



DHIRAJ BHAGWAT

CONTACT INFO

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EDUCATION

● Master of Pharmacy

UNIVERSITY DEPARTMENT OF
PHARMACEUTICAL SCIENCES, NAGPUR
2016 - 2018 8.03 CGPA

Project : Design and synthesis of novel flavone
derivatives of medicinal interest.

● Bachelor of Pharmacy

UNIVERSITY DEPARTMENT OF
PHARMACEUTICAL SCIENCES, NAGPUR
2012 - 2016 63.16 %

● Higher Secondary Certificate

G.S. Gawande Junior College, Umarkhed
63.67 %

● Secondary School Certificate

Sakle Vidyalaya, Umarkhed Dist. Yavatmal
76.40 %

SKILLS

• SOFTWARE

Educe eCTD
Lorenz eValidator
Veeva Vault
MS-Office
Windows-OS
Schrodinger Maestro

• INSTRUMENTAL

HPLC
UV Spectrophotometer
IR
FTIR
Dissolution Apparatus
Disintegration Apparatus

LANGUAGE

• ENGLISH • HINDI • MARATHI

CERTIFICATION / CONFERENCE/ TRAINING

2018 International English Language Testing System (IELTS)

2018 Workshop on computational methods in drug discovery
(Translational Health Science and Technology Institute, Faridabad, H.R., India)

2018 International conference on Emerging Trends in Drug
Discovery & Development (Department of Pharmaceutical Engineering
& Technology, IIT (BHU) Varanasi, U.P., India)

2010 Maharashtra State Certificate in Information Technology
Maharashtra State Board of Technical Education, Mumbai

OBJECTIVE

An experienced regulatory professional seeking to work in a regulated market & challenging atmosphere that provide me good opportunity for learning and growth and to work for achieving organizational goals.

WORK EXPERIENCE

Junior Regulatory Affairs Officer

IPCA LABORATORIES LIMITED, MUMBAI
(MAY, 2018- PRESENT)

Job Responsibilities

- ▣ Prepare & submit the product registration dossiers, re-registration dossier (Module 1 to 5) (CTD & e-CTD) as per the registration guidelines of Middle East and CIS Countries.
- ▣ Prepare and submit the post-registration variation application.
- ▣ Prepare query response raised by regulatory authority.
- ▣ Prepare change control proposals for approval from respective departments. Preparation of document for the registration and renewal of manufacturing plant locations.
- ▣ Ensure proper data management and keep the record of registration activities starting from registration upto getting approval from the respective authorities.
- ▣ Prepare & arrange the declaration and justification letters from various departments for registration purpose.
- ▣ Co-ordinate with various departments such as Quality Assurance, R & D, Analytical Development Labs, Quality Control, Marketing Department, Manufacturing Plant, Medical Department for collection of various technical documents as required for registration.
- ▣ Application of Legal documents such as Manufacturing License, Certificate of Pharmaceutical Product, Free Scale Certificate, etc.
- ▣ Arrangement of registration samples, standards for registration purpose.
- ▣ Responsible for getting the FDA documents legalized from Notary, Mantralya, Chamber of commerce and Embassies of respective countries
- ▣ Verification of specimen artworks.

Regulatory Affairs Associate

PAREXEL INTERNATIONAL, BENGALURU
(DEC, 2021- PRESENT)

Job Responsibilities

- ▣ Working for Europe Market Post-approval variations.
- ▣ Marketing Authorization Transfer (MAT) project for a multinational client mainly involving activities like preparation of packages for submission to health authority.
- ▣ Liaise with multiple stakeholder to assess requirement for each market, collate information in tracker analyze and track data.
- ▣ Responsible for handling all Veeva Vault activities like creation of Events, Binder, HQs & Submission Packages for submission to respective Health Authority (HA).
- ▣ Collate Reg Intel for each country from various sources.
- ▣ Supported PSMF project for client with preparation of packages and veeva vault updates.

PUBLICATIONS

- ▣ The potency of Eriosematin E from Eriosema chinese Vogel. Against Enteropathogenic Escherichia coli induced diahorrea using preclinical and molecular docking studies. Acta Tropica 2019; 193 : 84-91- Komal M. Parmar, Dhiraj S. Bhagwat, Saurabh K. Sinha, Nitin T. Katare, Satyendra K. Prasad.
- ▣ Antidiarrhoeal Potential of Eriosematin chinese Vogel. Against Enteropathogenic Escherichia coli induced infectious diahorrea. Pharmacognosy Magazine. 2019 ; 15 : 455 -461 - Parmar KM, Bhagwat DS, Prasad.Saurabh K. Sinha, Nitin T. Katare.
- ▣ Synthesis, Characterization and Biological Evaluation of Ciprofloxacin N-N Donor Metal complex, Asian Journal of Research in Chemistry. 2018 ;08 : 3599-3608- Prafulla M. Sable, Dhiraj S. Bhagwat, Karan Parwe.

I do here by declare that all the above information is true and it's my best of knowledge.

Dhiraj S. Bhagwat