalent military training) and five plus years of intense instrumentation experience in the Pharmaceutical/Quality industry or the equivalent combination of education and experience. Experience in project management, consulting, supervision and client relations is strongly preferred.