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| Salman_Akhtar**Curriculum Vitae** |

**Salman Akhter**

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**Profile:**

I’m an experienced pharmaceutical industry professional specializing in the field of Regulatory Affairs, Business Development & Compliance of regulatory authorities, CTD/ACTD preparation/compilation, dossier supervision and solution , minor changes, registration renewals, submissions and follow ups Agenda/Minutes until final approvals for Conventional (Generics & Innovators).

## Professional Qualification/Training/ Course :-

* MBA(Pharmaceutical Marketing Management) from Baqai Medical University(Institute of Health and Sciences)
* ISO Auditor 9001-2000
* Diploma in Computer Science
* Certificate Course in V.B 6 & Oracle 7/8 Developer 2000
* Attended Training/Meeting forums of conduction by DRAP official Mr. Obaid Ali FID and Mr. Sultan Ghani WHO Consultant on the following topics:
  + Generic Drugs & Promise of Regulatory Science,
  + Manufacturing of Sterile Products,
  + Post Marketing Surveillance & Drug Safety and
  + Culture of Quality

Skills:

* Preparing and reviewing Product Dossiers for regulatory compliance in DRAP.
* Preparing and reviewing Product Dossiers for regulatory compliance in CTD, ACTD formats or as per country specific requirement
* Responsible for determining appropriate regulatory strategy for the proposed new studies.
* Ensure the regulatory submissions are adequate and error free, with minimum open issues.
* Respond to queries from health authorities within predefined time with adequacy and accuracy.
* Review of SPC, artwork (Outer &Inner label) and pack insert.
* Drafting of all regulatory submission letters.
* Search new molecules and respective competitor’s data (nation and international)
* Preparing and reviewing the enlistment documents of OTC Healthcare products & Alternative Medicines (Nutraceuticals).
* Design and proof reading on Packaging of all products.
* Coordination with Procurement, Production, QC/QA and Marketing take them in loop onwards to Top Management for running, upcoming and new products.
* Handling of all regulatory matter related with DRAP, DTL, CDTL etc.
* Product Costing as per prescribed Format of DRAP
* Intellectual property/Trademark Registration of Brands
* Interactions and Communication/correspondence with DRAP, FDA, BFAD, Sole Agents/Distributors, Supply chain, Suppliers, Tool Manufacturer, Technical Operations etc.
* Record keeping of all the submissions and approvals.

**EXPERIENCE:**

**Having 12 years experience in the field of Regulatory Affairs (Local & International).**

**Having 3 years experience in the field of Business Development**

Hiranis Pharmaceuticals (Pvt). Ltd.-

**Presently working as Assistant Manager Regulatory Affairs at Hiranis Pharmaceuticals Pvt. Ltd. (A sister Concern Company of Platinum Pharmaceuticals Pvt. Ltd.)**

Platinum Pharmaceuticals (Pvt). Ltd.-

Worked in Leading Pharmaceutical Company Platinum Pharmaceuticals Pvt. Ltd. in the capacity of **Executive Regulatory Affairs** from Feb’2006 to May 2011.

***Responsibilities:-***

* To operate the Regulatory Affairs Department as Incharge
* Assure to include the Registration dossiers in Agenda of Registration Board meetings and follow-up until final registration.
* Internal Auditor of ISO 9000-2001
* Finally checking of Registration Dossiers at every aspect(Local and Export)
* To check the Minutes of Registration Board Meetings, PRC, PAC & Hardship cases.
* To handle the Quarries of International Market and fulfill the requirements. Follow up with relevant technical operations department until finalization.
* To make the coordination with all technical operations department by conducting the meeting to furnish the Task.
* Coordinate with Supply chain department/Supplier/Manufacturer for arrangement of Reference Standard, Working Standard, Impurities and documents.
* To ensure the Formulation and other technical data of New Products with International availability.
* To Search the New Products (Molecules) technical Data and other marketing promotional Litterateur.
* To investigate and reply of quarries asked by M.O.H.
* Product’s renewal of registration files
* Renewal of Mfg. Licence and Wholesale Drug Licence
* Work on Export Artwork and give support to International marketing department for finalization.
* To work on **Export** Registration dossiers of beneath mentioned countries and doing correspondence with their foreign Sole agents/Distributors and Regulatory body
* Philippines
* Thailand
* Sri Lanka
* Kenya
* Tanzania
* Vietnam
* Uganda
* Myanmar
* Indonesia
* Russian Federation
* ICS countries (Uzbekistan & Kazakistan)
* Sudan

Brookes Pharmaceutical Laboratories (Pakistan) Ltd.-

* Worked as a **QC Coordinator from April’2001 to Jun’2003 and QA Coordinator from July’2003 to Feb’2006** in **Brookes Pharmaceutical Laboratories (Pakistan) Ltd** (Q.C/Q.A /Regulatory/FDD Dept.)

***Responsibilities:-***

* Preparation of registration and other relevant documentation. Correspondence with **M.O.H**.
* Prepare product’s renewal files and application for renewal of Mfg. Licence.
* Manage the coordination of QC/QA & FDD Deptt. with all other Departments of Company.
* Renewal of Mfg. Licence
* Working on Export Documentation/Registration.
* Sending letters and other important documents to Marketing Coordination Secretariat for onward dispatching.
* Working on **Export** Registration of the products and correspondence related with their foreign Sole agents and foreign Ministries for the following countries.
* Srilanka
* Kenya
* Vietnam
* Uganda
* Myanmar
* Doing Documentation of Laboratory (QC,QA & FDD Departments)
* Manage the File Control System of Department.
* Make spread sheets, charts and formats on Excel.
* Presentation/chart on Power Point.
* Documentation on MS-Word.

**N.I.D.P**

* Worked as a **Trainee Programmer /Lab Instructor** in N.I.D.P from **May’99** to **Feb’2001**.

**JAFFER Brothers (Pvt.) Ltd**

* Worked as a **Data Entry Operato**r in Jaffer Brothers (Pvt) Ltd. from **June’2000** to **Feb’2001**.

## Qualification:-

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| ***Degree /Certificates*** | ***Year*** | ***Division Grade*** | ***Board/***  ***University Name*** |
| ***B.Sc.***  ***(Chemistry, Physics, Maths)*** | 2004 | 1st Division | Karachi |
| ***B.Com*** | 1998-2000 | 2nd Division | Karachi |
| ***F. Sc.*** | 97-98 | “C” | Karachi |
| ***S.S.C***  ***(Science)*** | 94-95 | “B” | Karachi |

### Personal Information:-

Father’s Name : Naseem Akhter.

N.I.C No : 42201-4801667-7

Date of Birth : 18th September,1979.

Religion : Muslim.

Marital Status : Married.