STEPHEN PURYEAR

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Summary

There are significant strategic advantages available to any firm that applies the principles of Measurement Uncertainty anywhere in their operations. While I recognize that this is an uncommon viewpoint, I welcome any engagement on this general topic, or topics associated with it.

I have become fascinated with the concepts of Measurement Uncertainty during three decades in which I have supplied technical services within the US Pharma and Biotech industries. I started in the field performing calibration and instrumentation duties, learning more about instrumentation and calibration, Pharma, and cGMP practices as I went along. Next, I began getting involved with ASQ (American Society for Quality) and achieved their Quality Engineer and Quality Manager certifications. Then I went back to school for an MBA. Throughout these transitions my fascination with the theory and practices involved in Measurement Uncertainty has deepened. I have studied and commented upon the BIPM's Guide to Expressing Uncertainty In Measurement (GUM) extensively. This includes writing papers, as well as producing an extensive series of videos on the topic. They are readily available on LinkedIn and YouTube. For further background, please feel free to visit my website to which I have referred above.

WORK EXPERIENCE

Genesis Solutions Providing services to
UC Berkeley Maintenance

May 2018-July 2018

Field Engineer

Acting in a contractor role, team with UC Berkeley Maintenance building managers to audit 20 campus buildings to support a pilot proposal for the rollout of the Maximo platform. Responsible for locating existing equipment, capturing attributes not previously required

and identifying previously unidentified assets with all of their attributes. Use Genesis Solutions tool to upload record enhancements and corrections to a master data base.

Naderi Engineering Inc. May 2017- Sept 2017 Providing services at Genentech/Roche Vacaville, CA

Bill of Materials Specialist

Acting in a contractor role, supported Genentech/Roche efforts to remediate current and legacy systems for BOM compliance. In this role, I audited system BOMS for both current and newly commissioned systems. I identified and remediated equipment no longer physically in place as well as equipment and systems whose BOMS needed additions or corrections. I also dealt with obsolete system components by finding equivalents that met SOP and cGMP requirements.

Naderi Engineering Inc. Oct 2013- Dec 2016 Providing services at Genentech/Roche Vacaville, CA

Instrumentation Specialist

Acting in a contractor role, support Genentech/Roche as an instrumentation/ calibration SME (subject matter expert). Duties include risk assessment, database survey, review and improvement. Research and provide equipment specification and purchase support. Also, support the Facilities Group as they manage the hardware and facility systems required for all phases of CGMP production. Review systems for calibrated component readiness during validation and commissioning of new $1B production facility. Qualify critical equipment service providers on Vacaville campus. Audit several hundred calibration data templates to ensure compliance. Audit and update archived templates for agreement with current versions.

RS Calibration Services Inc. Sept 2012- Sept 2013 Pleasanton, CA
Providing services at
Novartis, Emeryville, CA

Senior Instrumentation Technician

Responsible for the management of standards and calibrated equipment that require outside vendor calibration, either on or off site. Review reports or certificates to ensure that Novartis specifications have been adhered to and in cases in which the equipment is not found in tolerance, support Out Of Tolerance and/or Discrepancy Report procedures. Manage these activities in Maximo to comply with the monthly Maximo work order cycle. Acquire new standards as needed for calibration work being executed on site by Novartis contractors. Manage invoices for all required calibration services and provide monthly report. Manage traffic of standards flowing to and from global NAT field service representatives and have these standards calibrated in house or off site where necessary.

RS Calibration Services Inc. Apr 2012-Sept 2012 Pleasanton, CA

Metrology Laboratory Supervisor

Responsibleforthetechnicaloversightandoperationalmanagementofthein-house calibration services. Responsible for the management, maintenance and accuracy of the company calibration standards. Perform investigations supporting CAPA root cause analysis of calibrated instruments within the department. Hire department personnel and train them on calibration concepts and procedures. Guide department personnel on career development. Responsible for monitoring, reporting and improving the calibrated and shipped on-time performance of the lab. Assess RS capability as sales leads develop. Integrate expedited items into lab workflow after assessing current execution capacity.

Versa Engineering Inc. Aug 2011- Apr 2012 Providing services at Genentech/Roche Vacaville, CA

Quality Engineer

As a Versa E&T contract engineer, support the Facility Services group by ensuring the validity, location and compliance of calibration and operational specifications. Advise, create and provide training on Estimates of Measurement Uncertainty (referencing the GUM whenever possible) and risk-based uncertainty analysis. Write procedures, update training forms, assess equipment and system specifications for cost savings and audit risk reduction. System examples include HVAC, CIP, Clean Steam, Calibration Standards, and Fermentors requiring frequent interaction with equipment users.

V2 Engineering Inc. *Mar 2009-Dec 2010 Providing services at Genentech/Roche Vacaville, CA*

Quality Engineer

As a contract planner/scheduler supported 14 simultaneous capital projects by converting project work requests into SAP Maintenance module work orders and then managed them to completion under a site wide Quality target of 95% on-time. The projects were aimed at improving or installing GMP production or production support equipment such as CIP/SIP skids, WRO and WIFI water systems.

In separate assignments, located and surveyed 275 Rosemount pressure transmitters throughout the Vacaville site to verify their existence and identity. All of these instruments were classified as GMP devices. Next, re-specified all these devices with new and complete model numbers for the equipment Bill of Materials (BOMs) because all the transmitters had become obsolete and no longer supported by the manufacturer. Afterward, performed the same exercise on twelve thousand pieces of GMP equipment.

Cetus/Chiron /Novartis AG, 1989-1991, 1996-2009*

Emeryville, CA
**Cetus acquired by Chiron in 1991, which was acquired by Novartis AG in 2005*

Quality Engineer (2005-March 2009)

Reported to the Director of Facilities Operations, responsible for resolving Discrepancy Reports (DRs) and Corrective and Preventive Actions (CAPAs) for group of up to 100 department personnel. Employed audits and tracking to maintain and improve the compliance of the department vendor files. Wrote and submitted for QA approval all new and renewing department vendor descriptions. Tracked, trended, managed and delivered department Key Performance Indicators (KPIs). Act as engineering resource during the deployment and integration of computer applications to improve department performance and asset management.

Engineering Specialist (1998-2005)

Ledvariousprojectstoimproveefficiencyofdepartmentcalibrationandmaintenance functions. Responsible for supporting calibration technicians. Supported Facilities Operations Department by optimizing calibration resources. Improved hardware and process infrastructure to allow more timely control and data management. Track, trend and, wherever

Senior Instrumentation Technician (1989-1991, 1996-1998)

Installed, validated, calibrated and maintained a wide variety of laboratory, manufacturing and utility equipment and systems using written SOPs and subject to FDA audits and CGMP statutory guidelines. Where necessary, wrote new procedures.
Coordinated activities with equipment users and process owners to optimize maintenance support within an R&D or Manufacturing environment.

EDUCATION

University of Phoenix, Walnut Creek, CA – Master's Degree, Business Administration -- Heald College, San Francisco, CA – Associate in Electrical Engineering Technology--College of William and Mary, Williamsburg, VA - Bachelor of Arts, History

TECHNICAL

SAP PM, Word, Excel, PowerPoint, Mathematica, Trackwise, Maximo, Mudcats

AFFILIATIONS

American Society of Quality (ASQ), Society of Maintenance and Reliability Professionals (SMRP), Institute of Industrial Engineers (IIE), Instrument Society of America (ISA), Centre for TPM (Australasia)

CERTIFICATES & LICENSES

ASQ Certified Quality Manager, Certificate # 05553--ASQ Certified Quality Engineer, Certificate # 39527--State of California Certified: Engineer-in-Training, License #XE188969--EPA Universal Refrigerant Certification, Certificate # 0420387122400

ADDITIONAL ACHIEVEMENT

Tutor mathematics students seeking GED certificate, LEAP (Literacy for Every Adult Program) Richmond California