# GANGAM SOWMYA

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## PROFILE SUMMARY

I am a Regulatory Affairs Professional with **12 years** of experience. I have worked exclusively on **vaccines and/or biological products** for **India (DCGI), WHO, Europe, Canada, US FDA,** and **ROW** markets etc. I look forward to making a significant contribution as a manager with a company that offers a genuine opportunity.

As a Regulatory professional, my current work profile briefly includes:

1) Initiation, planning and execution of regulatory strategies (RSD) and meeting timelines for all the assigned projects and major post-approval variations/ regulatory submissions.
2) CMC Project initiation, planning, execution, and closure by consistently hitting targets, improve best practices and efficient organization of time.
3) Writes, coordinates, compiles, and submits Regulatory documents to FDA, EU, and other International Authorities
4) Preparation, review, and dispatch of product registration (high quality CMC), renewals and variations (post-approval changes), annual reports and response documents to questions from HA.
5) Assessing the change controls for the impact of the product/process changes and determine regulatory pathway for US, EU, and other international markets
6) Team Management, developing capabilities and competencies within the Regulatory affairs function

## WORK EXPERIENCE

**Assistant Manager,** **2018 - Till Date**
**Sanofi, Hyderabad**

- ❖ Responsible for authoring and review of high-quality CMC documents for Sanofi Pasteur products for Asia pacific, US, and European submission, applying agreed CMC global regulatory strategies assuring technical accuracy and regulatory compliance.
- ❖ Worked on Submission of Biological Master File (BMF) for IMOJEV Vaccine to US FDA
- ❖ Experience in Authoring and review of Annual Reports for further submission to CBER and BGTD.
- ❖ Worked on Submission of different types of EU variations (post-approval changes)
- ❖ Supported for the submission of Marketing Authorization Transfer of IMOJEV Vaccine to EU
- ❖ Authoring and review of CMC responses to questions raised by Health Authorities on submitted dossiers/ variations (post-approval changes).

- Experience on submission of Product Summary File (PSF) for pre-qualification and for re-assessment of vaccines for ADACEL Vaccine (Diphtheria + Tetanus + Pertussis)

- Experience on submission post approval marketing changes (variation) filings Annual report (PQVAR) to WHO.

- Experience on Assessing the change controls for the impact of the product/process changes and determine regulatory pathway for US, EU, and other international markets

- Working closely with Sanofi Pasteur- Global RA team for review and evaluation of critical documents to be submitted to HA.

- Actively participates as a member of the global Regulatory CMC team by contributing to the regulatory strategies, identifying critical issues and lessons learned.

**Officer and Sr. Officer,** **2011- 2018**
**Shantha Biotechnics Private Limited (A Sanofi Company)**

- Writes, coordinates, compiles, and submits Regulatory documents to International Authorities

- Product Life Cycle Management

- Worked on Phase III Clinical Trial Application (CTA) submission and Market Authorization Application (MAA) submissions of Shan5 Vaccine to DCGI

- Supported for submission of Phase III Clinical Trial Application (CTA) of Shan6 Vaccine to DCGI

- Experience on post approval marketing changes (variation) filings to National regulatory Authorities.

- Worked on Filing of Tender documents to different international countries

**Executive,** **2009- 2011**
**Crescent Therapeutics Limited, Hyderabad**

- Preparation, review, and dispatch of Vaccine registration applications in Asian countries, Latin American countries, Central American countries, and African and French African countries.

- Preparation, writing and review CMC responses to various regulatory authority questions during registration and product lifecycle.

- Preparation and review of supporting documents pertinent to post-approval changes (PAC) to DCG(I) and variations to other applicable regulatory authorities and WHO [PQVAR].

- Review of container and carton label artworks, package inserts as per country requirement.

- Worked on compiling of documents for various Quality approvals like GMP Certificate, GLP Certificate, WHO-GMP Certificate, Certificate of Pharmaceutical product (COPP), Free sale certificate etc.

## KEY ACHIEVEMENTS

- Prepared BMF for submission to US-FDA within much stipulated timeframe and under pressure which was then well received and well-appreciated by Sanofi- Global RA and higher management within the Company as well
- Prepared more than 100 Annual Reports and Variations for submission to US-FDA within one month time frame and is well appreciated by Sanofi- Global RA
- Timely preparation and dispatches of Clinical Trial Applications (to DCGI) and Response Documents to various Regulatory authorities.
- Received “Play to Win” Award for consistently meeting 100% quality and exceeding proficiency target
- Successfully handled newly introduced e-tools for document management and dossier management and provided Training and support on e-tools to the team.

## EDUCATION

- Bachelor of Pharmacy from Sarojini Naidu Vanitha Pharmacy Maha Vidyalaya, Osmania University, Hyderabad with 75 % score.
- Board of Intermediate from Kakatiya Junior College, Nizamabad with 74% score.
- Secondary School Education from Nirmala Hrudaya Girls High School, Nizamabad with 75% score

## TECHNICAL PROFICIENCIES

- Proficient in Regulatory e-tools like Veeva Vault RIM document management system and Dossier management System, Trackwise and Phenix systems for Change control Management
- Supporting the team with day-to-day activities and providing guidance on handling the electronic tools (SHARE, Veeva) for regulatory submissions and archival
- MS-Office.

## STRENGTHS

- Working precisely according to procedures, rules and regulations
- Flexibility to handle multiple tasks at time and ability to plan and execute assignments in case of changing organizational priorities
- Good communication, negotiation skill and computer skills
- Excellent work management and time management skills

## DECLARATION

I hereby declare that the above written particulars are true to the best of my knowledge and belief

**(Sowmya Gangam)**