Press Release

SOTAX Pharma Services celebrates GMP certification for its Indian site.

SOTAX Pharma Services India can confirm that Ortiv-Q3, a SOTAX joint-venture has received FDCA certification of compliance with Good Manufacturing Practice (GMP) for the testing of drugs and raw materials.

July 2022: The SOTAX Group is pleased to announce that less than one year after the inauguration of its site located in Ahmedabad, Gujarat (India), the facility has received its GMP certificate (Form 37, Lic n° GTL/37/70). Ortiv-Q3 has been inspected by the Food and Drug Control Administration and found meeting the requirements for GMP testing of drugs and raw materials.

This is the successful outcome of an in-depth Food and Drug Control Administration (FDCA) inspection. The certificate demonstrates compliance to safe practices and enables SOTAX Pharma Services to extend its offering to customers, supporting pharmaceutical developement from discovery and early development of candidate molecules to manufacturing drug products for clinical trials.

The FDCA GMP accreditation is the culmination of almost two years investment which has not only created a state-of-the-art facility but also brought together a dedicated team of experts specializing in pharmaceutical products testing. This significantly strengthens SOTAX position as a trusted partner to pharmaceutical, biotech, and animal health companies, relieving these clients of the burden of carrying out their own GMP audit and enabling them to speed their products through to the clinic.

Mukesh Kumar (Founder, Director Ortiv-Q3) highlights the importance of the FDCA certification to clients: “We work in partnership with our clients to deliver tailored, high quality and comprehensive Pharma Services, so having a GMP-certified facility further simplifies collaboration by providing upfront assurance that our facilities are compliant”.

“The past months were very exciting time for us. Our integration with SOTAX Group has allowed us to move beyond the limitations of other contract laboroatories – the team has worked tirelessly to achieve the defined targets: state of the art facility, clear processes, backed by a robust Quality system” comments Pawan Gupta (Founder, Director Ortiv-Q3) on achieving GMP accreditation.

”This most recent achievement extends the journey we take with our clients, empowering all companies – no matter their size – to experience a faster and reliable partnership, in complete confidence that their project is in the safest hands with our team” adds Ashish Gupta (Executive Director Ortiv-Q3).

Samir Haddouchi (Managing Director of SOTAX Pharma Services) concludes: “We have always been driven by a strong desire to be the best partner we can be to our clients. This means working to the highest standards, and the FDCA’s accreditation of our compliance with GMP is a clear reflection of how our people, infrastructure, skills, and processes combine to achieve excellence for our customers.”

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About SOTAX:
The SOTAX Group is an international leader in the development and manufacturing of equipment for dissolution testing, automated sample preparation and physical testing of pharmaceutical dosage forms. With a global network of service engineers, the company is also a trusted provider of technical services (e.g. instrument installation, maintenance, repair, and qualification services) as well as pharma services (e.g. R&D, routine testing, and support services).

For more information about SOTAX visit www.sotax.com.