

AS&T (QC) Specialist

Job ID
REQ-10036822
Jan 17, 2025
USA

Summary

We are seeking a highly skilled and experienced Analytical Science & Technology Specialist with knowledge in Inductively Coupled Plasma (ICP) techniques to join our QC/AS&T team. The ideal candidate will have a strong background in analytical chemistry, wet chemistry techniques and particularly in ICP analysis for the identification and quantification of elements in various materials. The candidate will have a strong technical writing skill and experience with validation of analytical methods and qualification of analytical equipment. This position is crucial to ensure the quality, safety, and compliance of our products, contributing to the regulatory adherence and scientific integrity of our testing procedures. The AS&T Specialist is responsible for site technical development of quality control methods/processes, method and instrument validations, and technical transfers associated with Analytical and/or Microbiological quality control testing of product, raw materials, and packaging components.

Location: Indianapolis, IN #LI-Onsite

Shift: This position involves shift work which will be defined through site start up and commercialization readiness.

About the Role

Key Responsibilities:

Demonstrates technical experience in aspects related to quality control testing development, including QC method and instrument qualifications as well as technical transfers from third party laboratories or other Novartis/AAA sites. Supports and provides technical insight for QC testing, while ensuring documentation completion and review remains in full compliance with GMP regulations, Novartis/AAA procedures, and product specifications.

- Executes testing for method and instrument implementation, as well as qualification/validation protocols.
- Supports deviation investigations and OOS/OOT/OOE investigations with testing, if needed.
- Provides technical insight for escalations in case of non-conformances and deviations.
- Responsible for successful on time completion of required training curricula comprising of the necessary Standard Operating Procedures (SOPs) and Aseptic Techniques, Gowning Qualifications, Testing and specifications, and other relevant training including HSE for the specific role.
- Prepares applicable documents, forms, and records, such as method or instrument qualification/validation records, and follows Good Documentation Practices.
- Supports internal and external Audits and Inspections, if needed.

Essential Requirements:

- Education: Bachelors' degree required in relevant Scientific discipline (e.g Chemistry, Microbiology).
- For analytical background, experience with chemical techniques and analytical instrumentation such as ICP, iTLC. For microbiology background, experience with aseptic processing principles and techniques, including cleanroom personnel and environmental monitoring. Ability to interpret analytical or microbiological data and convert into technical documentation.
- A minimum of 2 years of experience in a cGMP or aseptic environment with prior ICP experience, expertise in method validation and instrument qualification is preferred.
- In-depth knowledge of ICP (ICP-OES and/or ICP-MS) principles, operation, and troubleshooting.
- In-depth knowledge of instrument qualification and validation of analytical methods.
- Proficiency in technical writing.
- Experience with other analytical techniques (e.g., Wet Chemistry, TLC, HPLC).
- Experience with laboratory data management systems (LIMS) and electronic lab notebooks (ELN).

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$77,000-\$143,000/year; *however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities.* The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together?
<https://www.novartis.com/about/strategy/people-and-culture>

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up:
<https://talentnetwork.novartis.com/network>

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <https://www.novartis.com/careers/benefits-rewards>

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process or to perform the essential functions of a position,

please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division

Operations

Business Unit

Innovative Medicines

Location

USA

State

Indiana

Site

Indianapolis

Company / Legal Entity

U469 (FCRS = US469) AAA USA Inc.

Functional Area

Quality

Job Type

Full time

Employment Type

Regular

Shift Work

No

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