Resume for Regulatory Affairs

Syed Aqueeluddin Ahmed
Flat No. 102, **"Iftequar Residency"**
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Profile:

I am a highly accomplished Regulatory Affairs Professional with over 25 years of extensive experience leading submissions and deficiency responses in diverse Rest of the World (ROW) markets. My expertise spans a wide array of oral Sold dosage, Liquid Oral, and Injectable products, and I excel in strategically planning, executing, and maintaining precise registration dossiers for emerging markets, including both re-registration and company registration.

With a strong proficiency in getting Certificates of Pharmaceuticals Products (COPPs) and manufacturing licenses, I ensure uncompromising compliance with country-specific regulations and customer expectations. I effectively drive collaboration across cross-functional teams comprising international markets, R & D Quality Assurance Production, contract manufacturing sites, supply chain, and the medical division ensuring timely project delivery without compromise.

My skill set includes conducting thorough regulatory compliance audits reviewing and approving Chemistry. Manufacturing and Control (CMC) documents and performs critical assessments of the data from various departments, consistently meeting regulatory submission standards.
I have a proven track record of managing successful submissions and deficiency responses across multiple regions including CIS, Asia Africa, Central and South America, and the Middle East. My in-depth expertise encompasses various finished dosage forms, such as tablets capsules injection suspension ointments, and syrups backed by strong technical knowledge in CTD format submissions for countries including New Zealand, Malaysia, Jordan, Iran, Saudi Arabia, Turkey Serbia, and Israel.

Renowned for my exceptional leadership, project management, planning, and organizational skills. I am a compelling communicator with a keen eye for details. I am dedicated to delivering high-quality results efficiently and operate as a committed team player, driven by the goal of achieving regulatory compliance and surpassing business objectives.

Educational Qualification

1. Name of Course : M. Pharm
Name of University : Dr. Baba Saheb Ambedkar Marathwada University, Aurangabad.
Percentage : 67.45 %

2. Name of Course : B. Pharm
Name of University : Dr. Baba Saheb Ambedkar Marathwada University, Aurangabad.
Percentage : 63.09 %

3. Name of Course : H.S.C.
Name of Board : Maharashtra Board of Higher Secondary Certificate, Aurangabad.
Percentage : 75.83%

Present Employer and Responsibilities

1. Name of Company : Mylan Laboratories Limited R & D Centre **(A Viatris Company)**
Plot No. 34A, Block-3, 2nd Floor, ANRICH Industrial Estate
Bollaram Village, Jinnaram Mandal,
Sangareddy District - 502 325 Telangana, India
Department : Deputy General Manager Drug Regulatory Affairs
Period : 5th April 2018 to till date

Responsibilities

- Successfully led the management submission and responses of deficiencies of the Rest of the World Submission expertly overseeing all (OSD) Oral Solid products.
- Strategically Planned, Executed, and Maintained registration Dossiers for various emerging markets including re-registration and Company Registration ensuring thorough compliance and efficiency.
- Guaranteed the seamless generation of a Certificate of Pharmaceutical Products, & Manufacturing license strictly adhering to the country-specific regulations and exceeding customer requirements.
- Coordinated effectively with International Marketing, R & D, Quality Assurance, Production, Contract Manufacturing Sites, Supply Chain, and Medical Division to deliver Mylan's projects on time and to high standards.
- Conducted comprehensive regulatory compliance audits through on-site visits ensuring all filing requirements were not just met but exceeded.
- Reviewed and Approved Chemistry, manufacturing, and Control (CMC) documents for regulatory submissions with precision, showcasing diligence and expertise.
- Performed critical assessment of Data from Formulation & Development, Analytical Development Laboratory, Quality Assurance, Manufacturing site, and Quality Control Department ensuring data integrity and compliance.
- Ensured the prompt and effective submission of technical data in response to queries received from Regulatory Authorities for products under-registration demonstrating a proactive approach to compliance.

- **Software Handled:** Track wise, D2 DocuBridge, RIMS, Online WHO-GMP System, My Portfolio,

- **Skills Developed:** Team Leading Capabilities, Project Management, Planning, and Commitment. Adept at Organizing Work, Good Communication Skills, Time Management, Ability to Pay attention to Detail, Experienced Team Player, Target-Oriented and Focused.

Previous Employer and Responsibilities

2. Name of Company : Wockhardt Limited
Drug Regulatory Affairs,
Aurangabad-431210 M.S. India
Department : Manager Drug Regulatory Affairs
Period : 4th Dec 2006 to 29th March 2018

Responsibilities

- **Strategic oversight of submissions and responses for Global markets**
- Successfully oversight the submission proves and deficiency responses for the product development across the CIS Region, Asian Region, African Region, Central and South America Region and Middle East region.
- Strategically Planned, Executed and Maintained comprehensive registration Dossiers for emerging market including new registration, re-registration and Company Registration.
- Proactively applied & secured Certificate of Pharmaceutical Products (COPP) Good Manufacturing Practices (GMP) and World Health Organization Good Manufacturing Practices (WHO-GMP Certification and Inspection leveraging advanced software to obtain the COPP & WHO-GMP Certificate efficiently.
- Ensured the prompt generation of COPP & Manufacturing license in strict compliance with country specific regulatory & customer requirements.
- Collaborated effectively with International Marketing, R & D, Quality Assurance, Production, Contract Manufacturing Sites, Supply Chain and Medical Division to guarantee timely and successful delivery of project at Wockhardt.
- Provided expert level technical guidance in Common Technical Documents (CTD) format for submission to New Zealand, Malaysia, Jordan, Iran, Saudi Arabia, Turkey, Serbia and Israel ensuring adherence to their specific guidelines.
- Drafted and finalized comprehensive responses for audits conducted by Gulf Cooperation council (GCC) Saudi Food & Drug Administration (SFDA) Jordan Food & Drug Administration, World Health Organization Good Manufacturing Practices (WHO-GMP), Good Manufacturing Practices GMP (SEC Ukraine) and National Drug Administration (NDA) Uganda.
- Conducted thorough regulatory compliance audits through at various locations to meet filing protocols and ensure adherence to regulations.
- Reviewed and Approved Chemistry, manufacturing, and Control (CMC) documents for numerous regulatory submissions ensuring accuracy & compliance.
- Executed critical assessment of Data from Formulation & Development, Analytical Development Laboratory, Quality Assurance, Manufacturing site, and Quality Control Department with precision.
- Ensured the timely submission of technical data in response to queries received from Regulatory Authorities for products under-registration demonstrating our commitment to excellence.
- Leveraged deep expertise in managing a wide array of finished dosage forms like Tablets, ER Tablets, Capsules, ER Capsules, Injections, Powder for Injection, Suspensions, Ointments and Syrups etc.

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- **Skills Developed:** Team Leading Capabilities, Project Management, Planning, and Commitment. Adept at Organizing Work, Good Communication Skills, Time Management, Ability to Pay attention to Detail, Experienced Team Player, Target-Oriented and Focused.

Previous Employers and Responsibilities

3. Name of Company : Bravo Healthcare Limited.
208 Cosmos, Sector 11, CBD Belapur,
Navi Mumbai, M.S. India
Post Held : Executive-Registration and Regulatory Affairs
Period : 4th May 2005 to 30th Nov 2006

Jobs Responsibilities

- Planning, preparation, submission and maintenance of regulatory registration dossiers for various Pharma markets. i.e. Dominican Republic, Moldova. Macedonia, Peru, Trinidad and Tobago, Venezuela, Chile, Nigeria, Vietnam and Kosova.
- To obtain FDA licenses from Food Drug Administration for domestic and export products.
- To apply COPP, GMP and WHO-GMP Certification and Inspection.
- Trademark Registration for various products.
- To obtain the permission for banned products from DCGI.
- To obtain the permission for export of Narcotic products from NCB Gawlior.

4. Name of Company : Medley Pharmaceutical Pvt Limited.
Zari Causeway, Plot No.18 & 19,
Daman India
Post Held : Technical Officer
Period : 10th Dec 2000 to 2nd May 2005

Jobs Responsibilities

- To obtain FDA licenses from Food Drug Administration for domestic and export products.
- Production planning. WIP Statement. Stock statements.
- Production planning, manpower handling in various department Tablets, Capsules, Dry Powder and Liquid Oral.
- To co-ordinate validation activities with R & D People.
- Complete documentation of Tablets, Capsules, Dry Powder and Liquid Oral Department.

5. Name of Company : Atra Pharmaceutical Limited.
H-19, MIDC Area, Waluj,
Aurangabad-431136 M.S. India
Post Held : Junior Officer
Period : 18th May 1999 to 5th Dec 2000

Jobs Responsibilities

- Production planning, manpower handling in department Tablets, Capsules.
- To co-ordinate validation activities with R & D People.
- Complete documentation of Tablets, Capsules Department.

Personnel Achievements

- Approved in Tablets, Capsules and Liquid Orals from FDA Maharashtra & Daman.
- M.S. (Pharmaceutical Technology) from Vinayaka Mission University, Salem, Tamil Naidu, India.
- WHO-GMP Certification & GCC Certification of facilities.
- General Course on Intellectual Property.
- Successful filing & approvals in Mexico and CIS Countries of Wockhardt's Products.
- SFDA & JFDA Certification of facilities.

Research Project (M. Pharmacy - Quality Assurance)

- Thesis entitled "Pharmaceutical Development of Generic Drug Duloxetine HCl DR Capsules" under the guidance of Dr. Zahid Zaheer.

Computational Skills

- Retrieval of relevant information from various regulatory websites like FDA, EMEA etc.
- Information Retrieval from various other web sites.
- Well versed with Microsoft Word, Excel, Power Point, and Internet.

Personal Information

Father's Name	: Syed Khalil Ahmed.
D.O.B	: 5th March 1976.
Gender	: Male
Marital status	: Married
Nationality	: Indian.
Proficiency in Languages	: English, Hindi, Marathi and Urdu

References

Mr. Chetan Sharma	**Mr. Vasan S Thatai**
Senior Director – Global Regulatory Affairs	Director
Biocon Biologics Limited	Teambio Technologies Private Limited
Biocon House, Semicon Park, Electronics City, Phase – II, Hosur Road	Hemadurga Towers, B1-401, Miyapur,
Bengaluru 560100, Karnataka, India	Hyderabad 500049, Telangana
Mobile No.: +919000844687	Mobile No.: +917038124680
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Declaration: I do hereby declare that the above-provided information is true to the best of my knowledge and no false or misleading statement(s) or information is provided in this resume.

Place: Hyderabad, India.

Date: January 14, 2025

(Syed Aqueeluddin Ahmed)