Date : 16.09.2018

Dear Sir/Madam

I am having more than 28 years experience in Bulk- Drug Manufacturing. I am also having the exposure/have faced certain Regulatory Audits for API’s which includes six USFDA, Three times WHO, ISO, EU GMP MHRA and also some Customer audits. Beside a huge number of customer audits some customers of repute are listed below.

1. Siekfried
2. Sanofi Aventis
3. Mallinchrodt
4. Ivax
5. Sterwin
6. Secipharma
7. Teva
8. Ricket Benckiser and other
9. Johnson & Johnson
10. Mylon and others.

The organization in which I am working as a Deputy General Manager - Manufacturing is a leading pharmaceutical group of Indian origin and having the global presence in API’s and Biologics. The number of products we manufacture are on the top list of its kind. I have scale up more than 50 molecules , exhibit batches taken of more than 55 products with all regulatory requirements, from lab scale to commercialize feasible scale Further cost reduction of the products is of my measure are of thrust. Timely with quality and quantity of commercial products delivery.

I feel the exposure I have with me will certainly be more contributing to the organizations you are considering for.

Regards

**( S.H.HUSSAINI)**

**09824770786**

**Professional references:**

1. Mr.S.K.Baluni, Vice President , QC & QA,Wockhardt ltd,9924985847
2. Dr.Zakir, +91 3168968222, Cad,middle east
3. Dr. Shahed Ansari , Dy.General Manager,Lupin Laboratories, 09909014991
4. Mr.Rajesh Hedaoo, Project consultant (Total Solution) ,API.,09967570963

Mobile : 09824770786

hamedhussaini2007@yahoomail.co.in

**Current residential address**:

F-101, ASHADEEP SOCIETY

WOCKHARDT COLONY

SARDAR PARK NEAR GATTU SCHOOL

G.I.D.C ANKLESHWAR – 393002- GUJRAT, INDIA

**S. HAMEDULLA HUSSAINI**

Career objective : To work and contribute in the growth of a highly motivated organization by being one with its mission and vision.

**Since JULY 1996** : **WOCKHARDT LIMITED, ANKLESHWAR , GUJRAT**

**SENIOR MANAGER MANUFACTURING**

Planning and production of API’s with Pre-defined quality and quantity attributes and day today trouble shooting.

Ability to follow and maintained the regulatory requirement during API manufacturing , all the systems required for Smooth operation as per cGMP it covers stringent follow-ups as per SOP, BPCR, Change controls, Cleaning validation, Process validation etc. i.e. with all regulatory requirements.I have filed more than **55 DMF products**. And commercial production such as Enalapril maleate, Azithromycin anhydrous, Divalproes sodium, d-amide for Captopril, Zolpidem tartrate .Clopidogrel Hcl,Clopidogrel Bisulphate,Tamsulosin Adenosine,Nicardipine,Granisetro,DonepezilHcl, Pioglitazone,Fexofinadine Hcl,Nadifloxacin ,Bethanechol chloride , Pidotimod, Bethanechol chloride,Nadifloxacin IP etc.

Material management, costing of the Products and related reporting.

Participation as a team leader during different regulatory agencies/customer audits.

Contribution for Scale up, commercialization process optimization and related documentation required for new drug filings (DMF) to the regulatory agencies and also for commercial products.

Responsibility allocation for subordinates, performance evaluation and feedback.

**June 1983- 1992 WOCKHARDT LIMITED**

**AURANGABAD ( M.S)**

**OFFICE MANUFACTURING**

**June 1992-1996 NICHOLAS PIRAMAL**

**HYDERABAD ( A.P)**

**DEPUTY MANAGER PRODUCTION API’s**

**July 1996 onwards, WOCKHARDT LIMITED**

**ANKLESHWAR, GUJARAT**

**Dy.General Manager-Manufacturing**

(From June-2009 working as Dy.General Manager-Manufacturing.)

**Education**

\*M.Sc, ORGANIC CHEMISTRY

\*POST GRADUATE DIPLOMA IN PRODUCTION MANAGEMENT

DOB 11.05.1959

* During this more than 32 years of time faced about six times USFDA AUDITS along with other regulatory agencies audits for API. European audit, MHRA, EUGMP, CFDA, WHO ,all audits was successfully completed .
* Very well aware of the systems required for facing such type of audits with all regulatory requirements.
* Familiar with SAP environment.

**Present Salary 28 Lac/Annum + Accomodation**

Experience and Responsibilities

**OFFICER MANUFACTURING**

I have started my career with **WOCKHARDT LTD, AURANGABAD** , which was among pioneers for its products like Dextropropuxyphene hydrochloride and

Captopril I have worked for most of the scale up activities and commercial production of API’S.

Second group was **NICHOLAS PIRAMAL HYDERABAD**, Where I have served for about four years. The product I have handled in this organization was

* Ciprofloxacine
* Ibuprofen
* Intermediate of Diltiasum

**SENIOR MANAGER MANUFACTURING,API’S.**

The major time span of my carrier I have spent with WOCKHARDT LTD. Ankleshwar. Here I have contributed for about 54 products and few are given below for DMF filing,process scale up and with trouble shooting..

**Dy.General Manager -Manufacturing**

**Now I am working as Dy.General Manager-manufacturing.(API)**

* Dextropropoxyphene Hydrochloride.
* D-Oxyphene base
* Dextropropoxyphene napsylate
* D – Amide ( Intermediate of Captopril)
* Captopril
* Enalapril Maleate
* Nizatidine
* Fluoxetine
* Femotidine
* Fluconazole
* Felodipine
* Ziprasidone
* Trandolapril
* Granisitron
* Fexophenadine
* Pioglitazole
* Zolpidem tartrate
* Nadifloxacine intermediate
* Clopidogrel Hydrochloride
* Clarithromycin
* Azithromycin
* Tamsulosin Hydrochloride
* Alfuzosin
* Zoledronic acid monohydrate
* Pantoprazole
* Alfuzosine
* Adenosine
* Valacyclovir Hydrochloride
* Nicardipine
* Lansoprazole
* Nicardipine
* Duloxetine Hydrochloride
* Epinephrine Hydrochloride
* Donepezil Hydrochloride
* Brimonidine tartrate
* Clopidogrel bisulfate form-1
* Clopidogrel Hydrochloride
* Brimonidine tartrate
* Dexlansoprazole
* Fesoterordine fumarate
* Fosaprepitant Dimeglumine
* Epinephrine
* Bethanechol chloride
* Pidotimod and others

**COMMERCIAL PRODUCTION:**

Taken and running the following products production such as Dextropropoxyphene Hydrochloride, Dextropropoxyphene base, Dextropropoxyphene napsylate, Enalapril maleate, Captopril. Anhydrous Azithromycin, Clarithromycin, Divalproex sodium, Clopidogrel Hcl, Zolpidem tartrate, intermediate of Captopril ,Tamsulosin, Adenosine,Nicardipine . Granisetron, Donepezil hcl Fexofenadine Hcl.Tamsulosin Hcl

,Bethanechol chloride,Pidotimod and more.

**EXHIBIT BATCHES TO FILE DMF.**

Taken more than 55 products exhibit batches with all regulatory requirements to file DMF.Scale up of batches as per requirements, with cost control, quality, and quantity with timely and safely.

**Strength** : Having strong managerial , analytical, problem solving and training skills, Quick at grasping new techniques. Process Scale up from lab scale to feasible commercializes to file DMF, well aware with QA and regulatory formalities and commercial product production.

Achieving commercial production with quality and quantity, cost reduction etc.Based on lab process on new drugs, creating facility to suit the process.Effective utilization of manpower and equipments, timely product supply in time with cost control safety and required quality.

**Few more strength and key responsibilities of mine are:**

Ensuring on time delivery of finished goods as per business objectives.

Improving quality – both in processes and finished goods

Ensuring cGMP implementation in the site.

Improving productivity

Ensuring efficient (in terms of cost and quality) and timely absorption of new technologies for DMF filing and scale up of the batches for commercial feasible and commercial production of products with regulatory requirement, cost, time and safely and quality of products as per customer requirement.

Ensuring the good upkeep of the site (infrastructure, equipments and housekeeping etc)

Ensuring that entire site objectives for SHE and training are met

Creating a work environment that promotes safety, people training ,producing quality product .

Timely delivery of finished goods as per committed deadlines

Ensuring that all planned activities are carried out with in the budget given.

Inventory and utilities cost control and waste reduction

Minimising of maintenance expenses .

Training and development of personnel in the functional area

Timely customer audits and Finance audits

Adhering to the safety and quality guidelines

System building and integration

Provide guidance to purchase function for effective procurement solutions.  
\* Benchmarking of costs of finished goods from different suppliers

\*Final review & sign off for the Master documents of batch records, Process Validation, Hold time study protocols and stability study protocols.   
\*Co-ordination with planning, production and DRA department.  
\*Responsible for manufacturing control of Sterile and Non-sterile drug products.  
\*Contributing to filing in the Regulatory market.  
\*Failure's (OOS & other) investigation & review, CAPA and other regulatory requirements to fulfilled the c VMP.  
\*Handling and response of market complaint.

Note: Interested to work in abroad also if opportunity comes.

**PERSONAL PROFILE**:

Father’s Name : S. Gesudraz Hussaini

Residential Address : At Hyderabad (India)