



**Training on ICH-GCP and Indian Regulations in Clinical Trials**  
**18 Jul 2015**  
**Hotel Goldfinch**  
**Bangalore**

<b>Time</b>	<b>Topic</b>		
09:15	09:30	Introduction & Welcome	
09:30	10:00	Why is GCP required – Overview of new drug development	Dr Prem Pias (tentative)
10:00	10:30	Coffee Break	
10:30	11:00	Clinician as an Investigator	Dr L Sreenivasa Murthy
11:00	12:00	Investigator Obligations: <ul style="list-style-type: none"> <li>- Informed Consent</li> <li>- Detecting and Evaluating AE's/SAE's: Causality Assessment</li> </ul>	Dr Srikanth Krishnamurthy
12:00	12:45	Investigator Obligations: <ul style="list-style-type: none"> <li>- Managing Investigational Product</li> <li>- Handling Data and Documents</li> </ul>	Novo Nordisk Personnel
12:45	13:45	Lunch break	
13:45	14:15	Panel Discussion <ul style="list-style-type: none"> <li>- Current Regulations in India</li> <li>- Q&amp;A</li> </ul>	Dr L Sreenivasa Murthy Dr Srikanth Krishnamurthy Novo Nordisk Personnel
14:15	15:00	Sponsor's responsibilities <ul style="list-style-type: none"> <li>- Monitoring of Clinical Trials</li> <li>- Audits &amp; Inspections</li> </ul>	Novo Nordisk Personnel
15:00	15:45	Ethics Committee Responsibilities	Novo Nordisk Personnel
15:45	16:15	Wrap up & Certificate Distribution	
16:15		Tea & Departure	

**About Speakers**

### **Dr L Sreenivasa Murthy**

MBBS, MD (Internal Medicine), PDCR

Bangalore based diabetologist and physician, Dr. L Sreenivasa Murthy's 14 year long medical career has been a very research oriented one, apart from being rich in medical experience.



Dr. Sreenivasa Murthy has completed his MBBS and MD (Internal Medicine) from Dr. B R Ambedkar Medical College (Bangalore) and KIMS, Rajiv Gandhi University of Health Sciences (Hubli) respectively. He further underwent Advanced Diploma in Clinical Research which provided him with a clear insight into Good Clinical Practice and a good comprehension of Standard Operating Procedures for Clinical Research and Clinical Data Management.

Besides being associated with prominent medical institutions like Life Care Clinic and Research Centre, Columbia Asia Hospital, Fortis Hospitals and Cauvery Medical Centre. He has authored a multitude of books which have made their presence in reputed publications. He has an impressive track record for research activities and has conducted abundant clinical trials. He is a regular member in CME programs, medical conferences where he has presented award winning papers and delivered lectures on relevant areas of interest besides having gained in-depth scientific knowledge.

### **Dr Srikanth Krishnamurthy**

Former Professor and HOD department of respiratory medicine at PSG  
Consultant Pulmonologist,  
Sri Bala Medical Centre and Hospital, Coimbatore

A leading pulmonologist, he has lot of passion for patient care. He is one of the few practitioners who clearly understands drug development and also encourages his colleagues to get into research. He is an ardent supporter of activities of Indian Society for Clinical Research and is a front-runner of its initiatives.