

# Business Standard

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## Rubicon inaugurates India's first cGMP facility for CTS

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Rubicon Research Private Limited announced the inauguration of its cGMP CTS facility at Ambarnath, 50 kms from Mumbai International airport.

Rubicon inaugurated a Clinical Trials Supply (cGMP) facility near Mumbai thus vertically integrating its business model in the area of formulation development. "with CTS Rubicon is taking an important step towards completing the spectrum of pharmaceutical development offerings. We envision a strong structure, where we are the perfect strategic partners for our clients, where we create novel scientific applications as well as product life cycle management option for our clients and partners" said Pratibha Pilgaonkar, CEO Rubicon Research Private Limited while giving the welcome speech during inaugural ceremony of its CTS facility. Dr. Clive G Wilson professor of Pharmaceutics in the department of Pharmaceutical Sciences at University of Strathclyde, Glasgow, Scotland delivered the key note address emphasizing on the value and nature of Clinical Trials and significance of cGMP. He emphasized that "with the many variables that may become apparent in the conduct of a clinical trial, the goal of cGMP and several other product related factors is to maintain the study integrity from a drug product perspective".

Rubicon's CTS facility will allow submission of CMC data for any NDA/ sNDA/ ANDA applications, thus eliminating the need of technology transfer to other companies thereby protecting the Intellectual Property. Clinical trial supplies can be organized for multicentric trials in a structured way from this facility.

This is a first of its kind facility in India, offering the entire gamut of Clinical supplies, from Clinical manufacturing to Clinical Trial Material (CTM) depot. From the new facility, Rubicon also would extend for its clients its expertise and services in its current core areas of Formulation Development, Analytical Development, Stability Studies and Technology Transfer.

Rubicon's CTS facility has a built up area of 6,500 sq mts, with an additional area of around 8000 sq mts earmarked for future expansion. The facility has been built in consultation with a US Regulatory agency and is designed to meet USFDA /MHRA regulatory norms.

The Unique Selling Proposition (USP) of this facility other than being a one stop shop for Clinical supplies is its flexibility to manufacture batches from development quantities (< 5kg batch size) to 100,000 units (120 kg batch size) and its Containment Suite to handle NCEs and High Potency compounds along with Packaging capabilities to accommodate complex CTS requirements like blinding, randomization, patient packs etc.

**About Rubicon Research Private Limited:**

Rubicon Research Pvt. Ltd. is an independent product development company headquartered in Mumbai, India. It was established in 2000 as a contract research service company. Rubicon specializes in new drug formulations and has international JVs in the area of generic products for complex molecule. It also has the capability of rendering marketed product support e.g. range extension of existing products, combination products with optimized PK parameters of component products and other life-cycle management options. Rubicon has interesting and viable technology platforms which offer practical solutions to commonly faced problems in the drug development process. These are covered by international patent applications.