

# Dr. Anu Yadkikar

BHMS, MD, EMBA

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## PROFESSIONAL SNAPSHOT:

A self-motivated **medical & management skilled professional** with progressive **20 years** of experience in clinical and healthcare sector: **Pharmacovigilance, Project Management** and **Medical writing** for global MNCs

- ▲ Consulting Homoeopath, Shwet.Sanjeevani clinic, (Private practice) Aug 2017 to till date.
- ▲ Associate manager - Operations team: Quintiles Research India Pvt. Ltd, Mumbai (now IQVIA) from 01 Aug 2016 to 10 Jul 2017.
- ▲ Manager Pharmacovigilance & Medical writing in GVK-BIO Life sciences (Gurgaon & Mumbai) from 02 Jan 2014 to 29 Feb 2016.
- ▲ Team Leader- Pharmacovigilance in Cognizant Technology Solutions, Mumbai from 01 Oct 2012 to 19 Nov 2013 for a 60+ team members.
- ▲ Medical writer, SIRO Clinpharm Pvt. Ltd. from 09 Nov 2010 to 30 Sep 2012.
- ▲ Senior Process Associate, Drug Safety Specialist and Back-up Team Lead, Tata Consultancy Services from 16 Feb 2009 to 08 Nov 2010.
- ▲ Consulting Homoeopath, Shwet.Sanjeevani clinic, Koparkhairane, Navi Mumbai (Private practice) Jan 2002 to Nov 2013.
- ▲ Duty Medical Officer at M.G. M's New Bombay Hospital, Navi Mumbai, from Oct 2000 to Jan 2002.
- ▲ Duty Medical Officer at Smt. BCJ General Hospital, Santa Cruz, Mumbai, from Apr 2000 to Sep 2002.

## AREAS OF EXPERTISE:

### Project Lifecycle & Management

PV Operations Management

Transition Management

Client Management & Negotiations

### Leadership

Team Building & Mentoring

Succession Planning

Performance management

Team & Line Management

## KEY STRENGTHS:

- ▲ Decision maker, an active listener and energetic to handle different tasks and projects
- ▲ Ability to work independently, under pressure, demonstrating initiative and flexibility through effective innovative leadership ability and team management skills.
- ▲ Ability to work with employees at all levels of the organization.
- ▲ Committed, ambitious, disciplined and goal-oriented with practical approach.

## EXPERIENCE:

Company: **Quintiles Pvt. Ltd (now IQVIA): 01 Aug 2016 to 10 Jul 2017**  
Role: **Associate Manager-Operations team**  
Client: **Merck Pharmaceuticals**

### Accountabilities:

- ⬆ Implement and support operational decisions as determined and instructed by senior management. Assist in global initiatives-Change Management
- ⬆ Work closely with operations managers to address problem areas, work scheduling for current and projected projects, and projected peak workloads.
- ⬆ Monitor, assess and report utilization of staff. Identify and implement solutions to address poor utilization.
- ⬆ Ensure direct reports are cross trained on Lifecycle Safety service offering; monitor and develop training plans; identify training and development needs of staff in collaboration with Lifecycle Safety Infrastructure group and Lifecycle Safety Management (LSM).
- ⬆ Lead and encourage direct reports in continuous improvement of department work processes, procedures and infrastructure. Instruct and lead direct reports in efficient management of project budgets through effective timesheet reporting. Work closely with operations specialist managers.
- ⬆ Monitor and ensure that project processes and department deliverables meet expected quality, financial and productivity targets. Assist with meeting department utilization and realization targets.

Company: **GVK BIO Life Sciences/ 02-Jan-2014 to 29-Feb-2016**  
Role: **Manager- Pharmacovigilance-Medical Writing**  
Client: **Abbott Pharmaceuticals**

### Accountabilities:

- ⬆ Responsible for the end to end Service Delivery of project/s, meeting SLA's
- ⬆ Initiate start up meetings with the Study Teams related to the creation and development of the clinical document for regulatory submission
- ⬆ Act as a Change Agent and work closely with Quality, Transition, Training, Teams and Clients to optimize Quality, Efficiency, Cost and Customer Value in multiple client engagements
- ⬆ Analyze operational risks, extend support in managing client escalations (RCA/CAPA) and work across traditional functional boundaries to mitigate risks and establish common goals to deliver value to the business
- ⬆ Budget preparation, resource and strategic planning, develop proposals according to scope with resource and cost calculations
- ⬆ Drive Business Continuity Plan

Company: **Cognizant Technology Solutions, Mumbai/ 01 Oct 2012 to 19 Nov 2013**  
Role: **Team leader- Pharmacovigilance – Drug Safety; Team Size: 60+**  
Client: **Takeda Pharmaceuticals, Japan**

### Accountabilities:

- ⬆ Ensure process related metrics for the team (as agreed with the client) with respect to: Productivity, Case & Team Quality Scores, Measuring and Managing impact on Agreed Service Levels, manage employee retention (Manage attrition within a target range)

- ⤴ **Lean Navigator** in Optimize project at Cognizant – June-September 2013
- ⤴ Adherence to client SOPs and guidelines
- ⤴ Managing Average Processing Time (APT) of cases for the Team
- ⤴ Provide annual performance appraisals of direct reports and provide regular feedback, if applicable to Operation Manager
- ⤴ Leave Management and Timely Metrics capture
- ⤴ Leading operations team and ensuring quality of day to day service delivery
- ⤴ Coordinating, managing, relationship building and becoming a successful interface between the process team and Ops Manager
- ⤴ Drive Business Continuity Plan
- ⤴ Change Management-Has lead change management projects for offshore

Company: **SIRO Clinpharm Pvt. Ltd. / 09 Nov 2010 to 30 Sep 2012**  
 Role: **Medical writer**  
 Client: **Johnson & Johnson Pharmaceuticals**

**Accountabilities:**

- ⤴ Prepare clinical documents that are part of regulatory submission that include Narratives, Clinical Study Reports, Protocols, Investigator's brochures, Clinical Trial Registry Summary, ICFs, Efficacy Reports, and other regulatory submission documents
- ⤴ Quality check of the clinical documents- Narratives and ICFs for regulatory submission
- ⤴ Initiate start up meetings with the Client Study Teams for the creation and development of the clinical document for regulatory submission
- ⤴ To work in coordination, define and meet project timelines with all the members in the study team- internal and external for the development of clinical documents
- ⤴ Prepare the clinical documents with required quality standards within the target timelines
- ⤴ Have worked (drafted and QC'ed narratives, ICF [QC]) on Therapeutic areas: Oncology, Cardiovascular and Metabolism, Immunology, Infectious diseases and Neuroscience projects

Company: **Tata Consultancy Services / 16 Feb 2009 to 08 Nov 2010**  
 Role: **Drug Safety Specialist & Back-up Team lead**  
 Client: **Astra Zeneca Pharmaceuticals**

Project II: Clinical Trial and Spontaneous case handling: (31 Aug 2009 to 08 Nov 2010):  
 Project I: Mass Litigation Case Handling: (16 Feb 2009 to 31 Aug 2009):  
 Team Size: 20+

**Accountabilities:**

- ⤴ End to end analysis, evaluation, entry and closure of cases in Sapphire database
- ⤴ Capturing of information from the medical records into safety database
- ⤴ Triage of cases, Coding of medical terminologies using MedDRA dictionary
- ⤴ Draft narratives summarizing the case specific data and causality
- ⤴ **Narrative writing** for ICSR's and perform QRE on cases
- ⤴ Perform all activities within the required timeframes to ensure regulatory compliance
- ⤴ **Signal detection**, Signal validation and confirmation, Prioritization, analysis and assessment, Recommendation for action, Exchange of information

**ACADEMIC CREDENTIALS:**

Qualification	School/College	Board/	%	Year of Passing
Executive-MBA <b>(E-MBA)</b> (Marketing and Operations)	<b>NMIMS</b> , Vile Parle, Mumbai (Narsee Monjee Institute of Management Studies)	NMIMS, Mumbai (Deemed University), Maharashtra	<b>71.88%</b>	<b>Nov 2012</b>
Industry Programme in Pharma-Regulatory Affairs	Bio-Informatics Institute of India, Noida	Bio-Informatics Institute of India, Noida	55.5%	Jul 2011
Post -graduate diploma in Medico-Legal Systems (PGD-MLS)	Symbiosis Centre of Health Care (SCHC), Pune	Symbiosis Institute, Pune.	61.4%	May 2010
Post-Graduate Diploma in Clinical Data Management (PGD-CDM)	Institute of Clinical Research India, Mumbai	Cranfield University, UK	74%	Mar 2009
<b>HMD (2005-2008)</b>	British Institute of Homeopathy, London	British Institute of Homeopathy, London	<b>88%</b>	<b>2008</b>
BHMS (Bachelor of Homeopathic Medicine & Surgery)	Vengurla Homeopathic Medical College, Vengurla, Sindhudurg, Maharashtra	University of Mumbai	55.6%	2001

**KEY ACCOMPLISHMENTS:**

- ▲ Was awarded with **Applause award** at QuintilesIMS in **Dec 2016 for planning and successful executing the plan** to clear the backlog of a significant number of cases in Nov-Dec 2016
- ▲ Have presented for Client Audit conducted for projects at TCS in Mar 2009 and in Mar 2010 and was awarded with **TCS Gems** for **representing in external client audit** at TCS, Mumbai
- ▲ Was appreciated for **top-performance in team- 2009, 2010, 2012, 2013, 2015**
- ▲ Have participated in a project – “Business opportunities and generic market in today’s world” in the Life Sciences & Healthcare Annual “Stall War” competition held at TCS in Dec 2009
- ▲ Was an active member of TCS Pharma-COP newsletter–written many articles like “Recipe for Success” May 2010 onwards

**PERSONAL DETAILS**

- ▲ Husband’s name: Ar. Mandar Yadkikar
- ▲ Address: F-101, Renaissance Park 1 Apartments, Malleswaram West, Bangalore-560055
- ▲ Date of birth: May 25, 1978
- ▲ Marital status: Married
- ▲ Languages known: English, Hindi, Marathi
- ▲ PAN & Passport details: Will be shared if requested

**PROFESSIONAL ASSOCIATIONS:**

- ▲ National Journal of Homeopathy (NJH)
- ▲ Homoeopathy Integrated Medical Practitioners Association (HIMPA)
- ▲ Indian Society for Clinical Research (ISCR)
- ▲ DIA