IYYAPPAN ANGAMUTHU

Quality Control / Quality Assurance Regulatory /Software validation etc.,

Personal information

Cuddalore-District, Tamil Nadu, India (work in Chennai)

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+918248439263 & +919840716566

LinkedIn

https://www.linkedin.com/in/iyyappan-a-49930337

Skill Sets

- AUDIT COMPLIANCE
- GLP/GDP/GxP
- Qualification/Validation
- QMS/QRM/CAPA
- OOS/OOT/Deviation
- ALCOA++/Data
- CSV / Annex-11/Part-11
- Stability Studies
- Calibration/Qualification
- Audit exposure skills

US-FDA-7 times, EU-GMP-2 times, ANVISA, MHRA, WHO-GENEVA, ISO-9001series, Health Canda etc.,

Language

- English
- Tamil
- Hindi
- French
- Lingala

Personal Statement

Over 25 years' experience in the pharmaceutical's domain **(Sterile injection/Non Sterile/Liquid & Solid Orals)** with different specialization such as Quality Control / Quality Assurance / Regulatory and Software validation. Possessing sound knowledge on analytical instrument and worked in reputed organizations.

Work Experience

GM Quality Control Head (QA/QC) May'24 to Till date
Kausikh Therapeutics (P) Ltd., Chennai, Tamil Nadu, India.
Roles and responsibility are same as mentioned below.

DGM-Quality Control/Quality Assurance QC/QA:
EverGreen Pharmaceuticals -Africa Sarlu. Feb'23 to May'2024
Good Knowledge and command on cGMP, Risk Assessment knowledge Accountable for Deviation management, Responsible for the QA Operation investigation in Market complaints and OOS. Responsible for assessing any change control and provide on-time impact assessment. Responsible for CAPA review and approval. Ensure Quality incident associated with products manufactured
- Responsible for implementing Quality improvement in Plants, coordinating with CFTs to establish and spread the Quality Culture.

Sr. Manager-QC: Steril-Gene Life Sciences Ltd., Puducherry, India (US-FDA, ANVISA, EU-GMP, WHO-GENEVA, MHRA approved). Jan'18 to Jan'2023
Quality Manual, Quality Procedures (Documentation Management, OOS, OOT, OOC, QMS, QRM, FMEA, Fishbone tool, 5WHY tool etc., Change Control CC, CAPA, Deviation Handling, Data Integrity DI, ALCOA++, CSV as 21 CFR part-11, EU-GMP Annexure 11, GAMP 5.2.

- **Asst. Manager-QC/QA: BioGenomics Limited.,** Pondy, India.Jan'11 to Jan'2018
  Asst. Manager-QC: Steril-Gene Life Sciences Ltd., Pondy,Aug'2010 to Jan'2011

  Handling of Biomolecules Insulin Analog, Insulin Glargine, Insulin Aspart Aspart, Insuline Human, Filgrastim etc., Elisa, SDS-PAGE analysis, RT-PCR Peptide mapping, Stability studies, HPLC, GC, FT-IR, OOS, OOT, SEC

- **Executive-II-QC/QA: Sun Pharma Ltd.,** Chennai India. Apr'09 to Aug'2010

  Stability studies, HPLC, GC, FT-IR, UV-Visible spectrophotometry, Method validation and verification, method transfer, Handling of Non-Conformances NOC, Compliance, Training, WRS, RS Qualification, Calibration. Drug Master File(QC part) and 21 CFR part 11 (computer system validation) (CSV).

- **In-charge QC/QA Malladi drugs&Pharma Ltd.,**Chennai India.Mar'07 to Mar'2009
  Waters HPLC with empower software, FTIR, UV Spectrophotometer, KF titrate, Polarimetry, Malvern 2000 PSD, GC and TOC etc., Gained experience in Method transfer activities and new instruments

- **Executive QC Orchid drugs & Pharma Ltd.,** Chennai India. Jul'06 to Mar'2007
  Instrumentation HPLC and UV-VIS spectrophotometer analysis, Auto titrations, Wet analysis, volumetric analysis, In-process, Intermediate, Finished products analysis and R &D samples analysis.

- **Officer-QC Shasun chemicals &Drugs Ltd.**Tamil Nadu India. Jun'97 to Jul'2006

  In-process analysis, Working standard qualification, calibration, X-RD analysis, Computer system validation CSV, Cleaning validation sample analysis.

- **Lab Chemist-QC/QA Tagross Chem. India Ltd., TN,** India.Jun'1995 to Jun'1997

  Wet chemistry, Titrimetric analysis, Gravimetry analysis, sampling of Raw materials, Packaging materials etc.,

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Audit Handled/experience	
US-FDA	FDA
EU-GMP	EUROPEAN UNION GMP
ANVISA	ANVISA
Health Canada	
WHO-Geneva	World Health Organization
ISO 9001	ISO

Education

Masters in Chemistry (M.Sc.,)
Mar'2004 to Mar'2006
Annamalai University,
Chidambaram, India.

Bachelors in Chemistry (B.Sc.,)
Mar'1992 to Mar'1995
Madras University, Chennai, India

Diploma course in Instrumentation DCPIC.,
Mar'2003 to Mar'2004
Annamalai University,
Chidambaram, India.

DRA., Drug Regulatory Authority*
PGDCA., Computer Application*
Note: *online courses.

MANAGMENT KRA

Evaluation of **SLA, SPA, KPI**
Handling of team size: 75+ employees with multiple functions.

Native Address:
No.07, Vishali Nagar,
Unnamalai Chetty Chavadi,
Kondur-Post, Cuddalore-T.K & District, PIN: 607006
Tamil Nadu, INDIA.

Date of Birth: 03/06/1972
Age:53

Achievements in my Career path:

Handled of US-FDA 7 times with no 483 or critical b observations, ANVISA audit, MHRA, WHO-GENEVA etc., and obtained no major observations.

Reduce Testing/Skip testing of Excipients and Finished Products:

After receipt of the starting materials/Raw material, all parameters of the specification are tested. Risk assessment performed based on 3 consecutive batch of Vendor qualification, historical data analysis, ICH Q7 and Q9. As per the Guideline, Purity/Potency and Identity shall be proven for materials.

Hence Reduce Testing was proceeded by means of SOP, Protocol and it were executed for risk assessment.

Only a reduced number of parameters are tested, while the other parameters are taken from the certificate of analysis from the manufacturer CoA.

Discontinuation of Purified water System in QC:
A water purification system in QC, name: Milli-Q, the water was being used for all the solution preparation and HPLC analysis. System cost: 15000 US dollars, AMC 500 USD, spares: 4000 USD, in totally 20,000 USD, its totally saved to the company...as it was not required as justified and accepted by Quality team. Plant Purified water used from user point, instead of mini purified system water.

HPLC analysis Runtime shorten to 2 hours from 15-20 hours:
Many of drugs having analysis time of each run 60 to 120 minutes for In-process and Finished Products, when In-process sample is given, if you started HPLC system immediately it will complete and report after 15 to 20 hours only. In order to overcome such a delay in reporting and batch process holding. A HPLC method was developed to complete the entire analysis within a hour and report the result to production. Hence 20 hours reporting delay is avoided by means this methodology. Turnover three times increased for a particular drug.

Extension of UV Lamp hours through justification:
As we had 40 HPLC systems, around 30 UV lamps are frequently changed once in 6 months, as UV Lamp hours exceeded 2000 hrs. It costs around Rs. 40000 x 30=12,00,000 are saved to company, it was justified through a study protocol, did analysis in a new UV Lamp and a lamp with 5000 hours, report compiled and found that 0.7% variation, its less than the acceptable human error.

Hence concluded that to monitor Lamp energy along with Lamp hours to ensure the efficiency of Lamp.

Best trainer award in Sun Pharma, Won prize in GO LEAN management competition to save cost and improve productivity, Won prize.

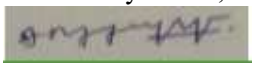
Computer System Validation CSV, successively completed for CSV project computers with the Analytical instruments as per 21CFR part 11 and approval received from Elly Lilly LLC.

PROJECTS

Actively participated Trypsin biomolecule activity analysis, collaboration study conducted by United States Pharmacopoeia (USP), study performed, data compiled and submitted to USP Pharmacopoeia.

I solemnly declare the information mentioned herein is true and correct to the best of my beliefs.

Sincerely Yours,



(IYYAPPAN ANGAMUTHU)