

Vinod Kuberkar, PhD, MBA

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EDUCATION

PGPX MBA, Apr 08 – Mar 09 Indian Institute of Management, Ahmedabad, India

Ph.D., Chemical Engineering, Aug 94 – May 99 **University of Colorado, Boulder**, Colorado, USA

Integrated 5-year **Masters in Biochemical Eng & Biotechnology**, Aug 89 – May 94 (This program covers both Bachelors and Masters, but skips the Bachelors degree) **Indian Institute of Technology at Delhi**, New Delhi, India

PROFESSIONAL EXPERIENCE

Head, Contract Services (May 09 to present) **Intas Biopharmaceuticals**

I am responsible for business development as well as execution of contract projects. In this role, I have strengthened client acquisition efforts by shortening the response time as well as by increasing the quality of response. I have introduced many new channels, including e-channels and advertisements, and have broadened service portfolio. I have shortlisted, and then initiated discussions with many MNCs for the strategic tie-ups. The discussions are well-advanced with one MNC for out-sourcing of early-stage molecules.

I also coordinate technical and techno-commercial activities of erythropoietin. In this role, I have cut COGS by nearly a third through cost-controls and eliminating low-priority projects. I have also initiated plan to introduce of vial presentation to capture untapped markets such as dialysis centers and select ROW countries.

Associate Director (Apr 06 – Mar 08)
Biotechnology Group, Wockhardt Ltd, Aurangabad, India

I worked at the Wockhardt's biotech business unit, which is focused on generic 'biosimilar' drugs.

Process Development and Technology Transfer Head (Nov 06 – Mar 08)

I started Process Development and Technology Transfer group from scratch at the Biotech Park manufacturing location to speedily resolve the challenges facing the facility. The team worked on Glargine, a modified insulin molecule, and erythropoietin. I also provided leadership on technical and scientific issues facing the biotechnology group. In that role, I strongly argued for accelerated development program for monoclonal antibodies.

Manufacturing Head on Interim basis (Oct 07 – Mar 08)

I headed Mammalian manufacturing facility on interim basis (Oct 07 to Mar 08). As an interim head of manufacturing, I introduced several process changes and streamlined manufacturing activities to improve process quality.

Quality Head on interim basis (Apr 06 – Feb 07)

Since the company lagged far behind the global standards on quality and regulatory fronts, I set global quality benchmarks, and launched an inter-departmental Quality team to address the deficiencies. Several initiatives were introduced through this exercise, including those related to specifications, stability, and validation.

I supported launch of Wepox 12000 in India for treatment of anemia caused by chronic kidney disease and treatment of cancer. I interacted with various departments such as R&D, Formulation, and Manufacturing, and ensured that all activities met the required quality standards.

Senior Scientist (Dec 04 – Mar 06)

Amgen, Inc., Thousand Oaks, California, USA

I worked on two major projects at Amgen, the world's largest biotech company by revenues. My first project involved development of a fusion protein drug for lupus and lymphoma. As a process team leader for this drug candidate, I was charged with the full development responsibilities from early stage research to initiation of clinical studies.

My other major project involved Epogen. I developed a new purification process that is scalable and does not use animal-sourced ingredients, stringently ensuring that the drug from the new process has the same properties as that from the old process.

Principal Engineer (Dec 01 – Jan 03)

Baxter Healthcare Corporation, Columbia/Beltsville, Maryland, USA

I worked at Baxter's vaccine unit, which is primarily focused on the Meningitis vaccines for infants. I helped develop the process for vaccines against Y and W serotypes of Meningitis. After developing the process, I led the transfer from R&D to Manufacturing. I provided on-floor technical assistance and supported lot disposition by helping close the non-conformances.

Process Development Scientist (Jun 99 – Oct 01)

Sulzer Biologics, Inc., Denver, Colorado, USA

Sulzer Biologics was conducting early stage clinical studies for its proprietary osteogenic therapeutic proteins extracted and purified from the natural sources. I worked with the vendors and outside consultants to improve the process, reducing cogs by 40%. I also supported development of a new product by purifying it from one of the waste streams, and then worked with Business Development to estimate the market for it.

Intern, Mehta Partners, Vadodara, India (Winter 2008)

I analyzed biosimilar industry and diabetic neuropathy area, and supported the team working on acquisition of an Indian company by a global pharmaceutical firm.

Intern, Hoechst India Ltd., Mumbai, India (Summer 1992)

I studied conversion of penicillin into 6-amino penicillinic acid.

CERTIFICATIONS

Project Management Professional or PMP (August 2005)

Project Management Institute, Newtown Square, Pennsylvania, USA

Supervision Certificate Program (August 2000)

Interdisciplinary Biotechnology Certificate (December 1997)

University of Colorado, Boulder, Colorado, USA

PUBLICATIONS

- 1. V.T. Kuberkar and R.H. Davis. **2001**. Microfiltration of yeast-BSA mixture using crossflushing and backflushing. *Journal of Membrane Science*, **183**: 1–14.
- 2. V.T. Kuberkar and R.H. Davis. **2000**. Modeling of fouling reduction by secondary membranes. *Journal of Membrane Science*, **168**: 243–258.
- 3. V.T. Kuberkar and R.H. Davis. **1999**. The effect of added yeast on protein transmission and flux in crossflow membrane microfiltration. *Biotechnology Progress*, **15**: 472–479.
- 4. V.T. Kuberkar, P. Czekaj, and R.H. Davis. **1998**. Flux enhancement for membrane filtration of bacterial suspensions using high-frequency backpulsing. *Biotechnology and Bioengineering*, **60**: 77–87.
- 5. V.T. Kuberkar and R.H. Davis. **1997**. The effect of secondary membranes on protein transmission in a multicomponent system. *Proceedings of the 27th Biochemical Engineering Symposium* (Editor: V.G. Murphy), pp. 64–73.
- 6. S.G. Redkar, V.T. Kuberkar, and R.H. Davis. **1996**. Modeling of concentration polarization and depolarization with high-frequency backpulsing. *Journal of Membrane Science*, **121**: 229–242.

Kubrekar – abstract

Here is the brief write-up on the presentation:

The 'biosimilars' market space has four different players:

- 1. Biosimilars same molecule and same delivery
- 2. Drug products that are likely to have a biosimilar molecule but a better delivery mechanism.
- 3. Drug products that will have same amino acid sequence, but would be modified (glycans, Pegylation, etc) to have superior therapeutic benefit
- 4. Drug products that has different amino acid sequence but same targets as proven drugs

I will assess this likely evolution and fragmentation of the biosimilar market in my presentation. I believe that this richness of options would lead it to be a much larger market than the biosimilars itself. There will be regulatory challenges and they would be overcome on case-by-case basis depending on the quality of the science behind a particular approach.