

## Datwyler starts commercial production at first line in Pune

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**Datwyler has been expanding its manufacturing site in Pune, India, which now starts commercial production according to First Line standard.**



Datwyler, the Swiss-based industrial supplier of state-of-the-art solutions for drug packaging and medical devices, presents its health care offering at this year's CPhI India in Greater Noida, Delhi NCR. As one of the strongest emerging markets in the global pharma industry, India will continue to be of key importance for the company in the future. Therefore, Datwyler started the expansion of the manufacturing site in Pune, India about a year ago and has completed it; the plant incorporates the First Line standard and starts commercial production now. "In the Indian market, Datwyler has been focusing on high-end rubber formulations for products like lyo and serum vials' stoppers, plungers for prefilled syringes and cartridges. With the introduction of the First Line manufacturing concept, the facility now is able to expand its portfolio with the innovative Omni Flex product line to meet the evolving needs in the health care market, especially for the biotech industry," explains Rahul Dev, Vice President India, Datwyler Sealing Solutions.

The CPhI India offers a platform, where international pharma experts network with over 50,000 representatives from 122+ countries and shape the future of the Indian and South East Asian pharmaceutical industry. At booth 14.A04, Datwyler will introduce visitors to its advanced solutions portfolio for the health care industry. Furthermore, visitors will learn more about the First Line manufacturing concept and the products which will be produced in the expanded site in Pune, India.

The Powerhouse of the Asian pharmaceutical industry

By leveraging lean production processes, building upon an optimized supply chain and entering emerging markets, Datwyler is prepared to master the challenges of the global health care industry. India, as the powerhouse of the Asian pharmaceutical industry, is one of these markets. There are two major reasons why India will continue to be of key importance in the future: the rapid growth and development of the pharmaceutical and biotech markets and the countries recognition as one of the global manufacturing destinations.

Datwyler values India as one of its most important markets. The production facility in Pune has been expanded in 2018 incorporating the latest First Line manufacturing standard and about 550 employees that now are working at this facility. An additional area of 24,000 m<sup>2</sup> is available for future growth. This second planned expansion would further double the capacity and could be ready by 2021.

## Omni Flex coating: Meets the highest demands for quality and performance

Within the parenteral packaging industry, market trends indicate a growing demand for coated fluoropolymer elastomeric closures, primarily to mitigate risks related to drug stability and compatibility. Due to the negative effects of extractables and leachables on protein structures and ultimately the drugs, many manufacturers of biologics or biosimilars are relying on fluoropolymer elastomeric closure solutions today. The Omni Flex coating is only produced in facilities incorporating the First Line manufacturing standard. This coating is designed to significantly reduce the risk of the medication interacting with the component's material. The lubricious barrier characteristics prevent the need of siliconization, eliminating interaction that could render the drug dangerously or make it ineffective. The Omni Flex coating is applied to a variety of components, including stoppers, plungers and specific small customized designs used in innovative drug delivery systems. The products which will be now produced in the expanded site in Pune, will be, among others, the V9048 and V9239 serum and compound FM259/0 OF+ 20mm serum stoppers. In addition, the entire non-coated stoppers portfolio, manufactured in alignment with the First Line standard, will be produced in India.

## State-of-the-Art Manufacturing Concept – First Line

First Line is specially designed to manufacture pharmaceutical elastomer components for vials and injectable drug delivery systems in a fully integrated good manufacturing practice (GMP) environment. The First Line standard incorporates state-of-the-art clean room technology, automatic production cells, fully automatic camera inspection and a unique washing process. The innovative manufacturing concept exceeds the highest quality standards of the European and American regulatory authorities and is certified according to ISO 15378. The implementation of this manufacturing concept in Pune, India allows the expansion of the portfolio with the innovative Omi Flex product line focusing on high-end rubber formulations for products such as plunger stoppers and customized rubber stoppers.