Mukta Garge
Unit 313, 2 Rean Drive, North York, Bayview Village, M2K 3B8
Email: muktad227@gmail.com

To
HR Manager
Johnson & Johnson Inc
Toronto, Ontario
Canada.

Dear Sir/ Madam,
I am writing to you to express my interest in the "Regulatory Affairs Intern position" at Johnson & Johnson Inc., Toronto, Ontario, Canada.

As an experienced Regulatory Affairs professional from the Indian Pharmaceutical Industry, I bring with me 3+ years of experience of handling regulatory submissions for new research projects (Generic APIs) of the organization, regulatory maintenance for the multiple commercialized APIs.

I am a driven individual with proven ability to interpret, apply and implement guidances, coordinate cross-functionally across various locations, proactively manage and communicate issues and handle multiple tasks. I am a timeline-oriented person with ability to manage changing priorities to meet the organizational goals. I have the relevant technical, computer and communication skills to actively complete the tasks assigned to me. My experience in the function of Regulatory Affairs enables me to be attentive to minute details and also understand the commercial as well as regulatory implications of the function.

I believe that, I will be able to actively contribute to the Regulatory function in the role of "Regulatory Affairs Intern" at your organization. Further, I believe that this opportunity will be professionally enriching to me as well.

Therefore, I request you to kindly consider my candidature for the aforementioned position. My CV is attached on the following page.

Your time and consideration in reviewing my credentials are appreciated.

I look forward to speaking with you soon. I can be reached at the email listed above.

Thank you and Regards,
Mukta Garge.

Mukta Swapnil Garge

Unit 313, 2 Rean Drive, North York, Bayview Village, M2K 3B8
muktad227@gmail.com

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, Liquent InSight,
Languages: English (Fluent), Hind (Fluent)
Marital Status: Married