MICHELLE O'SULLIVAN

Senior PMO

SIDEKICK NETWORK
selected experts

- Experienced professional with extensive experience in Project Management, Quality Management and Validation with the proven ability to manage and provide leadership within regulated environments, incl. Novo Nordisk IT
- Confident and articulate communicator with the organizational skills and decision-making ability to ensure targets are consistently achieved
- Proven track record in strategic planning and the ability to rapidly evaluate new environments and mobilize organizations towards execution
- Proven aptitude and expert knowledge in Computer System Validation, Equipment Validation, Compliance, Risk Management, GxP Practices, Change Control, Test and Document Mgmt.

Sidekick Network GmbH & Co. KG
Prager Straße 13
01069 Dresden

Your contact:
Andreas Weller
Managing Partner

Phone: +49 175 2249558
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EDUCATION

1990 – 1992	**University of Wollongong**, Australia Post Graduate Diploma Science: Total Quality Management
1987 – 1988	**College of Technology**, Ireland Diploma, Biochemistry, Graduated with Distinction

CERTIFICATION / FURTHER EDUCATION

Project Management PRINCE 2 Practitioner
ICE PQM Training (Novartis GIS, Basel)
ITIL Foundation Certificate (APMG-UK)
Laboratory System & Software Validation in a Regulated Environment (SQT Certificate, Dublin, Ireland)
Computer Systems Validation including 21 CFR Part 11(SQT Certificate, Dublin, Ireland)
Certified Auditor for Quality Management System (Institute of Quality Assurance, NSW, Australia)
Certificate in Quality Control, City & Guilds Institute, Carlow, Ireland

EXPERIENCE / BACKGROUND

Professional Experience	28+ years
Language	English (native) French (intermediate) German (basic)
Industries	Pharma IT Food
Methods & Management Skills	Project Management and Program Office Risk and Quality Management Document Lifecycle Management ITIL Processes / IT Service Management Training Management & Materials KPI Definition and Management Application Portfolio Management Global Services and Shared Services Regulatory Knowledge (FDA and European Regulations) Lead Auditing (Standards ISO 9001)
Technical Skills	MS Office, incl. PowerPoint, Excel, Word, Project, SharePoint

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PROFESSIONAL EXPERIENCE

Since 02/2018
Switzerland

Novartis Pharma AG, Novartis Business Services

PMO Lead
Responsibilities:

- Lead to a large cross functional global program to address the changes in China Cybersecurity Laws to ensure compliance with local regulations and guidelines using a risk-based approach to also protect Novartis assets
- Contributing to stable business operations and China growth strategy
- Establishing improved Network Access Control and Data Loss Prevention policies and implementing AWS Cloud Service in China
- Moving local China apps to local Novartis data center or China Cloud
- Most critical applications that are for China use only are dedicated to or cloned in China
- Strict control and limitation of access rights for high-risk applications with sensitive Novartis data

Program Manager
Responsibilities:

- Program Manager to a suite of projects created to provide one interaction layer across all Novartis Business Service domains
- The objective was to simplify and to automate customer interactions following user centric design standards (“Design Thinking”) and applying effective end-to-end case management of issues and service requests
- Implementing a virtual assistant/chatbot to help with FAQ and assist with IT self- solve issues
- Computer Telephony Integration (CTI) to recognize clients / callers for service agents
- Establishing a foundation for Integrated Knowledge, User Assistance, and Service Management on a new Global Service Portal

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08/2016 – 01/2018
Switzerland

Novartis Pharma AG, Global IT Operations

Process Consultant
Responsibilities:

- Process Consultant to IT Client System Devices to document & map the current processes with standard SOP & work instructions to migrate the system to the global standard IT system process mapping platform Program Manager

Audit Support
Responsibilities:

- Audit Support to support the internal audit of the recently completed global project for application portfolio management

Program Quality Manager
Responsibilities:

- Program Quality Manager to global Application Portfolio Management program established to transform IT by simplifying and industrializing the application landscape. Application elimination and archiving as required and reviewing & monitoring data consistency and establishing KPIs to measure & mitigate data completeness
- Establishing training modules & material to support the application managers & owners to maintain & manage a more simplified landscape

01/2014 – 07/2016
Switzerland

Novartis Pharma AG, Global IT Infrastructure Services

Project Quality Manager
Responsibilities:

- Project Quality Manager to various IT Projects either making changes to existing systems or introducing new systems for GxP & Non-GxP applications
- Document lifecycle management of all project & computer system validation documents in line with IT system governance requirements & processes
- Oversee document deliverables to meet project & quality requirements

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2003 – 2013
Ireland

Mason Technology Ltd.
Validation Manager

Responsibilities:

- Developed and supported a complete validation service, to include Equipment Validation, Computer System Validation, Testing, Temperature Mapping, Weight Calibration, Service & Maintenance Contracts to the pharmaceutical industry for a large portfolio of international laboratory equipment brands
- Increased IQOQ sales from 30% to approximately 90% across the complete equipment range into the pharmaceutical sector

1998 – 2000
Ireland

Pfizer
Quality and Validation Specialist

Responsibilities:

- Leading the complete validation document review cycle with a multi-disciplinary project team for a large global project to introduce and integrate automated warehousing, computerized dispensing system and a serialization tracking system

1994 – 1995
Australia

CSR Refined Sugar
Quality Assurance Engineer

Responsibilities:

- A part-time project role created to complete and co-ordinate the ISO9000 certification process and to achieve AS/NZS ISO9000 Accreditation for the Group Headquarters in Sydney and the Distribution Depot in Adelaide

1993 – 1994
Ireland

Pfizer
Quality Assurance Supervisor

Responsibilities:

- Developing and mentoring the QA Laboratory from an initial core group of 6 to a team of 20 analysts
- Providing training and liaising with the packaging and manufacturing functions on quality related tasks & issues
- Responsible for management of sampling & testing of packaging materials and sampling of raw materials to support a large QC test laboratory

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1990 – 1992
Australia

CSR Refined Sugar
Quality Service Engineer

Responsibilities:

- Managing the day-to-day operations of the laboratory across two shifts and providing product feedback & support to customers
- Designing and implementing SOPs using pictures, diagrams and flow charts to communicate procedures visually to all employees where English was not their first language
- Supporting& achieving ISO 9001 Group certification with alignment and optimization of internal processes and auditing tasks across the 4 Refinery sites to support the QMS
- Provision of training across multiple sites

1983 – 1988
Ireland

LEO Laboratories Ltd.
Laboratory Technician

Responsibilities:

- Developed a high degree of competency in all aspects of laboratory techniques and instrumentation and demonstrated functional expertise in a leading hand role.
- Completed the Higher Diploma on day-release program and 4 nights a week evening classes in ’87 & ’88

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