

Dr MIHIR GHARIA

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Sr. Manager Medical Affairs: Medical Advisor, Medical Projects, Team Handling, Post-Marketing Studies

About Me:

Seasoned professional, playing an imperative role in unlocking the full potential of scientific innovation and providing advocacy plans for new product launches by working with External Advisors and Partners within medical/healthcare industry.

Strong approach to implement up-to-date business principles and standardized marketing practices integral to a medical organization while dealing with external marketing partners and vendors. Valued Co-Strategist, provide medical direction to the regional & country teams to manage medical affairs as per in-line & late-stage development products in their research & development area

Over 10 years of experience in:

- ▶ Clinical Strategy & Trial Support
- ▶ Post marketing Management
- ▶ Stakeholder Management
- ▶ Key Opinion Leaders Engagement
- ▶ Research & Development
- ▶ Quality Management
- ▶ Pre-Launch Management
- ▶ Clinical Program / Project Management
- ▶ Resource Optimization

Academic Credentials & Enhancements:

- ☐ MBBS (Bachelor of Medicine & Surgery)
- ☐ EULAR Certificate in Rheumatology
- ☐ PGP-R (Rheumatology)
- ☐ MBA (Healthcare Finance, Marketing, Project Planning & Budgeting)
- ☐ PGDMLS (Diploma in Medico-Legal System)

■ PROFILE SYNOPSIS

- Excel in leading all aspects of Commercialisation, Launch and Post-Marketing of allocated portfolio of medical services and products from scratch
- **Advanced medical acumen** in conceptualizing & implementing medical affairs action plans with expertise in communicating both scientific and business needs credibly across a variety of stakeholders (internal & external) at all levels
- **Research & Development Skills** in monitoring technical and manufacturing integration of drug products (new & re-developed) with expertise in setting up sites across country for initiating global trials
- Ability to lead the overall market access strategy through design and execution of medical-marketing programs
- Proven contributions towards successful **New Product Introduction** by:
 - ✓ Providing oversight to technical transfer activities at internal and external sites
 - ✓ Monitoring product performance and supporting failure investigations (escalation of quality or compliance matters)
 - ✓ Defining and executing the Market Access Strategy
- Responsible for managing all aspects of Medical/Scientific Affairs & cross functionality working with Training, Sales, Marketing
- External stakeholder management - KOLs, KBLs & Medical Societies
- Executing registries and Phase 4 Studies
- Experienced in Rheumatology, Dermatology and Orthopedicians KOL management

Notable Accomplishments:

- Certificate of Excellence - BI Pharma for Launch business support in Boehringer Ingelheim CHC Business in India by Business Director CHC (India & EMEA Regional Business Head) | 2015
- Outstanding Contribution in Speciality Care division-MSD Pharma; Awarded by Business Unit Head and Head Medical Affairs of MSD Pharmaceuticals for overall performance in SURAKSHA Project
- Execution of ASPIRE registry of **Adalimumab Biosimilar** leading to more than 11 publications and 12 abstracts

Significant Projects Undertaken:

- ASPIRE Registry for Zydus Immunology division, PROMISE Project for Influenza Vaccination in Pregnant Women
- SURAKSHA (Indian version of Fracture Liaison service) for Countrywide Implementation
- Phase 4, MUSIC-OS study (Medication Use Patterns, Treatment Satisfaction, and Inadequate Control of Osteoporosis) for India followed by Asia-Pacific roll out

IT Purview:

Conversant with SPSS 21 and Minitab 16 for Bio Stats, QM For Operations Research, Wipro-HMIS, MS Project and MS Office Suite (Word, Excel & PowerPoint)

■ EMPLOYMENT EPISODE

Senior Manager - Medical Services ▶ **Zydus Cadila Healthcare Ltd.**, Ahmedabad

Since Oct '15

Therapy Area: Immunology/Rheumatology & Dermatology & Vaccines

Product: **Exemptia, VaxxiFlu-4, ZyVac TCV**

Key Deliverables:

Product Launch & Engagement:	<ul style="list-style-type: none"> ▪ Providing strategic clinical trial support for successful execution of major clinical development programs ▪ Translating the global medical goals into research, scientific communications, and solutions that improve patient outcomes and enhance access in their country ▪ Developing pre-launch plans and securing resources to support preparations for new product launch ▪ Directing regional MSL's identification of opportunities for post-marketing studies; travel across diverse locations for on-the-job including clinical trials, registry, KOL engagement and pre-launch ▪ Responsible for planning and maintaining an annual scientific congress meeting schedules
Medical Affairs Department Management:	<ul style="list-style-type: none"> ▪ Lead the development of medical procedures and technology and delivering clinical trial support for pipeline development ▪ Provide value-driven support to improve the performance of divisions Immunology – Rheuma and Derma Experts ▪ Provide medical review of brand content, align with overall strategy ▪ Ensure the smooth running of the unit (medical affairs) by: <ul style="list-style-type: none"> ✓ Playing a significant role in in-depth medical research and product development ✓ Developing the presentation slide-decks for internal & external stakeholder meetings ✓ Tracking the Clinical development program milestones for division's pipeline projects
People Engagement & High-Impact Collaboration:	<ul style="list-style-type: none"> ▪ Participate in Trust Board meetings to review action report in close consultation with clinical & non clinical units ▪ Work with Community Thought Leaders as well as other Health Care Practitioners to bring patient centric insights ▪ Interface with Research and Development to derive result-oriented inputs for successful clinical trails ▪ Interface with Medical Director and cross functional teams to track Clinical development program milestones for division's pipeline projects, project management deliverables and identify (PMS) ▪ Support the division by developing presentation slide-decks for internal & external stakeholder meetings. Develop relationships with KOL's In Rheumatology and Dermatology
Scientific Team Leadership & Training:	<ul style="list-style-type: none"> ▪ Leading a team of 4 Medical Science Liaisons for Immunology therapy area covering Rheumatologist and Dermatologists ▪ Developing medical training material towards Medical Publications including Study Newsletters, Abstracts, Journal submissions and manuscripts ▪ Delivering therapeutic/functional training to assigned teams and affiliate functions

ACHIEVEMENT IN CURRENT ROLE: Helped generate more than 25 publications for Adalimumab Biosimilar Exemptia in various Indications to generate usage, efficacy and safety patterns across all Indications at various national and International levels over 5 years' time as Immunology Medical Advisor. List available on website www.exemptia.com.

Medical Advisor ▶ **Boehringer Ingelheim Pharmaceuticals India Ltd.**, Mumbai

Aug '13 – Oct '15

Therapy Area: Consumer Healthcare

Products: Buscopan, Dulcolax, Pharmaton

Proven Contributions towards:

- ✓ Launch of Flagship brands of BI CHC across India BUSCOPAN and DULCOLAX
- ✓ Set up of Medical Affairs Unit for CHC with alignment in SOP's from Global BI

Key Deliverables:

- Managed a gamut of activities related to SOP preparation and Marketing & Promotional Planning, Medical Literature review and Approvals while working with doctors, chemist and key customers
- Engaged in Medical and Regulatory rationale development for effective new products development with quality assurance
- Provided strategic support to documentation of Regulatory Affairs Team for dossier submission to DCGI/FSSAI
- Led all aspects of the concerned Medical Training Department in order to create training modules with a purpose to Train the Trainers and Field Force during Cycle Meets
- Ensured Compliance for the division and strategized with marketing tactics in accordance with business goals

Therapy Area: Immunology and Bone

Products: Remicade and Fosavance

Key Deliverables:

- Recognized as a single contributor in conducting regular in-service programs and CMEs
- Coordinated with Sales and Marketing team to support the creation drug conversion pipeline and Phase-4 trails
- Spearheaded community outreach initiatives to increase public's awareness of programs & services that are accessible to them
- Delivered on-the job trainings to the organizational sales force to accomplish set business targets
- Represented the organization as Presenter as well as Speaker across local academic events
- Build & sustained long-term relationships with top 40 KOLs in territory through regular clinical discussions / in account clinical research projects / product evaluation programs / white paper creation and KOLs for CMEs.
- Maintained complete alignment with Frontline Sales Force at the front end and with Product Manager at the back end

Key Deliverables:

- Performed in-depth study of patient history with a view to deliver appropriate treatment plans for ICU Cardiac patients
- Facilitated medical meetings with all levels of hospital management with a focus to improve quality standards and delivery of best medical practices
- Handled post-operative patients and routine follow-up visits to ensure smooth running of hospital operations
- Coordinated the entire patient facilities care with various consultants and senior medical experts
- Assisted in managing the emergency patient unit and administered the monitoring & effects of the drugs on patients

■ EDUCATION & CREDENTIALS

2020 **EULAR** Certificate in Rheumatology

2013 **PGP-Rheumatology** from John Hopkins University

2011 **PGDMLS** (Medico-Legal Systems) from Symbiosis International University, Pune

2011 **MBA** (Healthcare Finance, Marketing, Project Planning & Budgeting) from Symbiosis International University, Pune

2008 **MBBS** from Veer Narmad South Gujarat University, Surat

■ PUBLICATIONS & POSTERS- <https://orcid.org/0000-0001-8321-7966>

- 1) Kapoor, S., Kaushik, V.V., Jain, R. et al. Real-Life Tolerability and Effectiveness of Adalimumab Biosimilar in Rheumatoid Arthritis: ASPIRE Registry Data. Rheumatol Ther 6, 451–459 (2019). <https://doi.org/10.1007/s40744-019-0166-2>
- 2) Kapoor, S., Kaushik, V.V., Jain, R., Rao, V.K. and Gharia, M. (2019), Real-life Tolerability and Effectiveness of Adalimumab Biosimilar in Ankylosing Spondylitis: the Adalimumab Biosimilar Patient Registry Data. ACR Open Rheumatology, 1: 480-484. <https://doi:10.1002/acr2.11067>
- 3) Gharia M, Sudhakar A. Reduced Injection Site Pain with Succinate Buffer-Based Adalimumab Biosimilar (ZRC-3197) Injection (SUFFER Study): An Observational Study. Indian J Rheumatol 2019;14:151-2
- 4) 2016: Poster on "Reduced injection site pain with succinate buffer based Adalimumab biosimilar injection (SUFFER Study): An observational study" at IRACON Kochi, INDIA 2016 Published in IJR Nov 2016 Supplement.