



## **Bela Nanavaty**

### **OVERVIEW**

Over 16 years of experience working with the Pharmaceutical, Biotechnology industries, that includes Managing Quality Assurance, Quality Control, R&D analytical, and DEA compliance departments. Her consulting realm includes FDA, EU and DEA. Bela's primary strengths are in Quality Assurance/Quality Control and Regulatory Affairs with emphasis on cGMP compliance.

### **PROFILE AND KEY AREAS OF EXPERTISE**

- ◆ Audited API manufacturer, finished product manufacturer, Contract labs, Dietary supplement manufacturer, etc.,
- ◆ Conducted GAP analysis for regulatory compliance and performed Risk assessment.
- ◆ Experience in working with the FDA during regulatory inspections. Managed Pre-approval inspections (PAI).
- ◆ Successfully Handled customer complaints, 483s & Warning letters issued by the FDA
- ◆ Conducted professional training seminars for fortune 500 companies. Trained staff as per the cGMP, GLP, QSR and DEA regulations.
- ◆ Provided regulatory compliance expertise and guidance to numerous pharmaceutical and medical device manufacturers.
- ◆ Prepared New drug application(NDA), US and foreign government Drug Master Files and filed 510(k) applications
- ◆ Managed Quality Control and Quality Assurance Dept.
- ◆ Successfully reduced costs and lead time by automating the laboratory analysis. Evaluated Lab equipment and budget management.
- ◆ Developed and reviewed SOPs, Regulatory documents , Validation protocols, stability protocols, and method transfer protocols
- ◆ Experienced in Analytical method development, method transfer and Validation
- ◆ Managed DEA compliance related issues for controlled substances.
- ◆ Managed Stability study program
- ◆ Prepared Annual Product Report (APR).
- ◆ Experience in Characterizing sample using HPLC, NMR, TLC, GC, MS and IR.
- ◆ Analyzed the commercial drugs as per Pharmacopoeia (USP, BP, IP and JP)



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### **EDUCATION/TRAINING**

- 1981 **B.S. Chemistry**, University of Bombay, India
- 1983 **M.S. Inorganic Chemistry**, University of Bombay, India
- 1990 **M.S. Analytical Chemistry**, Wright State University, Ohio
- 1995 Stability program and Investigating OOS results
- 1997 Marketing and strategy-planning courses
- 1998 Business law and Personal law
- 1999 Visual basic programming (VB 6.0), Web development (HTML & JavaScript),  
Microsoft Access Database
- 2001 Team Building and Communications
- 2001 Leadership Training
- 2001 Business Writing

### **CORPORATE HISTORY**

- 2002- Present **Compliance-Insight Inc**, Cincinnati, Ohio. Compliance Consultant.
- 2000 – 2002 **Eurand America**, Vandalia, Ohio. Manager R&D analytical/ QA / Compliance.
- 1993 – 1996 **Pfizer** (previously Pharmacia & Upjohn), Franklin, Ohio. Manager, Quality Control.
- 1992 – 1993 **Glaxo-Smithkline**, Research Triangle Park, NC. Analytical chemist
- 1990 – 1992 **Pfizer** (Previously Parke-Davis/ Warner Lambert), Ann Arbor, MI. Associate Scientist, Radiochemistry.
- 1989-1990 **Wright State University**, Ohio. Graduate Research/ Teaching Assistant.
- 1984 – 1987 **Industrial Testing and Analytical Labs (ITALAB)**. Analytical chemist.



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**PUBLICATIONS AND AWARDS**

- ◆ *Prediction of Retention Behavior in Coupled Gas Chromatographic Capillary Columns of less than 10 meters in Length* presented at Regional Meeting of the ACS, June 1990.
- ◆ *Employee Recognition Award* for excellent performance, Parke-Davis/Warner Lambert, 1990/91.
- ◆ *Synthesis of CI-973[14C]* presented at the meeting of the International Isotope Society (IIS), May 1991 and published in *Journal of Labeled Compounds and Radiopharmaceuticals*, Vol. XXXIII, No. 12.
- ◆ *Routine Determination of Specific Activity using Mass Spectrometry* poster presented at the meeting of the International Isotope Society (IIS), May 1992.
- ◆ *The use of Chiral Capillary Electrophoresis in the Separation of GI 189434A & GG211C* presented at Pittcon, 1995.