CURRICULUM VITAE
Laurence O'Leary

Personal Information

"Personal Description"

I am a customer and results -orientated person, dedicated to delivering on time what I promise. My strong systematic and driven personality ensures that every complex problem is quickly executed in an efficient manner.

I am extrovert by nature and bring humour and energy into my daily work.

First Name	Laurence
Surname	O'Leary
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Education	Diploma of Technology in Biotechnology, Process Technology and Chemistry (SDU)

Key Qualifications

Senior consultant with more than 20 years' experience from production, quality assurance and validation execution within the Pharmaceutical, Medical Device and Biotechnology industries both in and outside of Denmark. Gained a Diploma of Technology in Biotechnology, Process Technology and Chemistry and an Academy Profession Degree in Nutrition, Dairy, Food and Process Technology with a focus on Process Technology. Long track record in both large Pharma like Novo Nordisk, Leo Pharma, Pfizer and Astra Zeneca and Medical Devices like Convatec and Ortofon. I have a very open minded and customer centric focus. My technological skills are continuously advanced by continuous self- improvement by participating in courses and conferences globally in contemporary pharma/ devices subjects.

Keywords

Quality
CSV
Qualification
Validation
Project Management

Qualification

- Compliance Manager
- Computer Systems Validation
- GAMP 5
- Quality Risk Management
- GxP Inspection Readiness
- Data Integrity
- Qualification and Validation
- 21 CFR part 11
- EU GMP Annex 11
- Training (Engineer and lower levels)
- Lean Six Sigma Green Belt

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Language Skills			Spoken	Written	Understand
Native	Level 1	Danish	2	2	2
Fluently	Level 2	English	1	1	1
Good	Level 3				
Fair	Level 4				
Minimal	Level 5				

Work Experience

Year 2019 - 2020

Company: **Astra Zeneca, SWE**
Position: **Senior Validation Engineer**

Responsibility

- GxP Qualification and Validation
- URS, DS, IQ, OQ, PQ, CD, PQ
- Production/ Computer Systems
- Risk Assessment
- Protocol & report generation
- Qualification execution
- Inspection readiness expert packages
- Inspection Validation SME

Year 2018 - 2019

Company: **Leo Pharma, DK**
Position: **SAP Compliance Manager**

Responsibility

IT CSV and Documentation Quality

- GAP analysis for Inspection Readiness (DKMA, FDA, GAMP5, CSV and DI)
- Stakeholder Management
- Implementing Impact Assessment for GxP, GDPR and Business Criticality Risk Assessment for URS
- Ownership for specific business processes including new URS and DS templates creation, implementation and training SMEs
- Organizational Change Management
- Align activities with Other Inspection Readiness Projects in LEO

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Year	2018 -	2018	Company	**Ortofon, DK**
			Position	**Project Lead Validation Engineer**
			Responsibility	Project Management of Validation project Cooperate with stakeholders, communicate Validation strategy and train staff FMEA URS/FS/IQ/OQ and PQ Running protocols to approval Deviation creation/ reviewer substitute for QA Manager

Year	2018 -	2018	Company	**Novo Nordisk, HI, DK**
			Position	**Senior Quality Engineer**
			Responsibility	• Commissioning and Qualification (SAT/OQ) of Bosch Filling Machine for multi-product filling line together with Bosch • Documentation review • Qualification Execution

Year	2017 -	2018	Company	**Pfizer, Catania, Sicily**
			Position	**Cleaning Validation Lead Engineer**
			Responsibility	Communicate with stakeholders in Project Management, Operations, QC, site QP and QA management Train Production staff in Cleaning Validation methods Conduct Cleaning Validation GAP analysis follow-up to FDA WL Creating and update Cleaning Validation, validation documents, specific procedures/ working instructions Deploy Sampling spots for existing equipment (microbiological and chemical analyses) Following validation to approval of protocols Change request and Deviations input

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Year	2016 -	2017	Company	**Convatec, DK**
			Position	**QA Validation SME**
			Responsibility	• Communicate with stakeholders in Quality, R&D, PM, CI and Operations • Initiate, lead and implement Continuous Improvement projects (GAMP/ PV and PM tools) across multiple sites • Train Operations employees in Quality mindset and regulatory requirements • Maintaining and developing 21 CFR 820 and ISO 13485 validation systems • Responsible for reviewing/ approving validation documents (IQ/OQ and PQ) • GAP analyses • Internal Validation training on a global basis • Audit participator (Internal & DMA)

Year	2014 -	2016	Company	**Novo Nordisk, KA, DK**
			Position	**Cleaning Validation Engineer**
			Responsibility	• Planning and coordinating with stakeholders (Production managers, team leaders, QC and Process Operators). • Involvement in both internal adults (Novo Nordisk) and external audits/ inspections (medicinal authorities) • Driving protocols and reports to approval including training of personnel. • Change requests and Deviation handling regarding cleaning validation

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Consultant Project Experience

Company	Projects/Results	Role	Year
Astra Zeneca	Multiple GxP protocols, executions and reports to Green Field site, Inspection Readiness expert packages for Utilities Inspection Validation SME	Senior Validation Engineer	2020
Leo Pharma	Migration of documents, creation of new URS/DS templates and implementation	Compliance Manager	2019
Ortofon	Validated Moulding production line for ISO 13485 2016 certification	Validation Lead Engineer/ QA Manager (substitute)	2018
Novo Nordisk	Commissioning/ Qualification participation	Senior Quality Engineer	2018
Pfizer	Creation of CV SOPs/ protocols/ reports for Cleaning remediation project	Cleaning Validation Lead Engineer	2017-2018

Participation in Courses and Training

Start Date	Duration	Subject	Organizer
13th June 2019	1 day	Validation of software for QMS processes	Key2Compliance
29th September 2017	6 months	Lean Six Sigma Green Belt	6sigmastudy (www.6sigmastudy.com)
4th April 2017	1 day	Computer Validation: Introduction to Risk Management	ECA
5th April 2017	4 days	Computer Validation: The GAMP 5 Approach	ECA
3rd March 2017	2 days	Statistics for Process Validation	Per Vase, NNE
5th January 2017	2 days	Process Validation	Donawa LifeScience Consulting

IT Skills

			Level
		MS Word	1
Expert	Level 1	MS Excel	2
Good	Level 2	MS Outlook	2
Fair	Level 3	MS PowerPoint	2
Basic	Level 4	MS Projects	3