



Curriculum Vitae

Nanda K. Subbarao, Ph.D.
nsubbarao@bcg-usa.com
Senior Consultant
Biologics Consulting Group, Inc.
Plainsboro, NJ

SUMMARY OF EXPERTISE

- Explanation of FDA regulations
- FDA regulatory submission preparation and review
 - Biologics
 - Conventional drugs
- GMP systems design and implementation
 - Laboratory
 - Stability
 - Equipment
- PAI readiness
- QA oversight of contract services
 - Analytical testing
- Analytical validation development assistance and assessment
 - Stability testing
- Client training course development

EDUCATION

Ph.D. *Bio-organic Chemistry*, Indian Institute of Technology, Bombay (1985)

M.S. *Chemistry*, Indian Institute of Technology, Bombay (1980)

EXPERIENCE

Biologics Consulting Group, Inc., *Senior Consultant*
Plainsboro, NJ (June 2007 - present)

Sun Pharmaceutical Industries Inc, *Senior Manager, Quality Control*
Cranbury NJ (2006 – May 2007)

- Managed the QC department with 20 people in the validation and cGMP testing groups to support R&D regulatory submission and commercial operations.
- Established the cGMP systems based on Corporate Quality guidelines to prepare the laboratory for the first FDA inspection.
- Established the equipment qualification master plan, upgraded the stability program to current industry standards



Sandoz (Novartis), Manager, Stability,
Dayton, NJ (2003 – 2005)

- Managed a group of 7 chemists and 3 sample coordinators /stability administration personnel for the Research and Commercial Stability Program. Responsibilities included stability storage and testing, sample flow, controlled drug substances and Reference Standards.
- Recognized for significantly improving the cGMP compliance of the stability program, the sample flow system to facilitate testing metrics reporting.
- Improved communication in the company by flow charting processes, obtaining buy-in from other functional groups to improve sample flow from manufacturing into the lab and information out to Regulatory.

Pfizer, Principal Scientist (Group Leader, Stability Management)
St. Louis, MO (2001 – 2003)

- Managed a team of stability administrators and CMC documentation personnel for the Biologics Stability Program.
- Set up the cGMP systems required for the Commercial and R&D Biopharma Stability Program involving several contract facilities and Pfizer internal laboratories.
- Led a team of Engineers and Project Managers to construct and validate a state-of-the-art cGMP Stability Facility, completed on time and within budget.

Monsanto Company, Supervisor, Bioprocess QC
St. Louis, MO (1998 – 2001)

- Managed a team of 4 chemists in the General and Electrochemistry laboratories.
- Responsibilities included optimization and validation of analytical methods for the QC laboratory and release/stability testing of cGMP lots.

Monsanto Company, Scientist, Bioprocess QC
St. Louis, MO (Mar. 1998 – Jul. 1998)

- Participated in the team to set up cGMP systems for the new Biologics QC laboratory. Responsible for the electrophoresis laboratory.
- Designed a composite worksheet system for recording raw data. Presented worksheet system at Industry meeting with positive response.
- Designed and implemented validated spreadsheets for performing calculations in the Bioprocess Analytical laboratory.

Organics LaGrange, QA Methods Validation Specialist
Northbrook, IL (Feb. 1995 – Feb. 1998)

- Responsible for method validation and oversight of QC lab cGMP compliance.
- Optimized analytical methods for commercial QC lab.
- Served as company's technical contact with USP.
- Tripled the laboratory capacity by implementing chromatography system automation.
 - This project impacted virtually every group in the company, was completed on time, within allotted resources and performed error free after implementation.

Northwestern University, Post Doctoral Biochemist
Evanston IL (1987 – 1995)



- Interaction of proteins and peptides with liposomes and other lipid preparations. Protein and peptide conformation studies. Hands on experience in protein and peptide purification, synthetic organic chemistry, analytical techniques for amino acids, peptides and proteins, Circular dichroism, NMR, Fluorescence and other spectroscopic techniques.

University of California at San Francisco, *Post Doctoral Biochemist*

San Francisco, CA (1985 – 1987)

- Interaction of peptides with liposomes and other lipid preparations. Protein and peptide conformation studies. Hands on experience in peptide synthesis and purification, analytical techniques for peptides, Circular dichroism, NMR, IR and other spectroscopic techniques.

CONTINUING EDUCATION

- Obtained training in subjects such as Certified Quality Auditor, Audit Preparation, cGMP Compliance, Project Management and Negotiation skills.

INVITED PRESENTATIONS

- 1) “Understanding the effects of Global Regulations and Markets on Stability Programs” CBI’s Stability Programs Conference, June 7-8, Princeton NJ.
- 2) “Design and Implementation of a worksheet system to record lab data”. Barnett International conference on 'Laboratory Notebooks -- Paper and Electronic, Renaissance Hotel, May 10-11, 2001, Washington DC.
- 3) “Stability Facility GXP Compliance – Early Tox to Phase III Clinical Studies”, IBC’s 3rd International Conference on Formulation Strategies for Biopharmaceuticals, September 22-24, 2003, Philadelphia PA.
- 4) Taught the 2 day PTI course, “How to design and Implement Effective Stability Programs for Biotechnology Products”. July 2003, Boston, MA.
- 5) “Stability Assessment in Biotechnology Product Protocols”, 6th Annual Stability Testing Forum, July 15-16, 2004, Philadelphia PA.
- 6) “Handling OOS and OOT results”, IVT’s conference on Stability Testing, November 29-December 2, 2005, Amsterdam, The Netherlands.
- 7) Work shop on ‘Handling OOS and OOT in the Laboratory during Stability Studies’, IVT’s conference on Stability Testing, November 29-December 2, 2005, Amsterdam, The Netherlands.
- 8) "Effective Implementation of Stability Program", IPA’s Stability Program conference, Feb 20-21, 2006, Toronto, Canada.
- 9) Workshop on “Handling Stability OOS and OOT Results” IPA’s Stability Program conference, Feb 20-21, 2006, Toronto, Canada.
- 10) Moderator for the Regulatory Panel Discussion, “Design and Structure of Formal Stability/Accelerated Stability Studies” IIRUSA Conference on Formulation and Forced Degradation for Biopharmaceuticals March 27-29, 2006, San Francisco, CA.