Laurence O'Leary

Senior Validation Lead
Process Technology and Chemistry

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Competences

- CQV Lead
- Validation Specialist
- Risk Assessment
- CQV (COM/FAT/SAT/IQ/OQ)
- Process and Cleaning Validation
- GAMP
- Training
- Lean Six Sigma Green Belt

Key results

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 Ferrosan Medical Devices, Allarity, Convatec and Ortofon.

Personal Characteristics

Laurence has a very open minded and customer centric focus. His technological skills are continuously advanced by continuous self-improvement by participating in courses and conferences globally in contemporary pharma/ devices subjects.

Laurence is a customer and result-orientated person, dedicated to delivering on time what he promises. He is strong systematic and driven personality ensures that every complex problem is quickly executed in an efficient manner.

Laurence extrovert by nature and bring humor and energy into his daily work.

References

MEDICO LOGIC (2019 - present)

Senior QA Senior Engineer

Novozymes – Validation Project Lead (2021-)

Capacity and Compliance Improvement for Food industrial site. VMP/ GAP lists and improvement strategies. Lead for multiple minor improvement projects

Ferrosan Medical Devices (2021-2022) – Validation Specialist

CAPA mitigation project. Cleaning program creation and implementation. Including development, validation and monitoring procedures.

Bavarian Nordic - CQV Lead / Specialist

Lead for Risk (4 CQV), Specialist for CQV team
Multiple disciplinary-Utilities/ Equipment/ CSV
ENRA project

Novo Nordisk - Senior Cleaning Validation Engineer

Integrated team member of IM1 Purification support team
Sattline / LMES automation CIP recipes & configuration
Risk Assessment, (P&I CIP flow diagrams), URS
Protocol & report generation, Validation execution
Change control, Deviations

Astra Zeneca - Senior Validation Engineer

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

LEO Pharma - SAP Compliance Manager

IT CSV and Documentation Quality
GAP analysis for Inspection Readiness (DKMA, FDA, GAMP5, CSV and DI)
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

Ortofon - Project Lead Validation Engineer

Project Management of Validation project
Cooperate with stakeholders, communicate Validation strategy and train staff, FMEA, URS/FS/IQ/OQ and PQ

Pfizer - Cleaning Validation Lead Engineer

Operations, QC, site QP and QA management
Train Production staff in Cleaning Validation methods