Name : **Dr. Prafulla Nandi**

Designation : Adjunct Professor

Qualification : MPharm, PhD

Specialization : Regulatory Affairs

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Experience : 33 years

Professional Qualification :

- **Master's Degree in Pharmaceutical Sciences (MPharm)** from Birla Institute of Technology & Science (BITS), Pilani, Rajasthan.
- **Doctorate Degree in Pharmaceutical Sciences (PhD)** from University Department of Pharmaceutical Sciences, Utkal University, Bhubaneswar (Odisha).

Professional Experience :

- July 2022 to June 2023 with **Cadila Pharma**, Ahmedabad as Joint President
- July 2016 to June 2022 with **Laurus** Labs Ltd (Formerly known as Aptuit Larus), Hyderabad as Sr. Vice President & Head of Global Regulatory Affairs
- July 2015 to July 2016 with **Apotex** Inc (A Canadian Multinational), Bangalore as Head of Global Regulatory Affairs
- August 2010 to July 2015 with **Jubilant** Generics Limited, Noida as Vice President - Global Regulatory Affairs
- August 2006 to August 2010 with **Fresenius Kabi** (A German Multinational), New Delhi as Joint Director - Global Regulatory Affairs
- July 2004 to August 2006 with **Torrent** Research Centre, Ahmedabad as Assistant General Manager - Regulatory Affairs
- June 2003 to July 2004 with **Dr. Reddy's** Laboratories, Hyderabad as Manager - Global Regulatory Affairs and Compliance.
- December 2000 to June 2003 with **Alembic** Limited, Baroda as Manager - Regulatory Affairs.
- November 1997 to November 2000 with **Dabur** Oncology Limited, Ghaziabad (currently known as Fresenius Kabi) as Research & Development Scientist - Regulatory Affairs.
- November 1995 to November 1997 with **Wockhardt** Research Centre, Aurangabad as Research Associate - Pharma Research.
- October 1994 to October 1995 with **Sun** Pharma Advanced Research Centre, Baroda as Officer - Research & Development.

Research Areas:

- Global Regulatory Compliance
- Quality Management
- Product Development
- Quality By Design

RESEARCH PUBLICATIONS

- *Comparing Drug Master File Procedures in Highly Regulated Market* in Regulatory Focus, August 2012, Regulatory Affairs Professional Society, USA (PK Nandi, SK Sahu).
- *Regulatory Requirements for Development & Filing of Generic Drugs Globally – A Comprehensive Study* in International Journal of Pharmaceutical Investigation (PK Nandi, SK Sahu, Shweta Handoo, Deepak Khera, Vandana Arora).
- *Regulatory Procedures in EU: A Review* in The Pharma Review, July – August 2010 (PK Nandi, SK Sahu, Tarun Bharal).
- *Global Drug Master Filing Procedures* in The Pharma Review, November – December 2010 (PK Nandi, SK Sahu, B. Suresh, MD Azam)
- *Global Generic Drug Filing Procedures in* Indian Drug Manufacturing Association Bulletin, August 2010, (PK Nandi & SK Sahu).
- *Studies on Fabrication of Ibuprofen SR Product & its Release Pattern* in Indian Drugs (PK Nandi).
- *In vitro Evaluation of Theophylline SR Tablets* in The Eastern Pharmacist, October 1997 (PK Nandi).
- *A Guidebook to Generic Drug Registration in India*, Lambert Academic Publishing (Dr. PK Nandi, Dr. SK Sahu, CC Behera)

Academic activities

- Currently guiding 3 PhD Scholars in Pharmaceutics & Regulatory Affairs
- Also guided several PG students with specialization in Pharmaceutics.