

MTR HAS SUCCESSFULLY CLEARED USFDA INSPECTION

MTR study centres (Clinical and BioAnalytical, Selayur and Chrompet facility) saw a surprise (unannounced) inspection by a 3 member USFDA team from 17th May 17 to 26th of May 17. The company is of the view that this unannounced inspection could have been triggered due to number of studies done at our centres that have been filed to support the ANDAs by Pharmaceutical firms based in India and abroad. Recent, adverse regulatory development emanating from EMA for our centre could have been one of the reasons as well.

While MTR has moved on from the EMA decisions on the studies, the surprise USFDA inspection was a blessing in disguise and was an opportune event to establish the commitments that we have been giving to you in terms of the level of compliance followed at our centre.

USFDA inspections have been successfully cleared with only one minor and couple of minor observations at Selayur and Chrompet facility, respectively. Post the EMA decision, the company had also hosted a review of its centre by one of the World's leading inspectors in this area (ex-WHO Head of Inspections) and he had also cleared the facility to be in compliance with global regulatory requirements.

The EMA's criticism has been taken very positively by the company and it has actually led the institute to further improvements in the level of compliance and Quality Management system operating at the site. The agency was a bit harsh on the company in terms of extending the timelines of its decision, affecting studies which should not have been, thus unduly affecting our partners. MTR's plea in this regard was not accepted and it humbly accepted the same.

The company accepted EMA's criticism and decision with all humility.

While different agencies have their own evaluation standards and may throw up different outcomes, as a responsible leadership, Dr.M.Ganesan is stated that the centre has been following the best of compliance and has been meeting all the standards set up across the globe to carry out BA-BE studies.