



AALIYA ASIF NAGDADE

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Objective

To enhance my professional skills, capabilities and knowledge in an organization that would provide a challenging work atmosphere and an opportunity to learn, grow and contribute to its growth to the best of my knowledge.

Experience

- Experience in preparing and reviewing the dossiers in the format of CTD/ACTD/ECTD and country specific as per the respective country guidelines.
- Experience in preparing dossiers for various dosage forms like Parenterals, Solid (tablets and capsules), Liquid (syrops and suspensions).
- Hands on experience in drug and nutraceutical registrations.
- Responding to the queries raised by the clients and MOH of various countries in the stipulated time frame.
- Hands on experience in handling and online application of the FDA licenses, COPP application, Test license, Import license, NCC(No Conviction certificate), MMC (Manufacturing and Marketing certificate) PFC(Performance certificate) and FSC (Free Sale certificate) applications.
- Good knowledge of Sugam portal and application of various Clinical trial forms(CT-21,CT-10,CT-4, CT-11).
- Experience of Wholesale license application and WHO GMP renewal.
- Preparations of documents and performing gap analysis as per the regulatory requirements.
- Providing regulatory support for product changes/notifications, labelling and promotional material review and approval.
- Maintaining track record for submitted and approved application documentation.
- Preparation and review of draft labels and artworks with applicable regulatory standards.
- Checking and reviewing commercial artworks (pre and post batch manufacturing).
- Checking and approving pre-shipment samples.
- Coordinating for the batch analysis reports with third party laboratories.
- Maintaining the legal and regulatory database of the company (dossiers, trademarks, licenses, etc.).
- Coordinating with Management and Business Development teams for various agreements.
- Providing scheduled reports/reviews to concerned departments.
- Site/Plant visits and audits.
- Filing of various variation forms.
- Preparation of MSDS for export.
- Experience in preparing and reviewing the PDL for commercial purpose.
- Experience in preparing and arranging documents for Government and Hospital Tenders.
- Application of loan licenses and keeping track of the same.
- Handling and online application of Narcotic and Psychotropic drugs on CBN Site and maintaining the regulatory database of the same.
- Co-ordination and follow up with QC, QA and production department for the documents related to FDA applications and Dossier preparation.
- Sourcing new products and getting the quotations from the manufacturers.
- Preparing cost sheets and sending commercial proposals to the client.
- Managing inventory and database of received and dispatched samples required for registration and marketing purposes.

- **LIFESTARTER PROJECT PRIVATE LIMITED** 04/03/2022 - 31/10/2023
Senior Executive - Technocommercial
- **AMN LIFE SCIENCE PRIVATE LIMITED** 11/10/2021 - 03/03/2022
Regulatory Affair Officer
- **KILITCH DRUGS INDIA LIMITED** 21/10/2020 - 09/10/2021
Regulatory Affair Officer
- **KALSEKAR HOSPITAL** 01/06/2019 - 30/06/2019
Intern
- **WELLNESS FOREVER** 01/05/2017 - 31/07/2017
Intern

Education

- **AIKTC, School Of Pharmacy (New Panvel)** 2020
BACHELOR OF PHARMACY
7.64 CGPI (72.58%)
- **M.C.E. Society's Institute Of Pharmacy (Azam Campus, Pune).** 2017
DIPLOMA IN PHARMACY
73%
- **D.R.T Junior College Of Arts, Commerce and Science (Mumbra)** 2015
HSC
67.23%
- **MES Crescent English High School (Mumbra).** 2013
SSC
78.73%

Skills

- Team player with strong influencing skills and problem solving capabilities.
- Excellent organizational and multi-tasking skills.
- Ability to work in a fast-paced environment.
- Proficient in Microsoft Excel, Microsoft Powerpoint, Microsoft Word.

Projects

- **Study Of Disintegration property from natural drug.**
A 200 marks University Level project which enhanced my learning skills. It has taught me to work under immense pressure and manage time.

Seminar And Conference Attended

- Attended 71st IPC conference held at Chennai (Dec 2019).
- Attended Seminar by Agamy Pharma communication on marketing representative and pharma industry.
- Attended seminar on pharmacovigilance.

Webinar And Online Certificate Courses.

- Webinar on Regulatory Affairs: An interesting and challenging profession.
- Webinar on Mindset and Career Enhancement.
- Webinar on Avenues and Verticals of Clinical Research.
- Certificate course on Artificial intelligence and Drug Discovery.
- Certificate course on Medical Device Regulation.
- Certificate course on Introduction to Pharmacovigilance.

Intrests

- Cooking
- Travelling and exploring new places.
- Participating in Social events.

Extra Curricular

- Poster presentation(Role of Pharmacist in eradicating irrational use of medicine).
- Chess Winner in Bonhomie 2018 and runnerup in Bonhomie 2019.
- Runnerup in Football, Volleyball, Throw ball in Bonhomie 2019.
- Badminton winner in Pune district sports event organised by Indian Pharmacy Council(2016).

Personal Snippets

- Date of Birth :28/10/1997
- Nationality :Indian
- Address : Flat No:403, Plot no: 104, Om Residency, Sector-6, Nerul (West), Navi-Mumbai - 400 706.
- Passport no: V5036804