GOVIND DOULATRAO BHAGNURE

Objective

Seeking an assignment for GMP consultant having knowledge of training and quality audits in food hygiene food safety, HACCP & pharma and API manufacturing plants, operating in regulated and non-regulated markets.

Key Skills

36 years wide Experience in Quality Assurance, Quality Control functions, cGMP regulations and various FDA Requirements. Can provide effective leadership to help team members achieve their own and departmental task. Possess work skills and job related qualities.
Experienced in Regulatory and International Customer Audits.
Experienced in Chemical & Instrumental techniques and microbiological testing of Raw Materials, Finished Products and Packaging Components.

Address & Email

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Personal Details

Date of Birth : 15th Feb 1952
Passport : G 3571588
Nationality : Indian
Languages : English, Hindi, Marathi
Status : Married

Work Experience : 36 Years

Professional Experience

1 Company : Sanbook Quality consultancy

Tenure : Feb 2012 – present

Designation : Technical Manager

Is responsible to drive the team and guide them to make the timely project completion. Managing Mumbai office operations with the team of 20 staff. Involved with the numerous ISO standards consultancy and training namely ISO 9001:2008, OHSAS 18001:2007 and ISO 14001:2004

2.Company : NNE Pharmaplan India Ltd.

Tenure : Feb 2010 – Dec 2011

Designation : General Manager

Was responsible to drive the team and guide them to make the projects successful. Managing Mumbai office operations with the team of 20 staff. Helping in preparation of Layout complying to cGMP requirements wrt Men & Material movement. Coordination with vendors & client in selection of appropriate equipments as per designed batch sizes.Responsible for validation activities.

3.Company : Unichem Laboratories Ltd

Tenure : Feb 2009 Feb 2010

Designation : Head – QA (Contract Mfg.)

Responsible for QA activities at the contract manufacturing locations. To set-up Q.A systems at the associate company based at Dehradun in line with latest regulatory standards which ensures compliance to all Pharma requirement globally. Harmonization of systems and procedure across all locations of Unichem. To provide guidance to prepare for validation of the new plants/Equipments/processes and ensure smooth operations in line with MHRA/US FDA/WHO- GMP/ANVISA etc. Recruitment, training & development of new people . Draft & set Quality policies and assurance program in line with cGMP. Participate in all major audits of all locations. Upgrade skill of personnel across cross functions. Provide Pharma knowledge to raise the standards of Stores/production QC/QA , Maintenance personnel so as to assure compliance in all the departments. Maintaining the integrated management system in the organization as per the requirements of ISO 9001:2008, ISO 14001:2004, OHSAS 18001:2007

4.Company : Bilcare Limited, Pune.

Tenure : Feb 2007 – Jan 2009

Designation : Global Head –Quality Assurance

Responsible for setting up Quality systems for controlling Primary Packaging Materials which ensures compliance to all Pharma customers requirement globally. Harmonisation of systems and procedure across all locations. To provide guidance to prepare for validation of

the new plants/Equipments/processes and ensure smooth operations in line with Pharma industry. Maintain the documentation as per cGMP and ISO 9001:2000 and ISO 15378 special emphasis to GMP in Primary packaging materials , Quality System. Recruitment, training & development of new people . Draft & set Quality policies and assurance program in line with cGMP. Participate in all major audits of all locations. Upgrade skill of personnel across cross functions. Assuring that the quality management system is in line with the requirements of ISO 9001:2008. Provide Pharma knowledge to raise the standards of Primary Packaging Material manufacturing, QC/QA , Maintenance so as to assure Pharma customers.

5.Company : Beximco Pharmaceuticals Ltd, Dhaka, Bangladesh.

Tenure : Since Jan 2005 –Feb 2007

Designation : Executive Director Quality

Main responsibility was to commission new facility conforming to current regulatory guidelines. To set up Quality systems in compliance to US-FDA & MHRA requirements. To organize validation of the new plant and utilities which ensures approval. Recruitment, training & development of new people . To provide guidance to prepare validation documentation on facility qualification/equipments/processes and other utilities. Draft & set Quality policies and assurance program in line with cGMP and ISO 22716. Had set all cGMP systems conforming to regulated market requirement.

6. Company : M/s. Ranbaxy Laboratories Ltd. Dewas (M.P.)

Tenure : Dec 2001 to 9th Jan 2005

Designation : Senior Manager - Quality Assurance

Main responsibility is to ensure Regulatory and Quality assurance compliance for Formulation plants at Dewas.

- Responsible for Regulatory compliance in all individual plants in Dewas complex as key area was QA/QC.
- Customer interface with respect to understanding national and international customer's expectations, Complaints etc.
- Coordination with R&D, Drug Regulatory for new Projects / Product launches.
- Coordination with international customers, releasing sites etc for product flow, logistic, analysis and method transfer activities.
- Provide inputs for new Projects / Product launches and assist in preparing Quality Control, Validation and Stability plans.
- Coordination with Planning, Manufacturing, warehousing and logistics for smooth flow and Inventory management.
- Responsible for cGMP & GLP compliances.
- Vendor Audits & participation, self-inspection, training etc.
- Maintaining the quality management system (ISO 9001:2008) documentation.

7. Other Companies worked	Tenure	Designation
M/s. Sigma laboratories limited Nashik.	March 2001 to Nov 2001	Sr.Manager QA
Medreich Sterilab Limited Bangalore	Nov 1999 to Feb 2001	Head of QA
Microlab Limited Hosur.	Oct 1998 to Oct 1999	Sr.Manager QA
Magnachem Pharmaceuticals Limited	Nov1990 to Oct 1998 & Jan 1982 to June 1986	Manager Tech. Services

- **(Approved expert staff in Chem. Instrumental & Microbiological analysis in Food & Pharma. Also worked in food product development for more than 5 years)**

German Remedies Limited ,Patalganga.	June 1986 to Nov 1990	Sr. Officer QC
Lupin Laboratories Limited ,A'bad	June 1981 to Dec 1981	Sr . Analyst
Ana Laboratories Mumbai	Feb 1979 to June 1981	Sr . Analyst
Aristo Pharmaceuticals limited, A'bad	May 1977 to Feb 1979	QC Analyst

Achievements

- Successfully participated in getting MCA approval in Medreich for their Beta-Lactum and General products facilities in 1999 and 2000.

- Participated during US-FDA Audit in 2001 in my QC/QA role in Ranbaxy.Company could get clear approvals for no. of products.

- Involved in WHO-GENEVA Audit and obtained approval for Anti-retrovals in November 2003.

- Involved in audit by FDA-GERMANY and successfully passed for exporting number of products.

- Participated in ANVISA-Brazil audit in 2003 at Dewas & at Jejuri Plant in 2004

- Visited to Central Drug Laboratory Kolkata and successfully resolved quality issue regarding marketed product.

Academic Qualification

Master Degree : M.Sc. (Organic Chemistry) in May 1977 in First class With University Rank Third.

Bachelor Degree : B.Sc. Hons (Chemistry) in May 1975 with First class

Others : FDA Approval in 'Chemical and Instrumental & Microbiological Analysis' from Maharashtra - FDA, Bombay, India

Computer Knowledge

MS Word, MS Excel, MS PowerPoint. Microsoft Outlook

Training &/ Conference (To cite few ones)

- Attended Training & Seminar on HPLC in Singapore sponsored by Agilent Technologies year 2002
- Attended Quality compliance meet on marketing issues related to products in Singapore in year 2004.
- Visited LA (US) in regards to Technical discussion on Patented product year 2003.
- Attended ISPE conference on PAT in Mumbai –year 2005
- Attended USP 5th annual symposium in Hyderabad –year 2006.
- Delivered seminar on cGMP & QA in Annual Meet of Bangladesh Pharma Industry.
- Attended various seminars and IPC meets in India.
- Visited Singapore Plant of Bilcare Pte Ltd and delivered Seminar on GMP and Quality System.
- Visited Taiwan for Vendor Audit.
- Two days training program on UNCERTAINTY OF MESUREMENT CALCULATION AS PER ISO 17025 :2005 REQUIREMENTS

Training Conducted

- Performed as a Tutor for Lead Auditor & Internal Auditor course in ISO 9001: 2008.
- Performed as a Tutor for Lead Auditor & Internal Auditor course in ISO 14001:2004.
- Performed as a Tutor for Lead Auditor & Internal Auditor course in OHSAS 18001:2007.
- Performed as a Tutor for more than 5 sessions of Internal Auditor course in ISO 17020.
- Performed as a Tutor for more than 5 sessions of Internal Auditor course in ISO 17025.
- Performed as a Tutor for more than 5 sessions Laboratory safety course
- Performed as a Tutor for more than 5 sessions Uncertainty of measurement course

Hobbies

Arranging cultural program & get together
Listening Music
Reading books
Visiting new places and making new friends

Govind D. Bhagnure