RUCHA GHEEWALA

198E Central Street Phone: (718)-902-0059

Natick, MA-01760 Email: rucha1g@gmail.com

**OBJECTIVE**

To obtain a challenging position in regulatory affairs at a stable organization in Greater Boston-MA area where I can use my skills, knowledge and experience to contribute in DMRs, technical files, design dossiers, 510k applications, CAPA, CMC compilation, clinical study monitoring, ICH guidelines, ISO guidelines and project planning to the growth of the organization.

**EXPERIENCE**

**APP Pharmaceuticals- A Fresenius Kabi Company Buffalo, NY**

***Associate Scientist* June 2011- Feb 2013**

At APP pharmaceuticals I was highly involved with multi-site validation, analytical method development and regulatory strategy planning

* Solid working experience in new drug discovery research.
* Document and review analytical data in compliance with regulatory and departmental SOP requirements in a   
  cGMP and ISO regulated environment.
* Strong knowledge of Medical device reporting (MDRs), Medical vigilance reporting (MVRs), risk management, validations, design controls, validation, process development, monitoring and root cause analysis.
* Worked very effectively independently as well as in co-ordination with the other members of the team.
* Attained internal certification of qualified trainer and trained fellow employees on SOP writing skills.

**Perrigo Pharmaceuticals Piscataway, NJ**

***Formulation Research Scientist* Dec 2007 – Oct 2010**

At Perrigo pharmaceuticals I was actively involved in Formulation R&D where I managed and coordinated   
high-profile multi-site projects.

***Research Work:***

* Worked on patent analysis and strategy landscaping
* Managed projects from Pre-formulation studies, prototype development to scale-up and technology transfer
* Worked on training the team on SOP writing and ISO guidelines
* Sound understanding of clinical and regulatory aspects
* Worked closely with CROs for development of formulations
* Participated in audits performed by internal and external representatives for FDA compliance
* Strong knowledge of medical device reporting, medical vigilance reporting and risk management.

***Presentation/ Management skills:***

* Strong attention to detail with a results oriented approach and strong urgency in projects.
* Standardized the process of formulation department presentation renewed SOPs and power-point template.
* Worked with a multi-site team and co-ordinate/preside over various tele-conference meetings.
* Accountable for regulatory strategy, deliverables and results to support new product development.

**Pharmacy Department, Saint John’s University Queens, NY**

***Graduate Assistant* September 2005- December 2007**

* Coordinated and managed Dispensing and Compounding labs,
* Mentored students and conducted various classes of theory and experimentation for freshmen students.

**Zydus Cadila Ahmedabad, India**

***Pharmaceutical Trainee, Formulations Dept.* May 2004 – August 2004**

* Worked as a trainee, learning various formulation processes such as development of solid oral dosage forms, preformulation, stability study, documentation per cGMP practices, Design of experiments.

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**EDUCATION**

Northeastern University **June 2015**

MS in Drug regulatory affairs **GPA: 3.85/4.00**

Saint John’s University at Queens, New York **May 2009**

Master of Science in Industrial Pharmacy **GPA: 3.47/4.00**

Maharaja Sayajirao University at Baroda Gujarat India **June 2004**

Bachelor of Science in Pharmacy  **GPA: 3.65/4.00**

**PROFESSIONAL SUMMARY**

1. Familiarity with drug and medical device development process
2. Solid oral dosage form design for new drug products with main emphasis on PIV ANDA products
3. Escort government inspectors during inspections and provide post-inspection follow up
4. Formulation optimization using experimental design mainly DOE™ PRO software
5. Participate in internal and external audits and conduct employee SOP and regulatory trainings
6. Presented a poster at AAPS-2007 Annual convention on PEGylated nanoparticles.

**SOFTWARE SKILLS**

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| * CARD Design of Experiments (DOE software) * Documentum * Trackwise | * Empower chromatography workstation * MS Visio and MS Office * MS PowerPoint |

**EQUIPMENT SKILLS**

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| --- | --- |
| * HPLCDSC, FTIR, NMR, Particle size analyzer * Fluid bed coater * Expertise on multiparticulate unit dosage forms * Beads coating and beads compressed tablets | * Manesty tablet beta and Kilian compression press * Know-how on Comprima and OSDrC Technology * Accela Cota Pan coater * Fitz mill * Twin shell V-blender |

**COURSEWORK**

Drug and medical device regulation Food, drug and medical device law

International regulatory affairs International clinical trials

Product formulation and development Medical devices: Regulatory overview

Biologics development: Regulatory overview New drug development: Regulatory overview

**ACTIVITIES**

1. Member of Regulatory Affairs Pharmaceutical Society (RAPS)
2. Member of American association of Pharmaceutical Scientists (AAPS)
3. Member of Indian Pharmaceutical Congress (IPC)
4. Eudragit® workshop organized by Degussa.