

ABDO SUKARI

GMP Qualification and C&Q Specialist

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DAY ONE

Hit the ground running.

Qualification protocols written and executed in GMP sites across Switzerland.



FIRST TIME

Do it right.

DQ, IQ, OQ and PQ that hold up under inspection.



TRUST

Quality builds trust.

Swissmedic GMP inspection passed without critical findings.

Qualification and GMP quality specialist with fifteen years in pharmaceutical and biotech production and laboratory environments, at Merck, Thermo Fisher Scientific, Roche and BioAtrium. I write and execute qualification documents from URS and DQ through IQ, OQ and PQ, apply risk-based thinking, and keep every protocol, deviation and change inspection ready.

QUALIFICATION I HAVE DELIVERED

Utility systems, Merck

Executed IQ and OQ protocols for manufacturing equipment and utility systems.

Facility qualification, Merck

QC laboratory and new DNA laboratory brought to readiness, including facility qualification, SOPs and work instructions.

FAT to PQ, Thermo Fisher

Three parallel projects installed and qualified through FAT, SAT, IQ, OQ and PQ.

URS and DQ, Roche

User requirements, design qualification and FMEA risk assessments written before execution.

CIP and SIP, Thermo Fisher

Assay development, optimisation and transfer supporting CIP and SIP processes.

Risk-based approach

HACCP, FMECA and FMEA for contamination and system failure, with findings in the site risk register.

EXPERIENCE

August 2025 to present

Professional development Visp

Training, innovation and German for the Swiss market.

Training. Diploma in Next Generation Biosecurity at the University of Bath, covering containment, facility setup and 24/7 monitoring systems.

Innovation. Researched and drafted three patent applications filed in the US, UK, Japan, Germany, Sweden and France.

Languages. Intensive German coursework towards business fluency.

April 2024 to July 2025

Senior Expert Merck, Vevey, contract

Equipment, utilities and laboratories qualified and ready.

Equipment and utilities. Executed IQ and OQ protocols for manufacturing equipment and utility systems to full validation compliance.

Facility readiness. Responsible for readiness of the QC laboratory and a new DNA laboratory, including facility qualification, SOPs and work instructions.

Automated system. Delivered an automated Hamilton robotic testing system into operation.

Risk. Ran HACCP, FMECA and FMEA assessments for sample handling, microbial contamination and system failure.

Deviations. Led deviation teams through root cause analysis with Operations across sites, documented in CARA Mango and the QMS.

April 2021 to March 2024

QC Scientist and LIMS Specialist, then Laboratory Information Specialist Thermo Fisher Scientific, Lengnau, permanent

Systems qualified end to end on a biomanufacturing site.

Qualification lifecycle. Managed three parallel projects to install and qualify systems through FAT, SAT, IQ, OQ and PQ, including the documentation for each phase.

CIP and SIP. Led assay development, optimisation and transfer for raw material qualification, stability, impurities testing and CIP and SIP processes.

Environmental monitoring. Prepared specifications for raw materials, sterile products and environmental monitoring in LIMS and SAP.

Change and deviations. Managed risk assessments, CAPAs, change management and root cause analysis in TrackWise, including OOS and OOT investigations.

Inspection readiness. Prepared the department for a Swissmedic GMP inspection, passed without critical findings, and wrote and reviewed SOPs, protocols, reports and change controls.

Leadership. Led three scientists and five technicians and worked with Operations and Engineering to clear release bottlenecks.

May 2019 to April 2021

Scientist Hoffmann-La Roche, Basel, contract

Requirements and design qualification before execution.

URS, DQ and risk. Defined user requirements and developed DQ and FMEA documentation, aligned with the site QMS.

Validation. Authored and executed validation packages for laboratory instruments, with change control from plan to approval.

Facility. Built the sample storage unit in Basel, with tracking in LIMS, and prepared for a Swissmedic GLP and GCP audit.

June 2016 to May 2019

Scientist Covance, formerly Envigo, UK, permanent

Validation and data integrity in a GLP CRO.

Validation. Created and executed CSV documents for laboratory instruments.

Data integrity. Tracked samples and reviewed audit trails in LIMS.

Improvement. Identified process gaps and raised improvements through formal change control.

April 2014 to June 2016

Associate Scientist Covance, formerly Envigo, UK, permanent

Inspections and equipment records.

Quality. Performed internal site inspections and audited study reports, SOPs, deviations and equipment maintenance records under GLP, GMP and GCP.

January 2010 to April 2014

Research Associate University of York, UK

Projects. Sample collection, protein expression and purification, and medical device development in collaboration projects with Avacta, Paraytec and Apta Dx.

EDUCATION AND TRAINING

Sep 2001 to Sep 2006

BSc Pharmacy and Pharmacology, including pharmaceuticals and analytical chemistry

Sep 2013 to Feb 2015

MSc Bioscience Technology, with merit, University of York, conferred January 2015, certificate attached

June 2020 to Sep 2024

DAS Clinical Trial Practice and Management, including CAS Clinical Research I and II, 31 ECTS, University of Basel, awarded November 2024

June 2025 to June 2026

Diploma, Next Generation Biosecurity, University of Bath

March 2023, ongoing

Practical Process Improvement, and Six Sigma Yellow Belt in progress

SOFT SKILLS

Personal

team player multitasking clear communication solution oriented adaptability fast learner

Working style

well organised attention to detail time management decision making team leadership

HARD SKILLS

Qualification

DQ IQ OQ PQ URS FAT SAT facility qualification CSV

Utilities and process

utility systems IQ and OQ CIP SIP environmental monitoring

GMP quality

GMP change control deviations CAPA RCA Swissmedic inspection SOPs

Systems

Kneat Valgenesis TrackWise SAP COMOS LIMS Veeva Vault Power BI

LANGUAGES

Spoken

English, C2, fluent German, B1, conversational

INTERESTS

Leisure

swimming chess scuba diving travelling