BIBEKANANDA CHOUDHURY

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Personal Data

Date of Birth : 13.06.1986

Sex : Male

Nationality :Indian

Marital Status: Married

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Present address

Bibekananda Choudhury

Room No.:J17

Vahuchar Nagar Society

(Near to Wagheswari Society)

Near to Amit Nagar and L&T Circle

Vadodara - 390022

State-Gujarat

Permanent Address

C/o-Balabhadra Choudhury

At/Po-Baghamari

Dist:-Khurda

Pin-752061

State-Odisha

Contactno.09937057984,

09439943955

CAREER OBJECTIVE

To Work in a challenging environment where in I can make the best use of my academic knowledge and abilities to contribute for the success of the organization and thereby enhancing professional advancement in the pharmaceutical Field.

JOB PREFERENCE: COMPLIANCE/CQA/QMS

PROFESSIONAL EXPERIENCE

(1) **BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD.** From Jun 2021 to till now as Sr. Executive in QA-Compliance department.

(2) Worked with **Sun Pharmaceutical Industries LTD. Halol, Baroda** from Sep 2014 to Jun.2021 as an Executive.

(3) Worked with **Torrent Pharmaceuticals Limited, Indrad,** Ahmedabad as a **Technical Assistant (Officer)** from 2nd Feb.2012 to 6th Sept.2014.

(4) Worked with **Hagel Capsule Industries Ltd** , **Daman [Lone Licensee partner of GLAXOSMITHKLINE PHARMACEUTICALS LIMITED]** (WHO Approved) as **Officer from** Nov. 2010 to Jan 2012.

EDUCATION PROFILE

Degree : **Bachelor in Pharmacy in 2010**
CGPA : **7.68 (69.8%)**
University : BPUT, Rourkela,Odisha

Course : **Diploma in pharmacy in 2007**
% of Marks : 75.14%
Board : O.S.B.P, Bhubaneswar, Odisha

Course : **12thScience (2003)**
% of Marks : 43%
Board : C.H.S.E, Odisha

Course : **10th (2001)**
% Of Marks : 70.13%
Board : H.S.C., Cuttack, Odisha

AUDIT FACED

- **USFDA, (Faced to Ms Kellia Hicks in Sun Pharma-2019 and Ms Parul Patel in 2018)**
- **TGA (Faced to Mr. Noel in Nov-2017)**
- **MHRA Faced in Mr. Mark V.Berlo in Feb-2020**
- **ANVISA**
- **MOH**
- **WHO**
- **MCC**
- **S-FDA (Saudi Arabia),EDA (Egypt), Russia, EU-GMP,ACHE,TILLOMED**
- **More than 70 Costumers Agency Audits**

CURRENT JOB PROFILE In BDR as HOD in Compliance department

1. **Quality Management/Continuous Improvement:**
   - ✓ Implementation of regulatory requirements, management and control of documents, such as SOPs, Master Documents, etc.
   - ✓ Self Inspection/Internal Audit to all department as a **lead Auditor.**
   - ✓ Handling as a lead Auditor for Approval of **Vendor.**
   - ✓ Implementing at the site the complaint investigation system; qualification and validation system, change control system and system for handling of deviations.
   - ✓ Review of the annual product quality review.
   - ✓ Ensure that proper change control system is followed for changes made to facility/ equipment/product/process and master documents by following change control procedure.
   - ✓ Participate in investigation of customer complaints & deviation investigations.
   - ✓ Review of effectiveness of CAPA wherever applicable and maintain appropriate documentation related to the same as appropriate.
   - ✓ Play as a CTC of the organization giving training on DI,CGMP and Product mix up and contamination.
   - ✓ Handling and Participate in investigation of Out of Specification (OOS) and Out of Trend (OOT).

2. **Compliance:**
   - ✓ Ensure adherence to company quality standards, Local FDA, MHRA, ANSM, USFDA, ANVISA & other applicable regulations, by;
     - ✓ Understanding the requirements and update all concerned departments periodically through training/meeting sessions
     - ✓ Performing the gap analysis to find out the gaps in existing system.
     - ✓ Preparing a compliance plan for closure of gaps.
     - ✓ Execution of compliance plans in coordination with concerned department.
     - ✓ Prepare for and attend to external / regulatory quality audits/inspections.

3. **Validations & Qualifications:**
   - ✓ Participate in implementation of validation master plan.

- ✓ Ensure the compliance of validated status of all equipment, manufacturing processes and cleaning processes.
- ✓ Review of validation / qualification plans for facility / utilities / equipment / instrument / process / computer / cleaning as & when required.

4. **Documentation Control:**
   - ✓ Preparation/approval of quality system SOPs/Formats and participate in preparation of cross functional department SOPs ensuring compliance requirements.
   - ✓ Ensure the compliance of controlled distribution and archival of documents & record.
   - ✓ Review of procedure for control of master documents.
5. **Assuring quality of products by :**
   - ✓ Ensuring compliance to relevant SOPs/manufacturing instructions/packaging instructions during manufacturing & packaging operations as appropriate.
   - ✓ Review of batch manufacturing & packing records as & when required.
   - ✓ Ensuring compliance of implementation of corrective actions/preventive actions.
6. **Regulatory Compliance:**
   - ✓ Review of product dossiers as & when required.
   - ✓ Review of batch manufacturing record with regulatory dossier and ensure the product manufacturing process is in compliance with regulatory dossier as & when required.
   - ✓ Co-ordination with the regulatory department.
7. **Others:**
   - ✓ Review of site master file.
   - ✓ Coordinating with various agencies for making of the technical agreements.
   - ✓ Review of maintenance and calibration/Preventive Maintenance program.
   - ✓ Supplier audit/contract manufacturing audit/contract testing laboratory audit qualification and Approval.
   - ✓ To collaborate with other departments (e.g., Risk Management, Self Inspection,etc)to direct Compliance issues through appropriate existing channels for investigation and resolution.
   - ✓ Participate in performing the proactive/reactive risk assessments using FMEA, fault tree analysis methodology.
   - ✓ To identify potential areas of compliance vulnerability and risk (gap identification); develop/implement corrective action plans for resolution of problematic issues and provides General guidance on how to avoid or deal with similar situations in the future.
   - ✓ To develop, coordinate, and participate in a training program that focuses on the elements of the compliance, and seeks to ensure that all appropriate employees and management are knowledgeable of and comply with the pertinent GMP /Quality standards.
   - ✓ To provide reports on a regular basis, and as directed or requested, to keep the senior management informed of the operation and progress of compliance efforts.
   - ✓ To monitor and ensure data integrity compliance at site in coordination with respective department heads/designee.
   - ✓ Any other job assigned by the management from time to time.

PREVIOUS JOB PROFILE IN SUN PHARMA

- **Subject-Matter Expert for** Change Control Programme and Form Management System,LMS & EDMS
- Preparation of **Quality Metrics and Site QA operational report** in timely manner and to identify gaps and escalate to management**.**
- **Planning for closing of All QMS records.**
- **Organize the CAPA meeting**, Coordinate/Manage CAPA efforts and interact with Assign responsible person for CAPA owner in Track wise system for performing the activity.
- **Handling of Internal Quality Audit** to Other Department.
- Reviewing of **Annual Product Quality Review**
- Handling of Document Management Section and Record room **as an in Charge.**
- Qualified and approved trainer for EDMS, TW and FM System, cGMP and other subject. Provide training on quality system procedures and general GMP training.
- Coordinator of **Track Wise, EDMS, FMS** and **Learning Management System**.
- Review, Evaluation and closing of Change controls, Action Items, CAPA, Deviations in **Track wise system.**
- Execution of BMR, BPR, Specification and SOPs.
- Review and Closing of **Planned Modification Forms.**
- Preparation of **Global** SOP and **SMF (Site Master File).**
- Performing **PQ** of various software like FMS, Track wise and EDMS etc.
- **Reviewing of Open document** for closing propose and from the view of compliance.
- Ensure the timely approval of the Change control, BMR, BPR SOPs Protocol etc.
- Handling of Risk Assessment Reports.
- Handling of **ERP/LIMS/SAP** related activity.
- Distribution and retrieval of SOPs.
- Review of Master Formula Card, Batch Manufacturing Record, Process Validation Protocol, Validation Summary Report etc. **During Audit Time.**
- Reviewing manufacturing documents like SOP,MFR, BMR, Process Validation Protocol/Report, Stability Protocol/Report, Packaging Material Specification, Review of Audit trail etc.
- Review and compliance of online BMR for manufacturing process.
- Ensure that any types of deviation during activity are brought to the notice of higher management.
- Responsible for the documentation related to QA area.
- Performing line clearance before starting activity.

- Day to day reporting to the Senior General Manager.
- Management and planning of document issuance Section for issuance of BMR and BPR as per planning schedule delayed .

SKILLS

- Perform under pressure, meet deadlines.
- Good at diagnosing Problems.
- Knowledge and handling of Quality software & system (SAP, ERP, MINI TAB, METIS, TRACKWISE (Software regularizes the Deviation, CAPA, Change control and Market complaints), FMS (Form management System) & LIMS (Laboratory Information Management System) ,EDMS and E-log book etc.
- Microsoft Office applications (Word, Excel, PowerPoint, Outlook, Access) – Advanced
- Representation of the data by power point, graph and flowchart.
- Use and knowledge of Quality Tools like FMEA, Ishikawa diagram (fishbone diagram), Cause-and-effect diagram, Check sheet, Control chart, Histogram, and Stratification etc.
- Assertive & Result oriented outlook
- Good Communication and Interpersonal Skills.
- Hardworking, self-motivation, having problem solving skill, and working in a team or as an individual.
- Quick decision making & implementation
- Dedication to work. Relentless pursuit to learn new things and grow.
- Committee member of Audit team and Cultural team.
- Departmental in charge of Issuance team and Monitoring the planning of Issuance of BMR and BPR as per planning schedule.

HOBBY

Internet surfing, Singing songs, Listening Music, Playing chess, Reading story books, Watching TV etc.

STRENGTH

Quick Learning ability, Goal oriented Organized, Energetic, Self-motivated and Positive Attitude, Strongly believe in Adapting and Improvising and Leadership quality.

LANGUAGE KNOWN

English, Hindi, Odia and Guajarati.

DECLARATION

I hereby declare that all the above details are true and correct to the best of my Knowledge.

Date: **Yours faithfully**
Place: **Bibekananda Choudhury**