SANYAM GANDHI (British Citizenship)
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Key Skills

- Master's degree in pharmacy with 12 years of Hands on experience in Regulatory Affairs-, Pharma, Biotech, Rare Diseases and Generics.
- Regulatory Affairs Experience in Strategic planning and Project Management with emphasis on Executing Regulatory strategies, CMC-CTA authoring, and submissions.
- Early Sate Development: MAA planning, IMPD, Investigational Brochure, Scientific discussion and meeting with health Authorities, CMC Strategy, Local requirements.
- Post approval: Variations, PSUR Submissions, Safety updates, CCDS update, Site transfer project, Change controls, Annual reports, GAP Analysis, Renewals, compliance support.
- Adept in Regulatory systems i.e. Documentum, Track-Wise, Opal, IMMS. Web center
- Certified in many regulatory and project management courses with RAPS (USA), TOPRA (UK) and Management forum.
- Direction oriented, Individual contributor and excellent team player

PROFESSIONAL EXPERIENCE AND ACHIEVEMENTS

1. REGULATORY STRATEGY LEAD **Hematology -Rare Disease portfolio**
Takeda, Cambridge, USA (From May 2016 to present)

Received Top performer Award in 2018 for excellent performance

- Responsible and accountable for defining the Regulatory strategy for Hematology-Rare Disease portfolio to submit new MAA in major markets.
- Lead and direct supervision of SWG (submission working group) for assigned products with local regulatory affairs, global submission manager, SMEs (CMC, clinical, non-clinical), regulatory labeling, Regulatory project manager in many markets (more than 40 countries).
- Present Business cases, on behalf of local commercial to Global Regulatory team to receive endorsement from cross functional stakeholders for approval, launch and commercial supply.
- Many Successful orphan designation, devise registration, priority-accelerated review accomplished for assigned complex and innovative biological products.
- Lead and Track ongoing MAA effectively and highlight risk with mitigation strategy.
- Drive and operate regional requirements (Clinical and CMC) in early development for robust execution regulatory strategy and launch plan from different phases of clinical trials.
- Assess strategies and existing data against regional regulatory requirements and precedents to identify risks and opportunities. prepare and implement mitigation strategist.

  Coordinate supportive CMC mechanism like GMP audits, Samples, Local testing requirement, Normative document, Reference standards, transport validation etc.

- Support CTA with CROs, health authorities and register CCDS-Safety update, renewals, PSURs, Supply critical variations, annual reports.
- **Involvement in Baxalta and Shire integration**: Leading and implementing following work steam for process improvement in Shire:
  - Integration of Regulatory Process of Legacy Shire and Legacy Baxalta
  - Module 1 CMC document streamline between IRS, CMC and LOC
  - Harmonize CPP ordering process from USFDA, EMEA and Austria from Paddington
- **Involvement in Takeda and Shire integration**
  - Labelling operation and strategy process
  - Business case approval with regulatory affairs
  - Outsourcing regulatory activities to consultancies

2. SENIOR REGULATORY AFFAIRS SPECIALIST (USFDA and globally)
GW Pharmaceuticals, Sittingbourne, Kent (Mar 2014 – May 2016)

- Responsible for Global expansion of Sativex (cannabis based controlled oromucosal spray) in EU (With repeat wave MRP), Brazil and other Latin American countries.
- Manage Projects and strategy with commercial partners (Ipsen, Almirall, Neopharm and Novartis) on day to day basis for global expansion and many post approval activities.
- USFDA submissions for Type C meeting and NDA planning for Epidiolex.
- Coordinate CTA with local CROs and prepare IMPD, Investigational Brochures for Epidiolex and Sativex.
- Highlight risk and mitigation strategy to different stakeholders for ongoing regulatory processes and track submission plans with commercial partners effectively.
- Prepare and submit responses for queries raised by health authorities for ongoing MAA, CTA and post approval activities for EU, Australia, New Zealand, Canada, Asian countries

3. REGULATORY CONSULTANT (EU countries) Contract position
Catalent, Swindon (Jan 2013-Mar-2014)

- Update Module 3 sections for repeat wave MRP/DCP dossier with Reg CMC Strategy.
- Regulatory intelligence provided to Catalent client on different stages of life cycle for Novel Technology like Fast dissolving tablets and Zydis Technology.
- Coordinated with clients for uninterrupted product supplies and product approvals.
- CMC sections updated as per change control and updated sections submitted to health authorities.
- Post approval activities; Preparation and submission of variations for CP, DCP and MRP.
- Critically evaluate questions raised in relation to any application within the product lifecycle and ensured that they are fully responded.

4. REGULATORY EXCUTIVE (Emerging market) Contract position
GSK Pharmaceuticals, Stockley Park, London (Aug 2012-Dec 2012)

- Completed CMC post approval and compliance activities for integration of Stiefel laboratories-GSK project. (Prescription and OTC products)
- Prepared and submitted site transfer dossier, CMC compliance variation.

- Variations for Change in Manufacturing site, method, composition of finished product, packaging, analytical method, stability, specification of API and finished product.
- Performed Gap Analysis and find out CMC non-compliances in existing registration.
- Provided confirmation for resupply of Stifel Laboratories products in the region after completion of regulatory review and remediation activities.

5. REGULATORY PROJECT MANAGER (EU Regulatory affairs) **Contract position**
Ranbaxy Laboratories Limited, London **(Jan 2012-July 2012)**

- Lead the EU strategy and actively involved with the preparation of dossiers, setting up deadlines and on-time delivery of work to meet business plan.
- Define actions, identify and utilize resources to achieve project tasks, ensure that deliverables meet quality standards and that goals are aligned to desired project results.
- Proactively communicate with stakeholders regarding project status, budget, ongoing issues and dependencies across projects.
- Register RMS with European authorities for MRP, DCP procedure.
- Due diligent dossiers on CMC and bioequivalence studies with SMEs before submission to health authorities.

6. REGULATORY OFFICER (European Regulatory) **Contract position**
Teva Pharmaceuticals, Harlow **(Apr 2011-Dec 2011)**

- DCP and MRP Applications prepared and submitted with coordination to portfolio management, legal team, artwork, supply chain and medical team.
- Communicate with European Health Agencies for complete life cycle management.
- Performed a due diligence on Module 3 and Module 5 by reviewing R&D and clinical documents. (Prescription and OTC products)
- Crosscheck publishing standards of dossier before submitting to health agencies.
- Worked on advanced regulatory software like Wisdom, Global Insight etc.

7. REGULATORY AFFAIR AND COMPLIANCE OFFICER (UK and Ireland) **Contract position**
Aurobindo Pharma (Milpharm) Limited, London **(Sep 2010-Apr 2011)**

- Many variation packages Prepared and submitted for administrative, quality and safety updates.
- Update Patient information text (SmPC, Labeling and PIL) as per innovator, EU/MHRA notification or third party, distributor labeling.
- Resolve regulatory non-compliance issues between manufacturing site and Regional team/Business Units.
- Compilation/submission of the CPP, Sunset Clause, Withdrawal Application, PSURs.
- Coordinate with QA and QP for Change control, Deviation, Batch Release support.

8. REGULATORY ASSOCIATE (EU Regulatory affairs)
Ranbaxy Laboratories Limited, Gurgaon **(Jul 2009 – Apr 2010)**

- CMC writing experience (module 3) of Common Technical Documents
- Review and sign, due diligence with third party and R&D on quality sections.
- Write new and updated dossier for European applications.
- Identification of the variations based on the change control proposals.
- Liaise with internal stakeholders including Manufacturing, supply chain, QC and QA.

REGULATORY SOFTWARE, DOCUMENTUM worked on

- Maintenance Library, Wisdom, Global insight (OPAL), eCTD manager, IMMS (Informed Medical Management Services), Web center (labeling Review), Track-Wise
- E- Submission on MHRA portal and communication with agency for recent updates and ongoing activities.
- Cortiles for Regulatory Intelligence

EDUCATION AND CONTINUES PROFESSIONAL DEVELOPMENT

- Master of Pharmacy (Pharmaceutics) 2005-2007
  74.33%, IPS Academy, Indore, India.

- Bachelor of Pharmacy 2000-2004
  64.33%, B. R. Nahta college of Pharmacy, Mandsour, India.

- Management Essentials Certificate March 2020
  Harvard Business School Online, Boston, Massachusetts, USA

- Course completed on "Variations" by TOPRA, London, UK. 2012

- Course completed on "CMC" with TOPRA, London, UK. 2014

- "Project management for Pharma professionals" by Management forum, London 2015

- Course completed on "Clinical Trials" with TOPRA, London, UK 2016

- Regulatory Affairs Professionals Society certification, USA 2018

ACADEMIC RESEARCH PROJECTS

- "Formulation and evaluation a floating tablet of Metronidazole and Amoxicillin for peptic ulcer" as major project in Master's in pharmacy.
- "Formulation and evaluation of pellets of salbutamol sulphate for the controlled release pellets".

EDITOR IN SCIENTIFIC JOURNALS

Research Journal of Pharmacy and Technology
Journal of Biomedical and Pharmaceutical Research
International Journal of Drug Regulatory Affairs

Patent:

1. Floating drug delivery system (FDDS) comprising metformin, pioglitazone and glimepiride.
   Patent application number: 202121007124
   Published with Intellectual property India.

Scientific publications in Pharmaceutical journals:

1. **Regulatory Framework of Herbal Medicine In Mexico**
   European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 7, Issue 11, 2020

2. **Synthesis, Characterization and Anti-Inflammatory Activity of Novel 1, 5-Disubstituted Indole Derivatives**
   European Journal of Molecular & Clinical Medicine
   ISSN 2515-8260 Volume 7, Issue 11, 2020

3. **Effect of Lupeol in Diabetic Nephropathy and Its Antioxidant Mechanism**
   International Journal of Advanced Science and Technology
   Vol. 28, No. 20, (2019), pp. 1404-1413

4. **An Overview on Lagenaria Siceraria (Bottle Gourd)**
   Journal of Biomedical and Pharmaceutical Research
   Volume 4, Issue 3, May-June 2015, 04-10

5. **An Overview on Tannins**
   International Journal of Pharmaceutical and Biological Science Archive
   Volume 3 Issue 2; 2015, Page No.09-11

6. **Isolation and Identification of Keratinophilic Fungi from Soil of Gwalior Region and Their Control by Methanolic Plant Extracts**
   Journal of Biomedical and Pharmaceutical Research, 1 (3) 2012, 01-21

Following Chapter is authored in Book which is published in Elsevier.

Chapter 17 - Food and Drug Laws Affecting Pharmaceutical Product Design, Development, and Commercial Manufacturing
Book name: Dosage Form Design Parameters, Volume II, Advances in Pharmaceutical Product Development and Research, 2018 science direct.

Following Book is distributed by Albert Science International Organization

Regulatory Affairs Prospective for ANDA Submission
Publisher: CAB Publisher

Key Speaker in Pharmaceutical conferences

1. "Variation procedures – Industry perspective" at the CRED Managing Life Cycle, Renewals & post approval commitment organized by TOPRA, May 2021.
2. "Significance of Regulatory Affairs in Pharmaceutical Industry" at Laxmi Narain college of Pharmacy in 2021.
3. "Exploring Carrier Opportunities post COVID-19 for Pharmacist" at the R.D. Memorial College of Pharmacy & Research Indore on 07-May-2020
4. "IPR and Regulatory Affairs Prospective from Pharmaceutical Industry Perspective" at the Gov. Madhav Science PG college, Ujjain on 16-Jun-2020.

Scientific Poster presentations in Pharmaceutical conferences:

a. Subject: Prevalence and management of Hypertension in Indore –
   Date: 24th March 2007
   Conference: Indian Pharmaceutical Association, Pharma meet, IPS Academy, Indore, India

b. Subject: Phytosome: A Novel Approach for herbal Extracts
   Date: 27-28th March 2006
   Conference: "Recent Trends in Herbal Therapy"

Guru Ghasidas University, Bilaspur, Chhattisgarh, National Seminar on, Bilaspur, India

c. Subject: Formulation and Evaluation of Salbutamol Sulphate Pellets for Nocturnal Asthma
Date: 24-26th February 2007
Conference: International Indo-Canadian Conference on Pharmaceutical Science and technology, JSS College of Pharmacy, Ooty, India.

d. Subject: Generic Drug Registration comparison across countries
Date: 30-06-2007
Conference: Global Trends in Novel Therapeutics and Drug Regulatory Affairs by All India Council for Technical Education

Memberships:

Regulatory Affairs Professionals Society (RAPS), USA
International society of Pharmaceutical engineer (ISPE) **Emerging leader Committee**
The Organization for Professionals in Regulatory Affairs, UK(TOPRA) **North America Committee member**
America Association of Pharmaceutical scientist (AAPS) **Community leader in Regulatory Science**
Royal Pharmaceutical Society, UK

Publication in Open Media about Regulatory Affairs

1. article about "Regulatory Affairs Strategies for CMC" which was accepted and published by ISPE in "PHARMA BEST PRACTICES" series.
https://pbpw.in/blog/f/regulatory-affairs-strategies-for-c-m-c

2. Articles about the RWD and RDE with Pharma IQ
https://www.pharma-iq.com/regulatorylegal/articles/regulatory-perspective-real-world-data-real-world-evidence

I am certified peer reviewer with Elsevier and Publons Academy and reviewed many scientific publications for journals like;

- Pharmaceutical Regulatory Affairs: Open Access
- America Association of Pharmaceutical scientist Journal
- Journal of Sleep Disorders: Treatment and Care
- Biomedical and Pharmacology Journal
- International Journal of Dental and Clinical Study
- International Journal of Medical and Biomedical Studies
- Journal of Biomedical and Pharmaceutical Research