Contact

www.linkedin.com/in/huykhiemx (LinkedIn)

Top Skills

Presentation Skills
Project Performance
Business Case Preparation

Languages

Vietnamese (Native or Bilingual)
English (Professional Working)
French (Elementary)

Certifications

Supply Market Analysis
Lean Six Sigma Yellow Belt Certification
COVID-19: Tackling the Novel Coronavirus
Six Sigma: Define and Measure
Strategic Sourcing

Huy-Khiem NGUYEN-DAO

Project Manager at Abbott EPD Vietnam
Binh Duong, Vietnam

Summary

Project manager with a demonstrated knowledge in the pharmaceuticals industry. Skilled in Good Manufacturing Practice (GMP), Lean Six Sigma Methodology, Manufacturing Excellence, and Supply Chain Management. Strong pharmaceutical science background with a University Pharmacist degree from the University of Medicine and Pharmacy, Ho Chi Minh City.

Experience

Abbott

Project Manager
February 2022 - Present (3 years 2 months)
Binh Duong, Vietnam

- Defined and executed stringent GMP certification strategy (EU GMP) for Abbott Healthcare Vietnam site.
- Developed Quality Risk Management Plan for cross-contamination in multi products shared facilities, identifying necessary technical and organizational controls; defined capital investment plans for technical controls and collaborated with other departments to implement organizational controls.
- Developed and executed the Industrial Hygiene Containment Strategy for handling substances across different OEB bands (mild to high potency), meeting international and Abbott’s requirements.
- Defined target utility and energy profiles to achieve net zero carbon emissions.
- Managed Pharmaceutical Technology Transfer project with a total value of $90K USD.
- Collaborated globally to develop registration dossiers as per ICH CTD and EMA requirements (non-clinical, clinical, quality modules).
- Oversaw capital projects ranging from $20K to $855K USD.
- Acted as site business excellence manager for 6 months, driving recordable savings of $300K USD.

Sanofi

Quality Assurance
November 2021 - February 2022 (4 months)
Thủ Đức District, Ho Chi Minh City, Vietnam

- Supervised all qualification, calibration, and computerized system validation activities at D9 site.
- Reviewed facility and utility designs to ensure compliance with the latest GMP codes.
- Commissioned and qualified Data Integrity Maturity Model project (quality part) with a total value of €50K EUR.
- Reviewed and followed up on Quality Maturity Index gaps assessment and improvement plan.
Developed strategies to handle external audits from DAV, TGA Australia, MFDS South Korea, and GQA (Sanofi Global Quality Audit).

Davipharm (Dat Vi Phu Pharmaceutical JSC)
2 years 10 months

Validation team leader
July 2020 - November 2021 (1 year 5 months)
Bến Cát, Binh Duong, Vietnam

- Led a team of 8 responsible for all validation activities in the EU GMP project.
- Defined and implemented validation and qualification strategies for premises, equipment, processes, cleaning, and ongoing verification as per EU GMP Chapter 1, 3, 5 & Annex 15.
- Managed the establishment, prioritization, execution, and tracking of the Validation Master Plan for premises, equipment, processes, cleaning, packaging validation, and ongoing process verification.
- Drafted, reviewed, and monitored validation protocols; analyzed results and wrote validation reports; supported ACTD P3 review before submission.
- Ensured qualification of auxiliary systems and equipment; validated manufacturing and cleaning processes; maintained the state of validation at the site.
- Facilitated risk management for qualification and validation activities using ICH Q9 tools; provided guidance for system impact and component criticality assessments; built robust risk management plans.
- Developed cross-contamination control strategy for Oncology and High Potent API manufacturing processes according to ISPE Risk-MaPP.
- Built compliance strategies for critical GMP utilities: HVAC, water system, compressed air.

Achievement:

- Successfully validated High Potent Drug Manufacturing Workshop as per WHO TRS 957 Annex 3 requirements; cleared inspection from Drug Administration of Vietnam (November 2020).
- Passed EU GMP inspection from Chief Pharmaceutical Inspectorate (Poland) for Oral Solid Dosage Production line with no observations on Qualification & Cleaning Validation (August 2021).

Cleaning Validation Specialist
February 2019 - June 2020 (1 year 5 months)
Bình Dương, Việt Nam

- Led and performed risk assessments for determining critical cleaning conditions, cleaning matrix, family approach, critical cleaning parameters, and acceptance criteria.
- Developed final reports summarizing development data and risk assessments for determining worst-case scenarios for cleaning validation.
- Reviewed cleaning-related method validations, analytical methods, extraction studies, and recovery studies as applicable.
- Drafted, reviewed, and executed cleaning development and validation protocols within a non-sterile pharmaceutical environment.
- Performed sampling for cleaning studies, including rinse water sampling and surface swab sampling; submitted samples to QC lab for testing.
- Summarized results and wrote final reports; ensured timely review and approval of final reports and study data.
- Coordinated and scheduled cleaning development, validation, and continuous monitoring/verification activities with appropriate departments.
- Wrote and provided training on SOPs relevant to cleaning validation procedures; evaluated and revised cleaning procedures with process improvements as necessary.
- Interfaced with other departments in support of cleaning validation activities; participated in cross-functional activities to support overall Quality Assurance department.

OPV Pharmaceutical Joint Stock Company
Quality Assurance Officer
September 2018 - February 2019 (6 months)

- Followed up on the application of GMP roles in the production area.
- Monitored and followed up on all environmental monitoring in the production area.
- Supervised all job activities for the QA production inspector team.

- Conducted final checks and releases for each production step; performed in-process tests for the granulation process.
- Responsible for sampling all items received in quarantine, including raw materials and finished products.
- Managed the labeling system, pest control system, and dispatch area; verified all raw materials dispensed with the production officer before receipt in the production area; verified the weighing process.
- Followed up on change control, deviation, risk assessment, OOS-OOT, and CAPA plans.
- Participated in hosting periodic audits by GSK contractors.
- Attended training on Product Lifecycle Management concepts as per ICH Q9-Q10-Q12.

Education

University of Medicine and Pharmacy, Ho Chi Minh City

Pharmacist, Pharmacy · (2013 - 2018)

edX

Lifelong learning · (2013)

MITx on edX

Making Biologic Medicines for Patients: The Principles of Biopharmaceutical Manufacturing, Biotechnology · (2017 - 2017)

Le Quy Don High School for the Gifted-Danang

Baccalaureate, Chemistry · (2010 - 2013)