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Critical aspects for clinical trials

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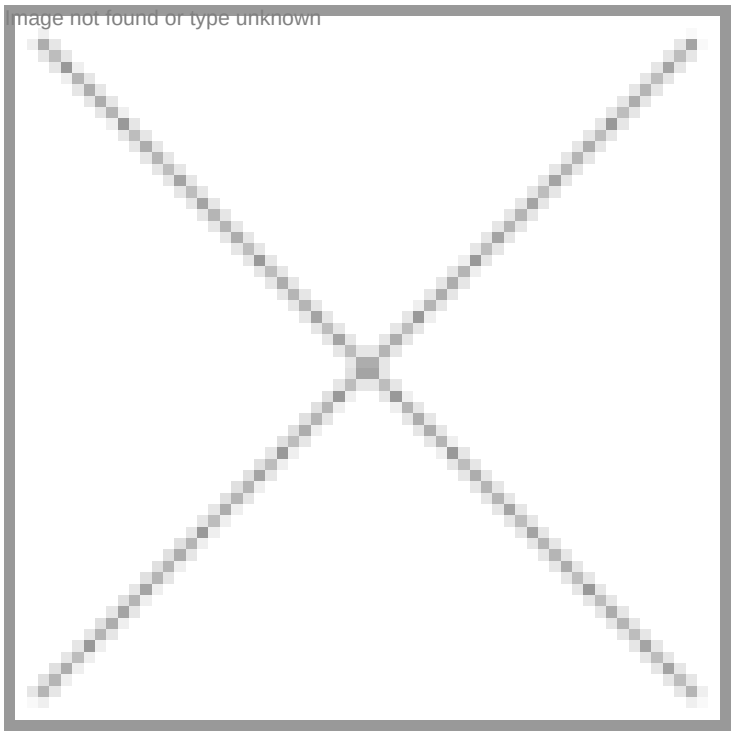

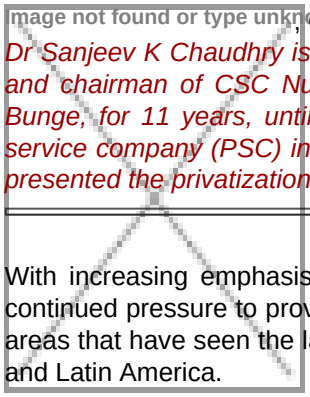

, CEO, Super Religare Laboratories, New Delhi

Dr Sanjeev K Chaudhry is presently the chief executive officer of Super Religare Laboratories; director of Religare Wellness; and chairman of CSC Nutrigenomics, Singapore. He was the South Asia Head of Solae, a joint venture of DuPont and Bunge, for 11 years, until June 2006. In 1989, Dr Chaudhry, at 30 years of age, became the youngest CEO of a public service company (PSC) in India. He earned accolades for turning around the ailing state-owned Modern Food Industries. He presented the privatization plan of India's first state-owned enterprise to the Planning Commission.

With increasing emphasis on treatments that can improve and prolong human life, pharmaceutical companies are under continued pressure to provide enhanced and newer therapies. This has led to an explosive growth in new drug research. The areas that have seen the largest growth include emerging markets such as India, Asia Pacific, parts of Eastern Europe, Africa and Latin America.

The increased number of clinical trials in trial-näive countries is posing significant challenges to regulators all over the world. To overcome these challenges, regulators in the US (US FDA), European Union and Japan are putting considerable emphasis on:

- Validation of scientific methodologies to verify if the study will yield reliable and interpretative results
- Selection of patients through a robust informed consent process
- Strict adherence to inclusion and exclusion criteria as defined in the trial protocol
- Continuous monitoring of safety data

- Analysis of any adverse events and/or serious adverse events to balance risks and benefits of the trial
- Adherence to International Conference on Harmonization-Good Clinical Practice (ICH-GCP) guidelines

The central laboratory services provide the crucial infrastructure and support to the pharmaceutical industry to address these critical issues. Selecting a reliable central laboratory provides consistent quality, complete, secure, timely and retrievable data and accurate reporting.

A central testing laboratory provides support functions like data management, information technology, project management, operations, logistics, kit assembling, quality assurance, accessioning and materials.

Accreditations such as college of american pathologists (CAP) and national accreditation board for testing and calibration laboratories (NABL) ensure technical competence of the staff, instrumentation, methodologies, documentation, and also endorse quality framework and its management systems that need to be followed to perform and report reliable and clean results.

It is absolutely critical to have a reliable central laboratory, as this will set the trend for inclusion/exclusion criteria, unbiased and blinded reporting, customized database, confidentiality of data, subject protection and finally, the future of the drug under evaluation.

Key differentiators that a central laboratory brings on table

- Reliable testing and calibration services
- Reliable delivery of accurate and timely data
- Test design and statistical validity
- Primary instruments as well as the backup instruments/methodologies in place, that ensure business continuity and reliability
- Setting up and validation of protocol-specific laboratory assessments, or conduct method transfer and validations
- Flexible reporting options in terms of conventional and SI units, flagging of critical alerts, deltas, trend analysis
- Support to extensive menu of safety and specialized clinical testing
- Seasoned and GCP-trained operations staff, ensure business continuity and safety compliance
- Support to a wide range of therapeutic areas