

Mukta Swapnil Garge

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Experience:

Unichem Laboratories Limited – Executive, Regulatory Affairs

April 2017 – Oct 2019

- Responsible for eCTD/non-eCTD compilation and timely filing for Drug substances.
 - coordination with cross functional, multi-locational teams to collect CMC data as per project-timelines
 - review, compilation of information in country-specific eCTD/non-eCTD formats and submission of eCTD and non-eCTD API DMFs to various regulatory authorities
 - No of submissions: USDMF – 03; DMF to ANVISA – 01; China: 01
- Responsible for maintenance of ‘Regulatory compliant’ status of existing/commercialized Drug substance projects (Number of Projects assigned: 13).
 - coordination and compilation of CMC data in order to respond to queries/Deficiency Letter received from various regulatory authorities. (Number of DL/queries responded: US: 04, EDQM: 02, Canada: 01, PMDA: 01)
 - Regulatory impact assessment of proposed Post approval changes and collection, review and submission of the required GMP documents/ CMC data through amendments to regulatory authorities.
 - Tracking of annual update timelines, compilation, review and submission of relevant CMC data to Drug authorities in eCTD/ non-eCTD formats within those timelines.
- Responsible for Customer support for assigned projects

Perrigo API India Pvt. Ltd – Assistant– II, Regulatory Affairs

Nov 2015 – March 2017

- Assistance for compilation and coordination of CMC data requirements with various departments of various regulatory documents such as USDMF and CEPs for new R&D projects including API molecules for Para IV submission (Number of Projects assisted: 3)
- Regulatory maintenance for assigned projects (No of Projects assigned: 6)

Perrigo API India Pvt. Ltd – Trainee Apprentice in API R&D

July 2015 – Nov 2015

- Assistance in setting up and performing lab trials for ongoing API synthesis project.
- Active involvement in execution of QbD and optimization studies for R&D project.

Education:

Degree/ Certificate	University/ Institute	Grade/ %	Year
Masters degree in Pharmacy with specialization in Pharmaceutical Chemistry*	University of Mumbai	7.45 CGPA	July 2013 – June 2015
Bachelor’s Degree in Pharmacy	University of Mumbai	aggregate 68.25%	July 2009 – April 2013
HSC Exam	Maharashtra State Board	78.5%	April 2009
SSC	Maharashtra State Board	86%	April 2007

* Thesis for Masters degree in Pharmacy: Studies on Pharmacologically Potential and Novel Synthetic Compounds

Awards and Achievements:

- Unichem Laboratories Limited:* Awarded for timely compilation and submission of USDMF thereby saving the difference of increased GDUFA DMF fees applicable from 1st October 2018.
- Perrigo API India Pvt. Ltd:* Awarded for contribution to USDMF filing of API molecule for Para IV submission.
- Masters Degree:* Awarded certificate for Academic Excellence for securing 63.18% in First Year M. Pharm (Branch - Pharmaceutical Chemistry) by Vivekanand Education Society’s College of Pharmacy.

Additional Information:

Computer: MS Office, Adobe Acrobat X, Educe, Lipient InSight,
Languages: English (Fluent), Hind (Fluent)
Marital Status: Married