

Pranjali Shitole

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Experience:

1. IM&S Associate at Sandoz, Novartis.

24th Jan 2022 - 5th December 2022.

- eCTD submissions for UK and Europe region.

Cover letter, application form, tracking table, module 1 to 5 documents processed using SARA and docubridge application.

2. Senior Regulatory Affairs Associate at TCS for client AstraZeneca.

15th May 2019 - 17 December 2021.

- Document Management Specialist for US, EU, ROW, Global market.

Standalone document publishing and v doc creation for study, project, safety, literature reference documents.

Regulatory clinical trial application forms for health authority submission, outcome and interaction requests.

- Experience of working on CARA, Publish Now, SMRT, Connected Regulatory Insights software application for publishing, planning and tracking submissions.
- Performing quality and pre-approval check on documents.
- Global regulatory operations lead co-ordinator for document publishing team.
- Point of contact for editorial team of biannual newsletter MaestroScope edition 7.

3. Key Account Executive at Cordlife Sciences India Pvt Ltd.

4th September 2018 - 11th February 2019.

- Patient counseling for stem cell based treatment, promoting cord blood and cord lining banking services.

4. Technical Services Trainee at Evonik India Pvt. Ltd.

6th November 2017 - 4th May 2018.

- Formulation and application services based on granulation, compression, coating, hot melt extrusion, spray drying and pelletisation technologies for EUDRAGIT® range of Polymers.
- Preparation of detailed reports, crafting key messages and presentations for the pharmaceutical clients.

5. Academic Researcher at University of Mumbai.

1st May 2016 - 14th July 2017.

- Research Project entitled Novel Approach to Design and Develop Drug Delivery System.
Formulation of dry powder inhaler for sustained release and site specific delivery of anti-tubercular drug.

6. In-Plant Trainee at Meyer Vitabiotics.

26th May 2014 - 25th June 2014.

- Overview of tablet, capsule production and quality control.

Education:

Master of Pharmacy in Pharmaceutics, 2015-2018.

Maharashtra Education Society's H.K. College of Pharmacy, University of Mumbai.
Grade: CGPA 7.82, O-Outstanding.

Bachelor of Pharmacy, 2011-2015.

Saraswathi Vidya Bhavan's College of Pharmacy, University of Mumbai.
Grade: First Class

License and Certifications:

Registered Pharmacist License issued by Maharashtra State Pharmacy Council, India, July 2015.

Scientific poster presentations, 2015-2016.

1. In-situ micronization: Emerging novel concept in drug delivery.
2. Design, Formulation and Evaluation of Levocetirizine hydrochloride orodispersible films.
3. Nanotech engineered carrier system: Pillar of personalized medicine.
4. Fusion Pro QBD software: Requirement for formulation development as per US FDA.

Scientific paper presentations, 2016.

1. Techniques to enhance dissolution rate, particle size distribution and stress stability of isolated sterile active pharmaceutical ingredient.
2. Capsule in capsule technology.

Seminars attended, 2011-2017.

1. Regulatory updates - Biowaivers and importance of BCS and TCS.
2. Continuous manufacturing real time release and regulatory risk classification system.
3. Changing regulatory environment for development of semisolid dosage forms.
4. Novel evaluation strategies for transdermal delivery.
5. Bioavailability and bioequivalence implications of topical dermatological product.

6. 67th Indian Pharmaceutical Congress:

- Critical role of technology transfer and integration for business continuity.
- QbD: Tools to create and monitor Quality.
- Regulatory affairs in FMCG pharma.
- Challenges of data integrity in pharmaceutical industry.
- An overview of current trends in product recalls.
- Multi regional clinical trials - Advantage India.
- The status of regulations on herbals in India.
- Present and future scenario of regulatory guidelines.
- Challenges and ethics in scientific publications.
- Insight into drug regulatory frame work and opportunities of synergy with Indian FDA.

7. National seminar on recent breakthrough innovations in pharmaceutical research with future perspectives.

8. Advances in pharmaceutical development.

9. New vistas in medicinal chemistry research.

10. National conference on pharmaceutical industry scope and management.