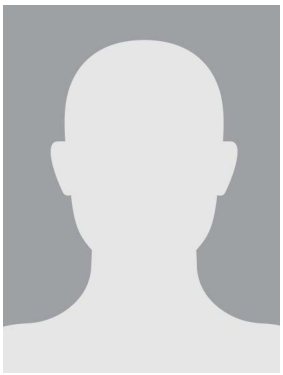

NN
MSc. Pharmacy, Copenhagen University

Qualification, Validation and Operation

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Competences

- Validation, Qualification and Operation
- CQV packages – URS, CARA, DQ, FAT, SAT, IQ, OQ, PC/PJ/PFV/PV), CV and CM.
- Risk assessment + FMECA
- SME in Process Cleaning of multipurpose and dedicated facilites
- Cleaning Operation (CM)
- QA and product release.
- GMP, GdocP
- Deviation handling
- Change request process management
- Logbooks for operation

Key results

Validation Specialist and Cleaning SME with more than 10 years' experience in the pharmaceutical industry working dedicated within projects Validation and Operation.

Improved CIP validation of filters and with increase of facility manufactory capacity up to 30%.

Created specific CIP with 40% reduction of water use.

Validated a complete facility with more than 25 vessels, filters, centrifuges, pipes, wash machines, columns and more.

Design and qualification of a completely new facility with more than 110 routes.

Software/standards

Extensive Project knowledge in compliance with following standards:

- EMA Annex 15
- FDA CFR 211.182
- PDA Technical report Validation
- Eudralex Volume 4
- PIC validation PI 006-3
- Health Canada GUI 0028
- ISO 9001 QMS
- ISO 17025 Calibration
- ISO 22716 Risk Mitigation
- ISO 13485:2016 Quality Management System

QMS Systems:

- Qualitydocs, Global-lims, Novoglow.

General:

- Microsoft Office

Personal Characteristics

He has a pleasant personality who is creative, professional and engages with high energy and dedication. As a Lead and supervisor for more than 20 senior and junior professional he gathered a team of success that despite any challenge operates in positive, comfortable and efficient work environment.

He invented several pioneering CIP processes for complex and sophisticated equipment in the pharmaceutical industry. Innovation, optimization and development characterize the way Ali work.

He do thrive within high level of expertise and systematical way of working that promise on time delivery and successful results.

References

Medicologic A/S (2024 – Present)

Validation Specialist and SME

Novo Nordisk 2022 - 2024

Specialist - LEAD of Cleaning setup for new Recovery Factory with more than 110 CIP routes + CIP team > 20 member. Package of URS, CARA, FAT/SAT, SER, DQ, OV, SAR, CV, CM, VSS.

Novo Nordisk 2020 - 2022

Area Specialist – Recovery factory - cleaning design, qualification and validation responsible + new product to facility validation, SAR, CV, CM, VSS.

Novo Nordisk 2019 - 2020

Senior Cleaning Responsible – Fermentation factory - cleaning qualification and validation of primary and secondary multipurpose equipment. New design, steam cleaning, risk assessment etc.

Novo Nordisk 2018 - 2019

Cleaning Responsible – Purification factory - cleaning qualification and validation of purification dedicated equipment. Risk assessment + electronic logbooks. Wash machines validation. CIP optimization.

Novo Nordisk 2013 - 2017

Senior QA professional - Quality responsible for Qualification and validation processes. Training, Coaching and optimization of training system and training materials. Audit and inspection responsible. Ensure compliance and quality of projects during qualification and validation activities (URS, FAT/SAT, DQ, IQ, OQ, PQ, CV, VSS) + Quality risk management system (QRM).

Pharmacy 2012 - 2013

Owner deputy and management.