Contact

www.linkedin.com/in/aaron-flanagan-gannon-651908104 (LinkedIn)

Top Skills

Microsoft Office
Troubleshooting
Problem Solving

Certifications

MBI in Bioprocess Facility Design
Commissioning and Qualification of Equipment and Systems
VCA diploma - Safety for Operational Supervisors

Aaron Flanagan Gannon

Commissioning, Qualification & Validation (CQV) Engineer at Kite Pharma
Amsterdam, North Holland, Netherlands

Summary

I am goal-driven with distinguished communication skills and I strive for excellence in all activities undertaken. I am a skilled problem solver who also excels working independently and as part of a team in fast-paced dynamic environments. I have a strong passion for environmental sustainability and awareness.

Experience

Kite Pharma

Commissioning, Qualification & Validation (CQV) Engineer
May 2022 - Present (1 year 9 months)
Hoofddorp, North Holland, Netherlands

Create and execute commissioning, qualification protocols, and validation protocols (CP/IQ/OQ/PQ), including identification and resolution of exceptional conditions.
Responsible for performing routine validation activities and support of validation projects.
Temperature mapping and other miscellaneous validation activities.
HVAC system qualification and commissioning.
Support of vendor protocol executions.
Creation of Computerized System Validation (CSV) documents including computerized system Risk Assessments, Validation Project Plans, User Acceptance Tests and Reports.
Create and execute of CSV commissioning, qualification, and validation protocols
(CP/IQ/OQ/PQ), including identification and resolution of exceptional conditions.
Review technical documentation including protocols & summary reports for CQV lifecycle documentation, other testing, and validation SOPs.
Perform investigations and implement corrective actions related to CAPAs and deviations.
Coordination of validation instrument inventory calibrations
and/or certifications.

Review of technical documentation including protocols & summary reports for CQV lifecycle documentation, other testing, and validation SOPs.

uniQure
Process Development CMC
January 2021 - April 2022 (1 year 4 months)
Amsterdam, North Holland, Netherlands

Project management, planning and organization to provide Gene Therapy product candidates.
Early stage phase I/II clinical testing for drug development to transition to first in human clinical phase.
Responsible for planning, preparing and executing experiments on USP & DSP of AAV based products.
USP activities: Cell culturing, Wave Reactor/ 50L STR Bioreactors and Buffer Preparation.
DSP activities: Affinity Chromatography, Ion Exchange Chromatography, Nanofiltration and UF/DF.

Mylan
Microbiologist
July 2020 - October 2020 (4 months)

Autoclave validation. Operation and
Validation of incubators, fridges and freezers via temperature monitoring and data loggers.
Performance of Sterility, Bioburden and Endotoxin testing.
Environmental monitoring of classified areas.
Preparation, Growth promotion and Sterility testing of microbiological media.
Performance of test method validation/verification as per Ph. Eur.
Execution of comprehensive investigation reports using Risk Analysis tools.
Support of process qualification and stability programs.

Amgen
Process Technician
August 2019 - July 2020 (1 year)
Dublin, Ireland

Validation and operation of semi automatic visual inspection instrumention(SAVI).
Carried out all duties associated with the inspection process of batches, with strict adherence to SOP's and batch records.

Process taskes include: the manual and automatic inspection of syringes and vials, reconciliation of products post batches, the use of electronic batch records (PAS X and LIMS) in adherence to Acceptance Quality limits.

Troubleshooting any issues while assisting with any investigations and deviations.
Compliance with all site quality and safety policies.

Pfizer
Process Technician
December 2018 - August 2019 (9 months)
Dublin, Ireland

Validation and operation of the Filling lines of Pfizer products.
Validation of ESAI instrumentation using challenge sets.
Some of the tasks include: Ebeam Validation, Aseptic setup of the Filling line, filter integrity testing, glove leak testing, turbidity testing and stopper height checks.

Operation of tasks involved in the Inspection Line of Pfizer products.
Some of the tasks include: Operate of automated inspection instrumentation, manual inspection of samples and end of batch reconciliation.

The use of different quality systems such as SAP, EBR's, iMax and LIMS for daily operations.

Environmental Protection Agency (EPA) Ireland
Scientific Officer
June 2017 - August 2017 (3 months)
County Dublin, Ireland

Performed Environmental Sampling, Environmental Monitoring and Site Inspections of lakes, ponds, rivers, estuaries, landfills, wastewater treatment plants and industries. Types of water sample collection was taken from surface water and groundwater using boreholes.

Environmental monitoring of the Eutrophication levels of water bodies around Ireland.
Carried out routine analyses of water samples in an ISO17025 accredited wet laboratory chemistry laboratory.

The types of analyses included: chlorophyll testing, suspended solids, dissolved oxygen (DO), ph and chemical oxygen demand (COD).

Operation of instrumentation such as: Lachat, Aquakem and Spectrophotometer.

The daily use of quality systems such LIMS, Citrix Quality Analyst and Paradigm software.

Audits carried out audits on Information sheets, Technical amendments, licenses and LIMS to check for discrepancies across different parameter limits.

Education

GetResSkilled

Certificate · (February 2022 - June 2022)

Dublin City University

BSc Environmneal Science & Health, Environmnetal Science · (2013 - 2018)