

“We want to be a strategic partner for our customers”

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image not found or type unknown, president, Millipore India

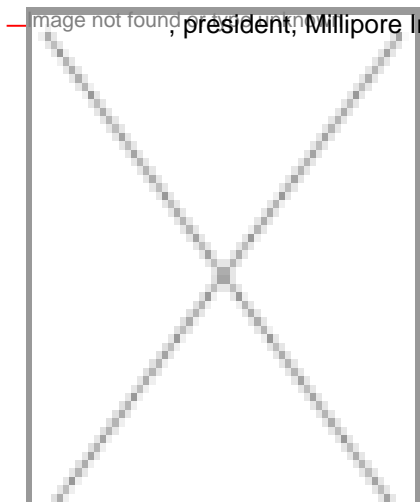
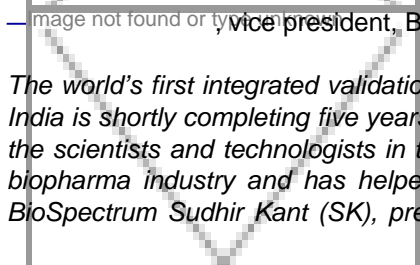


image not found or type unknown, vice president, Bioprocess, Millipore India



The world's first integrated validation and process development services lab, popularly known as the Access Lab in Millipore India is shortly completing five years of stellar service for pharma and biotech manufacturers in India. During these five years, the scientists and technologists in this lab have made a measurable difference to the quality of consultancy available to the biopharma industry and has helped manufacturers speed up their market entry initiatives. In an exclusive interview with BioSpectrum Sudhir Kant (SK), president, Millipore India and MS Mahadevan (MSM), vice president, Bioprocess, Millipore

India, share more insights.

When was the Access Services Lab opened in India?

SK: It was inaugurated by our worldwide chairperson in December 2003. It was approved in July 2004.

What was the thinking behind opening the Access Services Lab in India?

SK: Millipore always places the interests of customers before anything else. Before our Access Lab came into being, Indian biopharma manufacturers had to go to labs in the US and Europe for their validation and process development needs. This causes months of delay at a time when 'speed to market' was critical for their success. The cost incurred was also high due to more expensive services abroad. In addition customers faced tremendous difficulties in coordinating and communicating with the labs abroad. Millipore understood this pain point being faced by its customers and responded with the world's first integrated validation and PDS lab in Bangalore.

MSM: The result is that projects that used to take 6-9 months to complete in labs abroad are now being done in Bangalore where our labs deliver in 45 days to three months depending on the scope of the study/project.

What have been the achievements of the Access Services Lab over the last five years?

SK: Our Access Lab is the first one to deliver validation services for pharmaceutical and biotechnology manufacturers and start a filter validation lab in India. Through this lab we have worked with more than 30 top biopharmaceutical companies for filter validation and process development services. We have developed downstream processes for more than 10 biotech products and have trained more than 700 pharma and biotech customers through 'Back to School' training and paid certification programs.

What are the services offered by the Access Services Lab in India?

MSM: Millipore has always been at the forefront of validation support, process development and QA/QC. Millipore makes a measurable difference with a full range of services spanning validation, process development, process optimization, project management, microbiology, training and consultancy. The studies conducted at Millipore include extractable, bacterial retention, product integrity, filter compatibility and preservative binding tests. In addition we develop and optimize processes, we are good at aseptic processing and in developing/optimizing processes for difficult to manufacture biologics – particularly recombinant proteins and monoclonal antibodies. In fact worldwide seven out of every 10 units of MAbs manufactured involves partnering with Millipore.

Where else does Millipore Corporation have comparable labs?

SK: Other than India we have labs in Billerica (US), Molsheim (France) and Yonezawa (Japan). There is no difference in terms of the quality of infrastructure and expertise. We are more tuned to the specific needs of Indian customers, the regulatory requirements of advanced highly regulated markets (US and Europe) are being addressed by Indian manufacturers. We offer regulatory support and validation services for both biologics and pharmaceutical customers.

MSM: In addition to similar infrastructure, we have access to the same database. This is critical for being sure about our data and results. Our technologists are in regular touch with each other. Many of the trainings are common with either faculty from abroad coming over or our people being trained in the US and Europe. Work methods and protocols are the same. Plus we benefit from the presence of Millipore experts who consult constantly with regulators.

What has been the growth of the Access Services Lab in India?

SK: As a practice we do not share numbers. But we have been on target each year for the last five years. The return on our initial investment was recovered in the first nine months and our Compound Annual Growth Rate (CAGR) has been impressive. Almost all the top 30 Indian manufacturers have consulted with us and what is gratifying is that a high percentage keep coming back to us with more projects.

In which areas have you offered your solutions and services through the Access Lab?

MSM: Oncology, ophthalmics, recombinant proteins, monoclonal antibodies, anti-diabetics and sterile active pharmaceutical ingredients (APIs) are some of the most popular therapeutic areas. There are of course many other niche areas in addition.

What are the areas that you feel will emerge in future?

SK: Flexible bioprocessing solutions, mycoplasma, rapid microbiology are the new areas. We are also looking at an incubation center. In a couple of months we will organize an advanced training program to teach our customers to manage people and processes together. Disposables will become very popular in the coming years. The pace of acceptance is going to grow fast.

What is the profile of your technology group?

SK: Millipore has more than 80 years of combined industry experience. We have a dedicated team of experts who are either PhD holders or have a master degree in microbiology, biochemistry, pharmacology or chemical engineering. Millipore has

always concentrated on education. We have regularly been conducting training programs. In partnership with Eppendorf and Metrohm we have also launched a mobile lab, we have installed several equipments in it along with the literature. The lab moves from college to college and educate students by giving them demonstrations.

Ch Srinivas Rao and Jahanara Parveen