**Metrology/Calibration/CMMS/Facilities Leader**

Results-driven professional with 14 years of experience in FDA and EMA-regulated GMP manufacturing industries, specializing in facilities management, equipment maintenance, and cross-functional collaboration. Expertise in troubleshooting equipment, managing preventive maintenance programs, and optimizing operational performance in compliance with cGMP standards. Known for driving process improvements and fostering teamwork to achieve organizational goals.

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| * Team Leadership and Development
 | * Budget Planning and Vendor Management
 | * Data Analysis and Reporting
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| * Practical Process Improvement
 | * cGMP Compliance and Documentation
 | * Cross-Functional Collaboration
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|  | **Career Experience** |  |
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**CMMS Asset Management Consultant ∙ Independent** **Contractor ∙ July 2024 – Present**

Provided specialized consulting services to enhance CMMS functionality and ensure regulatory compliance, with a focus on tool crib management, quality assurance, and workflow optimization for clients like Qualer and GL Technologies.

**Key Accomplishments**

* Partnered with organizations like Qualer to develop and enhance CMMS tool crib functionalities, focusing on compliance, technician workflows, and audit readiness.
* Proposed system enhancements, including tailored categorization for diverse tool types and quick-verification tools for regulatory audits.
* Delivered CMMS Admin and Quality Assurance (QA) consulting services for GL Technologies, optimizing system configurations and ensuring alignment with regulatory standards.
* Provided cross-functional support for audit readiness, streamlining processes to enhance efficiency and compliance outcomes.

**Metrology Supervisor ∙ Thermo Fisher Scientific, Carlsbad, CA ∙ March 2021 – July 2024**

Managed the commissioning and cGMP lifecycle of a 67,000 sqft GMP Manufacturing Warehouse and PD Facility, including all GMP and Non-GMP calibration activities performed by on-site technicians and vendors, ensuring adherence to GDP and Safety requirements.

**Key Accomplishments**

* Instrumental contributor in the successful commissioning and facility readiness of a new GMP Plasmid-DNA Single Use manufacturing site, ensuring on-time delivery, budget adherence, and operational excellence.
* Successfully oversaw both the commissioning and decommissioning of multiple systems, playing a pivotal role in shutdown processes and equipment validation.
* As site CMMS Admin, led the implementation of the Maximo Asset Management Program, managing 1,500 assets to ensure accuracy and cGMP compliance.
* Developed and implemented Standard Operating Procedures (SOPs) for site and facility readiness, ensuring operational consistency, enhanced productivity, and maintained compliance with auditors.
* Played a key role in the Integrated Facilities Management (IFM) implementation and decommissioning, standardizing services across multiple departments and managing service and supply contracts for equipment maintenance.
* Achieved a 25% reduction in the Metrology/Calibration annual spend within two months without impacting operational compliance.

**Senior Calibration/Metrology Specialist ∙ Pacira Biosciences, Inc., San Diego, CA ∙ June 2014 – March 2021**

Managed the cGMP Calibration Lifecycle of approximately 5k assets for a four-building (150,000 sqft) GMP Manufacturing, Warehouse, and PD Facility.

**Key Accomplishments**

* Led the timely commissioning and decommissioning of numerous systems, ensuring successful outcomes within budget and maintaining operational excellence.
* Developed and implemented SOPs and calibration documentation, including equipment induction, calibration certificates, change controls, and out-of-tolerance deviation reports, ensuring site readiness and compliance with internal and external auditors.
* Key team member for major manufacturing system updates, whole-site electrical shutdowns, and the complete commissioning of a new research facility, enhancing site capabilities and productivity.
* Collaborated with cross-functional teams to revise preventive maintenance programs, ensuring compliance with cGMP standards and improving maintenance schedules.
* Utilized CMMS to manage asset lifecycles, schedule routine and emergency calibrations, and assist with troubleshooting, repairs, and new equipment acquisitions.
* Provided Lab and Field training to Calibration/Metrology Technicians, enhancing team proficiency and ensuring consistent execution of maintenance activities.

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|  | **Additional Career Experience** |  |
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* **Sangart, Inc.** **| Instrumentation Specialist** **, San Diego, CA ∙ February 2012 – December 2013**
* **GL Technologies**(Contractor)**, San Diego, CA ∙ April 2010 – June 2014**
* **Instrumentation** **Technician** | Biogen Idec, San Diego, CA | April 2010 – February 2011
* **Sr. Calibration Specialist** | Sangart, Inc., San Diego, CA | February 2011 – January 2012
* **Site Calibration Manager** | Pacira Biosciences, Inc., San Diego, CA | January 2014 – June 2014

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|  | **Additional Training and Software Experience** |  |
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* OneMaximo(OMX): Implementation and Admin
* BlueMountain(RAM): Implementation and Admin
* Qualer: Maintenance WOs and Asset Management
* AMMS: Calibration and Maintenance WOs
* TrackWise: Calibration OOT Investigations, Deviations, Change Controls, CAPAs, Action Items.
* MasterControl: Calibration OOT Investigations, Change Controls, SOP Reviews and Updates.
* Documentum: SOP Creation, Edits and Reviews.
* Bluebeam: ENG Project Reviews and Approvals
* Siemens Apogee PPCL Programing
* Siemens Desigo CC Workstation

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|  | **Education** |  |
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**Instrumentation and Industrial Automation** | Perry Technical Institute, Yakima WA