Five minutes with

Saharsh Davuluri

Managing director, Neuland Laboratories

Mitch Garcia of the C&EN Media Group had the opportunity to interview Saharsh Davuluri, managing director of Neuland Laboratories, about his company's achievements, the challenges his firm faces, and his career path.

What are your company's major accomplishments over the past 12 months?

The last 12 months have been very exciting for Neuland. We have started shipping commercial supplies of our first NCE API [new chemical entity active pharmaceutical ingredient] to the Japanese market. Given the general challenges of compliance set by Japanese regulators, it has given us at Neuland a great sense of satisfaction.

In addition, we've had two facilities inspected by the U.S. FDA, one for a PAI and another for a regular periodic audit. In the case of the inspection of our research facility, the FDA found no observations. In the case of the second inspection, there were two observations which were minor in nature. We understood from the FDA that Neuland's facilities were categorized as "low risk" from a cGMP [current Good Manufacturing Practice] noncompliance point of view. We consider this to be a major accomplishment, given the kind of challenges in cGMP that the industry faces.

Among the challenges the industry faces, which do you think are most pressing?

I think the number of cases emerging from inspections over concerns of basic adherence to cGMP and falsification of data in manufacturing records across various CMOs is a matter of grave concern. Pharmaceutical manufacturers play a key role in the health care supply chain, and these incidents are causing severe damage to the confidence of patients and health care professionals.

What areas of innovation or technology development in the company are you most excited about?

Neuland's business model is centered on excellence in API development and manufacturing. To develop robust, cost-effective, and environmentally friendly processes for commercial API manufacturing, Neuland recently created a "quality by design" (QbD) lab in our research center. It is equipped with state-of-the-art process engineering and analytical equipment that helps us study each reaction from a QbD perspective, generate data around safety and robustness, and ensure that we can face future expectations from regulatory agencies.

What are the major challenges that could impact your company's growth or plans in the near future?

Neuland's business model has been built on the dual pillars of high quality and our pure-play API model. We have a 33-year track record of making high-quality APIs and have always believed that adherence to quality supplies of API in a reliable manner supersedes all other business priorities.

Protecting this philosophy is our greatest challenge. At Neuland, we are vigilant about compliance, and as a result we are constantly assessing our quality systems to see how we can make them better.

What happened, in a milestone way, that made you choose industry as your career path?

Neuland was started by my father, D. R. Rao. In that way, the company's origins are in my DNA. However, I am an engineer by training and spent most of my career prior to Neuland in sales. It was only when I went back to business school in the U.S. and ended up in a biotech-focused venture fund in Research Triangle Park that I could appreciate the importance of the health care industry and the role that Neuland could play in it. This was in 2005 when venture capitalists were funding lots of biotech and pharmaceutical companies but didn't want them to invest in creating noncore infrastructure for chemistry and manufacturing.

Credit: Mitch Andre Garcia