First Last

PROFESSIONAL EXPERIENCE

Company - Parent Company Life Sciences

Jun 2020 - Present

Quality Engineer

City, XX

- Reduced quality lead time by 6 days through implementing client-specific release disposition workflows representing a 20% quarter-on-quarter increase in revenue
- Conducted 50+ audits as an ISO 9001 qualified auditor to drive continuous improvement initiatives
- Directed process mapping and time capability studies to eliminate obstacles and improve throughput by 35%
- Facilitated quality non-conformance investigations and CAPAs to drive QA closure within a 30 day period

Quality Control Analyst II

 Improved sample testing turn-around-time by 15% through implementation of Kaizen to revise quality documents to allow for more efficient batching of release materials as a CMO

Quality Control Analyst I

- Performed 30+ biological QC assays to support manufacturing throughout the products lifecycle in compliance with all cGMPs, SOPs, and established quality standards
- Facilitated quality investigations and root cause assessments for overall product quality impact and ensured corrective action for quality events such as deviations and CAPAs for manufactured raw materials
- Assisted with method validation protocol generation and technical transfers to reduce overall lead time

Name of University (Grant-funded Contract)

Apr 2019 - May 2020

Analytical Researcher

City, XX

- Developed a semester long teaching program based on polarity, TLC, and HPLC for the general chemistry laboratory at Name of University taken by 125+ students each year
- Created and maintained operating protocols to run an HPLC and refined reproducible experiment methods
- Disseminated research results in oral presentations at 12+ public lectures and research conferences

City Name Public Services (Contract)

Apr 2018 - Mar 2019

Water Quality Analyst

City, XX

- Administered processing changes from SCADA analysis and subsequent quality systems
- Prepared monthly water quality reports for submission to the State Department of Health
- Spearheaded quality investigations to determine the root cause on aberrant water quality results

EDUCATION

Name of University

City, XX

Bachelor of Arts (B.A.), Chemistry

Certified through the American Chemical Society (ACS)

REGULATORY COMPETENCIES, SKILLS, & REFERENCES

- Regulatory Competencies: 21 CFR Parts 11, 210, 211 & 820, ISO 9001 Related Standards, ISO 14644 Series
- Skills: MasterControl, Smartsheets, Microsoft D365, Qualer Asset Management, PRISM GraphPad
- References:
 - First Last Current Position at Company
 - First Last Current Position at Company
 - First Last Former Position at Company

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