

## Choosing a CMO and manufacturing of NCE API in India

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This case study presentation centers on steps that can be taken to achieve successful chemical development in India. The presentation talks about the chemical development of Crofelemer, the first botanical drug approved by United States Food and Drug Administration (USFDA). The Contract Manufacturing Organization (CMO) in India is a very reputed and successful generic manufacturer and this is the first New Chemical Entity (NCE) jointly developed with a US company. This was the first time the CMO from India was developing a small active pharmaceutical development (API) that did not involve chemical synthesis.

The case study will discuss strategies to deal with project management challenges that are difficult to anticipate. These challenges include resource limitations, communication and lack of infrastructure. This session will be helpful for delegates in the manufacturing, quality and project management departments of organizations that are working with or exploring opportunities for working with CMO's in India.

The presentation will examine a few specific examples of such challenges that are impossible to anticipate. I will also present strategies we used to address these challenges and how did we prepare to better anticipate the unpredictable and keep the project from slowing down.

### Biography

Kamalesh Rao is the founder of Lifescient, a CMC consulting company. He has more than 15 years experience in the pharmaceutical/biotech industry and has worked in US and India. He has held positions of increasing responsibilities and directed chemical development of more than 10 products. He brings with him an established network of contacts, both in US and India that will help clients establish a robust development program to meet aggressive timelines. His expertise is to help small to mid-sized companies manage chemical development, define regulatory strategy and relationship management. He is also a certified Yoga instructor in the San Francisco bay area and his focus is on stress management.

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