**Rama L Doddi**

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**SUMMARY**

An Ex- HR enthusiast, want to unfold my passion for science. I would like to kick-start my career as a Regulatory Professional. During the course work, I have gained knowledge and expertise in the aspects like Understanding FDA regulations, Regulatory Compliance, Strategic Product development- Investigational Application - IND (US) for both drugs & biologics, CTA for EU; IDE for devices, Drug Marketing Applications like 505(B)(1), 505(B)(2), 505(J), Special approvals 506(A), 506(B), 506(C). Device Marketing Applications - PMA. De-Novo, 510k. Understanding of concepts includes safety sciences, Human experimentation, Medical Devices, Pharmaceuticals, therapeutic product development, Legal issues International Food, Drug & Medical device regulations, GxP (GMP, GCP, GLP, GDP, GTP), thorough understanding of IRB, ICH, FDA, EMA guidances.

**EDUCATION:**

**Northeastern University**, Boston, MA,

Master of Science in Regulatory Affairs, GPA – 3.951/4.0 Apr- Present

*Coursework: Regulatory compliance, document control, control designs, Regulatory Strategies on Product development, Human Experimentation, Pharmaceutical sciences, Therapeutic Product Development, Medical Device Development, Legal issues Pharma & Medical Device Law, Safety Sciences, Global impact of electronic common technical document, biomedical product development from Boardroom to Market.*

**Andhra University**, India, 2010

Master of Arts in Human Resource Management – First class with Distinction GPA: 8.3/10

*Coursework: Organizational behaviour, Performance Management System, Recruitments, Labour Laws, Statistics, Marketing, and Research.*

**Andhra University**, India, 2008

Bachelor of Science in Biotechnology, Bio-Chemistry, and Chemistry – 77%  
*Coursework: Genetic Engineering, Analytical Chemistry, Organic chemistry, Microbiology, Molecular biology, RNA DNA Sequencing, Gene therapy.*

**EXPERIENCE­­­­­­­­ ­­­­ \_\_\_\_\_\_\_**

Northeastern University (On-campus) August 2022 – Present

Scheduling Assistant

Northeastern University (On- campus). September 2022- Present

Global Student Mentor

**ACADEMIC PROJECTS**

**Northeastern University**

* Hypothetically created a drug development process **“magic dust**” which we named after 4 of our group mates **“KRAMP”** which is about a drug available with a tribe located in the outskirts of the USA. How we have convinced the tribe and ethically handled the entire drug development till the post-market release has been presented.
* Presented the Regulatory compliance issue on Opioids and its overdose death in USA.
* Drafted an **Informed Consent form(ICF)** which is mandatory for all the human subjects involved in the trial to voluntarily understand and sign the form. (3 major aspects are information, Voluntary, and Comprehensive)
* Drafted the **DSUR** (which is predominantly mandated in EU regions) if the drug is global we need to produce the DSUR in the US.
* **The therapeutic Product Development cycle** is hypothetically being presented on weekly basis starting from drug discovery till its release into the market (Ongoing assignment)
* Drafted an **FDA Meeting Request**.
* Regulatory strategies provided on **case studies** like BKK, Alnylam, and Adaptive platform clinical trials, Nanoparticles in Cosmetics major difference in US and EU market, EU Regulation on Invitro diagnostic medical devices to name few of them.
* Paper presented on a Medical device “***COSMOflex***” artificial IRIS a **class III** medical device.

**TECHNICAL/PROFESSIONAL SKILLS**

* Strong detail orientation, organizational skills, and the ability to prioritize tasks.
* Strong verbal, written, and presentation skills.
* Strong proficiency in Microsoft Office tools (Word, Excel, PowerPoint) and in-depth knowledge of internet research and recruiting tools.
* Hands on experience working on ATS like Avature, Bullhorn4Salesforce, Job Diva and Trello.
* Languages Known: English (Expert), French (Beginner).

**ACCOMPLISHMENTS \_\_\_\_\_\_\_\_\_**

* + Won an Agile Star Award in the category of Excellence and Eminence award 2019 at IBM.
  + Got a distinction in M.H.R.M Course in the Master’s Program
  + Won the best student award for the M.H.R.M 2008-2010 batch of Pydah College.
  + Stood first in the “MISSION-HR TALENT ‘09” content Organized by Husys (HR Consulting Firm)
  + RAPS Student Member
  + Go-getter attitude never give up easily.

**Prior Experience:** I have prior 8 years of experience in the HR Domain in Talent Acquisition, Employee Engagement, Induction, Training & Development.

**References will be provided upon your request.**