

**NAME: GANESH KUMAR**

**NATIONALITY: MALAYSIAN**

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**WORKING EXPERIENCE:**

**Production Manager**

**Biocon (M) Sdn Bhd September 2023- current**

* Ensuring GMP compliance for production shopfloor and ensure compliance in line with site audit from regulatory audit.(USFDA,EMA and NPRA requirement)
* Mentoring the downline and give appropriate GMP training and coaching, data integrity champion training for the shop floors)
* Ensure all QMS elements closed on time and reduced the TAT downtime with increase the production yield, and reduce cost.
* Collaboratively working with other cross functional in order to improve the process in manufacturing/production area.
* Managing production budget including OPAX and CAPEX.
* Ensure the production system in compliance with review all CSV and performed periodic evaluation.
* Ensure availability of production materials and shopfloor consumables and plan and timely initiation of purchase requisition via SAP software for production requirements via OPAX/CAPEX.
* Managing and plan the shift schedule for the shift workers and ensure sufficient manpower for the smooth operation.
* Liaise with engineering and instrumentation team for production related issue and joint weekly meeting for the updates.
* Collaborate with cross functional pertaining any issue arise during the downtime and timely got engage on the resolution.
* Involve and give inputs for phase 2 investigation by working collaboratively with warehouse RND and Quality Control.
* Collaboratively working with QC and supply chain on timely release the production material for the production usage.
* Review the production batch manufacturing records and analyzing the trends.
* BMR/MBR review and ensure OPAX improvements projects with liaise process improvement team.
* Involved in report HSE if in case found potential risks and propose appropriate CAPA.
* Participate in HSE risk assessments and involved in preparation and participation to internal HSE audits.
* Involve in production process improvemnt amd process optimization.

**Assistant Manager (IT CSV validation lead )**

**(Quality Control and Production) Feb 2022-September 2023**

**Novugen Pharma Sdn Bhd**

* Involved in Computer System Validation and system compliance for entire Novugen Pharma.
* Involved in CSV for Production, Quality Control and Engineering.
* Performed Audit trail review for all GxP systems.
* Involved in USFDA pre inspection and successfully completed the audit.
* Trained the new joiners for systemcompliance and Data security.
* Administrator for the all GxP systems.
* Involved in URS, DQ, IQ, OQ and PQ preparation for CSV related.
* Involved in IT Infra Qualification.
* Identified all the systems gaps in the GxP system and getting involved on the closure.
* Qualify internal quality auditor and involved audit for the cross functional team

**Quality Assurance Assistant Manager (medical Device)**

**DKSH Malaysia Sdn Bhd**

 **(Operational , Qualification and process validation) October 2021-January 2022**

* Involve to review protocol and report for freezer, cold chain qualification (ORCA), cold room qualification and transport qualification and thermal mapping.
* Review and approve document related temperature monitoring and RH monitoring for overall facility.
* Approve the SOP and work instruction for temperature monitoring.
* Involve CSV document review for electronic signature, software and etc.
* Involve in quality management ISO 9001 and 13485 for medical device.
* Involve in quality manual updating for medical device, ISO and site master file.
* Involve in CAPA tracking and ensure documentation review for medical device
* Involve in preparation of impact assessment and person in charge for cold room monitoring for medical device (Roche Diagnostics, Alcon vision care and etc.)
* Involve as documentation owner for good distribution practice, Good distribution practice for medical Device.
* Involve in SOP and related Work instruction review and as a approver.

**Quality Assurance Assistant Manager (Section Head)(Quality and Production)**

**Novugen Pharma Sdn Bhd July 2020-October 2021**

* Involve in Document review for ANDA(USFDA) and NPRA submission.
* Involved in Production BMR/MBR review.
* Review URS,IQ,OQ and PQ for all qc related equipments and instrument
* Succefully completed NPRA pre inspection and GMP approval.
* Review and approve method validation,method transfer,specification,standard Testing Procedure and Standard operatinfg procedure for Quality Control and Quality assurance.
* Involved with quality system-Deviation,CAPA,OOS report preparation and internal audit report preparation.
* Involve in API vendor Qualification and laboratory qualification according to USFDA requirement.
* Involved in revieweing of microbiology method validation report,investigation and etc
* Involved in Batch manufacturing reviewing(BMR) and BPR.
* Involved in IQ,OQ and PQ document review and approval.
* Involved in handling reference samples(RLD) and control samples.
* Area owner and key personnel for handling Reference Sample and Control samples inward and outward for sendng sample for clical research organizarion(CRO).
* Prepared USFDA gap assesment for overall Quality Control.
* Ensure overall compliance of Quality Control with reviewing audit trail record.
* Involved in preparation of SOP for market complaints and product recall.
* Monitor subordinates and trained accordingly.
* Involved in Change control approval and track Change Control for Quality Control
* Monitor analytical development,formulation development and plant quality assurance document approval and transfer.
* Prepare the SOP, protocol and reports for multimedia dissolution for Bioequivalence study.
* Ensure Quality Control Compliance and plant complliance.
* Involved in review and approve the Certificate Of Analysis for raw material and Finish Products.
* Ensure overal compliance for ANDA submission.
* Direct report to site QA head and reporting overall compliance for plant,and Quality Control.
* Review and approve analytical test report inprocess and finisheh product.
* Involved in Batch manufacturing record review and Master Manufacturing Formula(MMF).
* Involved and succefully completed NPRA approval for facility audit.
* Incharge for monitoring product complaints for FDA,NPRA,ROW and MHRA after product registration.

**Quality Control Senior Associate (Team Lead) Nov 2013-July2020**

**Biocon Sdn Bhd (Biologics and medical device)**

**Work Description :**

* Writing technical reports, protocols, and prepares specifications , processes, and test.
* Familiar with quality system-Deviation,CAPA,OOS report preparation and internal audit report preparation for analytical.
* Involved in material release for semglee for US market.
* Involved in preparation and review Certificate Of Analysis for raw material
* Involved in water Out Of Specification investigation and author for all water OOS reports.
* Review and approve the reports. Qualified reviever and approver for qualification reports and protocol,change management,and SOP and EOP revision.
* Involved in lab projects by perform Instrument Qualification for Portable TOC and Raman spectrometer(BRUKER),BOD Incubator.
* Expertise for handling and calibration for Shimadzu TOC.GC agilent and Waters HPLC and Karl Fisher instruments and trained new comers.
* Involved in USFDA,EMA,AVISA,Health canada,Mexico,BRAZIL,NPRA,QP audit.
* Prepared and revised the SOP and EOP for raw material team.
* Lead material testing team and water testing team.
* Qualified reviewer for QCA audit trail HPLC,GC and KF.
* Released and approved QCA raw materials to production usage.
* Involved and lead the team to warehouse sampling.
* Prepare checklist to warehouse sampling.
* Involved in approval for material testing for Insulin Glargine,Human Insulin and insulin aspart.
* Prepare impact assesmement and risk assesment for Quality department.
* Checked and verified calibration and PM reports for QCA instruments,
* Request quotation for PM activity from external party.
* Involve in IBMS monitoring,ELPRO system monitoring for room temperature and thermal equipments temperature monitoring.
* Involved in medical device testing projects.
* Trained a new anayst on trouble shooting for HPLC,Gas Chromatography,UPLC,TOC and etc.
* Raise complaints via SAP for QCA laboratory maintenance activity.
* Involve and train newcomers on chemical handling.
* Train and supervise newcomers on PPE usage at laboratory during chemical handling.**:**
* Liase with vendor and and external service engineer for preventive maintenance laboratory instruments.
* Give appropriate training for newcomers on handling and calibrate the major instruments.
* Involve in thermal mapping and freezer requalification,BOD by kaye validator
* Instrument & equipment commissionning for quality.
* Handling and perform monthly, yearly calibration and preventative maintenance instruments such as HPLC, GC, TOC Analyzer, Densitometer, Polarimeter ,Autotitrator Karl Fisher and UV VIS Spectrophotometer and thermal mapping.
* Involve in method validation for Quality Control.
* Involved in commissioning for Biocon Malaysia specifically Quality Control Lab set up and site visit for phase 1.
* Involved in Method transfer and Method validation for Insulin glargine, Human Insulin

 and insulin Aspart with Biocon India.

* Undergone training in India for 3 months.

 Performing routine testing of in-process and finished testing samples for Drug.

* Substances and Drug Product as well Stability and Hold time Study samples.

 Well acquainted with qualitative and quantitative analysis of compounds by chemical

* and instrumental analysis.
* Qualifying the analytical columns, GC standards, and working standards.
* Handling and reporting of the OOC, OOS, Deviation, Change Management and Protocols.

**MEDICAL SALES EXECUTIVE Feb 2013 – Oct 2013**

**Unimed Sdn Bhd (Based In Johor)**

**Work Description :**

• Increasing sales from existing accounts and developing new accounts for clinics and pharmacy.

• Promote wide range of antibiotics and syrups to the clinics and pharmacy.

• Consistently achieve monthly sales target.

• Cover area of Johor Bahru, Batu Pahat, Muar.

• Implementing all the sales & marketing activities to achieve sales target.

• Do market survey on competitor’s product and promotion.

• Survey bioequivalence studies for the products.

**HOSPITAL BUSSINES EXECUTIVE March 2012 – Feb 2013**

**RANBAXY (M) SDN BHD merge with Daichii Sankyo (Based in K.L)**

**Work Description :**

• Responsible for presenting and promoting product range to Medical Professional

 carrying hypertension, cholesterol, diabetic products n etc.

• Manage to penetrate branded generic atorvastatin to KPJ tawakal,Damai Hospital,Tung shin, Lourdes medical centre.

• Manage to achieve monthly sales target.

• Increasing sales from existing accounts and developing new accounts at private hospitals.

• Implementing all the sales & marketing activities to achieve sales target.

• Do market survey on competitor’s product and promotion.

• Cover area Kuala Lumpur, Shah Alam, Kuantan, Johor Bahru.

**EDUCATION BACKGROUND:**

2008- 2011 DEGREE IN BIOMEDICAL SCEINCE - Management & Science University.

2005-2008 DIPLOMA IN MEDICAL LABORATORY TECHNOLOGY

 (Advanced Management & Technology Centre (PTPL),Shah Alam.)

**STRENGTH & SKILLS :**

* Involved in EMA , USFDA, Health Canada, NPCB, Mexico Audit and Local Internal Audits
* Involve in document review and preparation for ANDA and NPRA regulatory.
* Handling on Change Management, Deviations, OOS, QMS, etc.
* Strong knowledge in Good Manufacturing Practice(GMP)
* Strong knowledge on Quality compliance.
* Certified Life Science Analytical Specialist by MOPI.
* Certified in troubleshooting and calibration specialist for Waters HPLC,UPLC and GC agilent.
* Involved in Computer System validation(CSV) for Quality Control Unit.
* Cetrified in pharmaceutical method validation.
* Computer Literate in Microsoft Word, Excel, PowerPoint & Animation.
* Able to perform calibration HPLC, UPLC, GC, TOC ,Karl Fisher.
* Involve in Equipment and Instrument qualifications and commissioning.
* Involved in preparation of URS,DQ,IQ,OQ and PQ.
* Able to do troubleshoot for HPLC, GC, Karl Fisher, UPLC, FTIR.
* Able to prepare protocols as well as execute analytical method validation, analytical method transfers and cleaning validation.
* Knowledge on SAP system
* Knowledge on cGMP, GLP and conversant with Pharmacopoeia (USP,Ph.Eur,IP).
* Monitoring calibration and preventive maintenance for lab equipment.

**INSTRUMENTS & TRAINING :**

* Lean Six Sigma Black Belt
* Good Manufacturing Practice Training(GMP)
* Cleaning validation and method validation training.
* Training on HPLC, GC, UPLC analysis and trouble shooting by Waters and Agilent Experts.(Waters Aquity, Waters, Agilent)
* Training on compliance and Empower by Waters and Agilent Technologies
* TOC (Shimadzu)
* FTIR
* Weighing Balance & pH & conductivity meter (Mettler Toledo)
* Thermal mapping.

**Key Accomplishment :**

* Knowledgeable and certified of Lean Six Sima green belt and Black Belt .
* T.R.I.C.E award recipient for getting involved with extraordinary performance during USFDA audit.
* Key personnel for analytical quality assurance and owner for few SOP.
* Key personnel for IT Computer system validation and compliance.
* Perform Instrument Qualification project within short period for laboratory usage to reduce man power and time.Etc Raman Spectrometer and Portable TOC(URS,DQ,IQ,OQ and PQ).
* Implement internal PM activity for laboratory instruments.
* Certified as analytical specialist by MOPI.
* Closed all Laboratory incidents, OOS and deviation within timeline.
* Successfully completed NPRA,USFDA,EMA audits.
* Implemented laboratory incident SOP and reduce Deviations in Quality Control Department.
* Reduce the TAT for production from 5 days to 3 days.
* Reduce the downtime of production by reduce the QC result release.

**References :**

**MR.BHAVILKUMAR**

**EX QC DIRECTOR**

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* Biocon SDN BHD

**Sivakamy**

**Associate manager**

+60109312549

* Novugen Pharma SDN BHD