Executive Regulatory Affairs
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Delhi, India

Shweta Tiwari

Profile

Currently seeking for a challenging position as an integral part of esteemed organization that will make best use of skills, experience and offer prospects for further growth and progression.

Employment History

Executive Regulatory affair at Arbro pharmaceutical Pvt limited, Delhi, Kirtinagar

08/2022–2022

1. Preparation of Dossier in CTD and ACTD format.
2. AYUSH application.
3. FSSAI application
4. Upload of the PP on ONDLS

QA officer at ACG group (Custom capsules pvt limited), Boisar, Maharashtra

03/2021–05/2022

1. Issuance , archival and control of documents.
2. Preparation and compilation of APQR(Annual product quality report).
3. Handling of change control and deviation.
4. Review of BMR, BPR.

Regulatory affair officer at Kamla life sciences Limited, Boisar, Maharashatra

03/2020–03/2021

1. To prepare, Review of application of Product Permission for FDA purpose and arrange for submission and Upload on FDA portal.

2. To compile data and review for Certificate of Pharmaceutical Product.

3. To check, review and approval of Artwork for new developed product for Domestic and Export Market and maintain the record for artworks of packaging materials.

4. To check, update & maintain artwork record, product permission records, COPP records, registration status records, DMF records, Formula records sheet etc.

5. Any other work assigned by superior example Loan license application work, Job description.

Skills

Leadership and Teamwork 5/5
Ability to Learn Quickly 5/5

Hobbies

Travelling on different places, Playing badminton, cooking

6. To study and update regulatory guidelines of assigned countries (ROW Market-Nigeria, Nepal, Mayanmar, Kazahkistan, Phillipinnes) and to prepare checklist/template for registration dossier.

7. To request, collect and review, verify all technical documents and information required from QA, QC, Purchase, Marketing, and Production department before compilation of planning of dossier.

8. To prepare and compile registration dossier in CTD ,ACTD and Country specific Format and submit to concern party, Country

9. Co-ordination for registration requirement that is technical and legal document, sample etc.with party and Marketing team.

Regulatory affair officer at Enicar Pharmaceutical Pvt. Ltd. , Boisar, Maharashatra

08/2018–01/2020

1. Dossier preparation/compilation/submission in CTD, Country specific format for ROW market

2. Country handle -Srilanka, Ghana,Nigeria,Congo,Liberia,Domnican republic

3. Responsible for query reply raised by regulatory authorities.

4. To coordinate, request, collect and verify all technical documents and information from various department (QA, QC, Production and Purchase, Packaging development) before compilation of dossier

5. Artwork preparation request, review and approval of carton, label, DS for new developed product for registration purpose and coordination with Packaging development department.

Regulatory affair officer at Naprod Life Science Pvt. Ltd, Boisar, Maharashatra

08/2016–08/2018

1. Keep track of all documents for product registration application.

2. Prepared dossiers in ACTD and CTD formats.

3. Country handle-Myanmar, Srilanka,Moldova,Iran,Turkmenistan,Peru,

Tanzania, Colombia.

4. Replying to the technical queries related to product registration and re-registration.

5. Arrange and maintain all quality related documents for dossier preparation.

6. Reviewing & Preparing stability summary reports and protocols as per ICH guidelines.

7. Coordinate and consult with other departments and associates for accurate and timely assembly of regulatory documents for submission.

8. To co-ordinate with legal department for arrangement of PP, COPP and FSC and maintain the record for same.

9. Preparing gap analysis and review comment sheets to address the possible adequacy issues which can trigger queries from MOH.

10. To arrange all requirements for registration & re-registration as per regulatory.

11. Preparation and compilation of drug product dossiers in country specific format for registration purpose in ROW market.

12. Artwork preparation request, review and approval of carton, label, DS for new developed product for registration purpose and coordination with Packaging development department.

Education

SSC, PES, Boisar Education School, Maharashtra

2009–2010

Secondary schoolcertificate(S.S.C.) Got the **79.64 %**

HSC, Tarapur Vidya Mandir, (TVM), , Maharashtra

2011–2012

Higher secondary certificate examination (H.S.C.) Got the **64.00 %**

Bachelor of pharmacy, PES,Modern college of pharmacy, Pune , Pune university, Maharashtra

06/2012–04/2016

Bachelor of pharmacy and got the **67.62 %**

Extra-curricular activities

Extracurricular activities

1. Participated in one day seminar on “current scenario & practices in clinical research”

2. Industrial visit to Emcure ,Pune

3. Made visits to various hospitals.

4. Participated in AVISHKAR -2015, Allana College of pharmacy, Pune.

5. Participated in MIND QUEST 2K15, Pratibha institute of business management, Chinchwad, 2015, Pune.

6. Participated in NSS camp

7. Attended the seminar on value education and personality development, NSS, Siddhant College of pharmacy.

8. Participated in Blood Donation Camp,Pune

9. Participated in National Pharmacy week day, Add mad act, DY Patil College of pharmacy, 2014.

10. Participated in English Vinglish session in Naprod Life Sciences Pvt. Ltd, Boisar.

11. Participated in Blood Donation Camp in Naprod Life Sciences Pvt. Ltd, Boisar.