

New Drugs and Clinical Trial Rules, 2019

Schedule: 25th July 2020 – 11.00 am to 12.30 pm

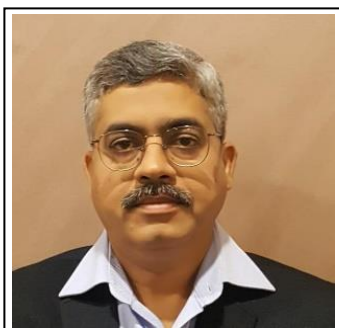
The New drugs and Clinical trials rules 2019 was introduced on 19th March 2019 by Government of India. All existing licenses, orders, directions will continue to remain valid. The most important among those issues are those aimed at reviving the clinical research industry in India, bringing more global clinical studies to India and promoting Indian indigenous drug development.

Overall, the new rules are comprehensive, well-balanced and will likely improve the ethical and quality standards of clinical trials in the country, which also will further benefit patients and industry.

TOPICS:

- 1) Impact of CTR 2019 on the drug development process and commercialization.
- 2) Phase IV and Post-market surveillance implications.
- 3) Features of the new CTR 2019 related guidelines. Changes in current rule before & after CDSCO
- 4) How the rule has affected in the current situation?
- 5) Challenges CRO Industry in facing in running BA BE study for CRO Industry in covid pandemic situation
- 6) Why the CDSCO made changes in the CTR rule 2019?

SPEAKERS:



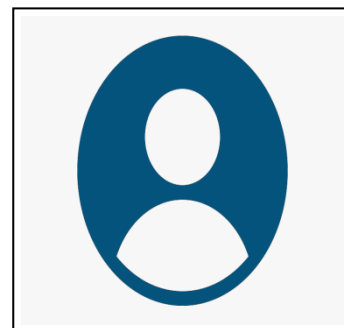
Dr. Abhay Muthal
Sr VP RA Slayback Pharma



**Dr. Rajendran
Sankhmedev Devendran**
Director Scitus Pharma
Services Pvt. Ltd.



Dr. Bangarurajan
Ex Jt Controller CDSCO



Niles Saluja
VP Regulatory Science
Mylan

Who should attend?

Clinical Trial Team members, Regulatory Team members, Pharmacovigilance
Medical Team members.

Single delegate Fees: 2000/-