# RTPMED-2013

## Three Days Intensive Residential Training Programme on

# Toxicity, Safety, Biocompatibility Evaluation of Materials, Medical Devices and Combination Products

### Invitation

It is a great pleasure and a privilege to invite you to the three days Intensive Residential Training Programme on 'Toxicity, Safety, Biocompatibility Evaluation of Materials, Medical Devices and Combination Products' organized by Sree Chitra Tirunal Institute for Medical sciences and Technology (SCTIMST), Thiruvananthapuram, Kerala, India from 17 to 19 February 2014.

It is a unique event where all the distinguished scientists, researchers and technologists from various parts of India are expected to participate. The technical sessions will provide wide opportunities for informal and intensive exchange of views on emerging ideas in the fields of Toxicity, Safety, Biocompatibility Evaluation of Materials, Medical Devices and Combination Products.

The objective of the three days Intensive Residential Training Programme is to discuss and share an in-depth knowledge of the recent advances in the evaluation of biomaterials, medical devices and combination products. This structured training programme will be an update on the current status of biocompatibility evaluations as per ISO, FDA and EU regulations. The know how originated from this training will be greatly useful for the scientific community, technologists, industry or regulatory authority for sharing the new trends in the safety, biocompatibility evaluation of materials, medical devices and combination products.

The organizing Committee invites you to participate in this 3 days training programme and a warm welcome awaits you at SCTIMST, Thiruvananthapuram, the capital of Kerala and God's own Country. Please accept our invitation and do honour us with your participation.

**Participants** The participants of the conference will be biologists, toxicologists, material scientists, technologists, regulators, young scientists in any area of biomaterials and medical devices. Registration is on first come first serve basis.

### Course Fee

Rs. 17000/- for industry and Rs.13000/- for academic (before 30th October, 2013). Rs. 18000/- for industry and Rs.14000/- for academic (before 30 December 2013) for three days residential training. The course fee includes, registration, course material with CD, Training certificate, accommodation charges for three nights (shared accommodation), three days break fast, lunch and dinner.

For those not seeking accommodation, Rs. 10000/- for Industry and Rs. 6000/- academic (before 30th October, 2013). Rs. 12000/- for industry and Rs. 7000/- for academic (before December 2013) for three days symposium. The course fee includes registration, course material with CD, Training certificate, lunch and coffee.

**All payments should be send by a crossed demand draft in favour of '*The Organizing Secretary, RTPMED-2013*' payable at Trivandrum.**

### SCTIMST

Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) is an Institute of National Importance under the aegis of the Department of Science and Technology, Government of India. The Institute signifies the convergence of medical sciences and technology and its mission is to enable the indigenous growth of biomedical technology, besides demonstrating high standards of patient care in medical specialties and evolving postgraduate training programs in advanced medical specialties, biomedical engineering and technology, as well as in public health. The Biomedical Technology Wing of SCTIMST has been engaged in the research & development of medical devices and biomaterials for over two decades and has built up extensive expertise and facilities. Institute has played a pioneering role in the development of the medical device industry in India by developing and successfully commercializing a wide range of biomedical devices and implants. The BMT Wing is also accredited as per ISO/IEC 17025 by the COFRAC, France for testing biocompatibility of materials and its physicochemical characterization (www.sctimst.ac.in)

### Access

Thiruvananthapuram, also known as Trivandrum, is the capital of the Indian state of Kerala famed as 'God's own Country'. The city's long beaches, palm fringed backwaters, enchanting picnic spots, historic monuments, and a rich cultural heritage have positioned the city in all tourist maps. It is located on the west coast of India near the extreme south of the mainland and is characterized by its undulating terrain of low coastal hills and busy commercial alleys. The city is the state capital and houses many central and state government offices, organizations and companies. Apart from being the political nerve centre of Kerala, it is also a major academic hub and is home to several educational institutions.

Thiruvananthapuram is well connected by Air, Rail and Road.

For details visit: *http://www.kerala.gov.in http://www.keralatourism.org*

### Climate

It is advisable to wear natural fibres than synthetic fibres as the climate of Thiruvananthapuram is quite humid. The weather in Thiruvananthapuram is pleasant throughout the year and in February (21-27°C), it is most salubrious and is a good season for the tourists.

### Organizing Committee

**Patrons** : **Prof. Jagan Mohan Tharakan** *Director, SCTIMST*

**Dr. KS Rao,** *President, Association of Toxicology, India*

**Co-Patron** : **Dr. CP Sharma,** *SCTIMST*

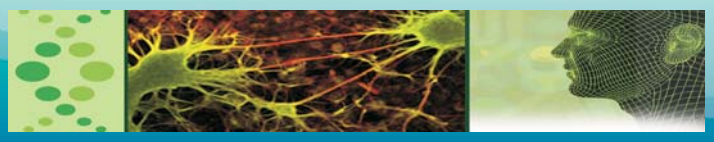
**Chairman** : **Mr. CV Muraleedharan,** *SCTIMST*

**Co-Chairman** : **Mr. DS Nagesh,** *SCTIMST*

**Organizing Secretary** : **Dr. PV Mohanan,** *SCTIMST*

**Jt. Organizing Secretary** : **Dr. V Gayathri,** *SCTIMST*

**Treasurer** : **Dr. A Maya Nandkumar,** *SCTIMST*



*Organized by*

**Sree Chitra Tirunal Institute for Medical Sciences and Technology**

Govt. of India, Thiruvananthapuram, Kerala, India

*In Association with*

**Association of Toxicology, India**

## February 17-19, 2014

**Venue**

The Residency Tower

Press Road, Opp. Secretariat, Trivandrum, Kerala

### Course Schedule

| Time | Topic |
|---|---|
| | **17 Feb 2014 - Monday** |
| 9:00 - 9:30 | **Inauguration** |
| **9:30 - 10:00** | **Science and Technology activities in Biomaterials and Medical Devices in India: Dr. Rajiv Tayal,** DST New Delhi |
| 10:00 - 10:30 | **Tea** |
| 10:30 - 11:30 | **Medical Devices**<br>**A:** Medical Devices Defenitions & Markets<br>**B:** Approaches to Safety Evaluation in Device Development<br>**C:** Reviewing Prior Art: Sources of Information for Consideration in Study Program Design |
| 11:30 - 13:00 | **Regulatory Requirements:**<br>**D:** FDA, ISO and Pharmacopeia Requirements (ISO 10993-1)<br>**ICH Requirements:** |
| 13:00 - 14:00 | **Lunch** |
| 14:00 - 15:30 | **Toxicity:**<br>**E:** Toxicological Manifestations, Mechanisms and Endpoints<br>**F:** Road Map to Testing (ISO-10993-1) and ICH M-3 (R2) |
| 15:30 - 16:00 | **Break** |
| 16:00 - 17:30 | **G:** The CMC section: Physical and Chemical Properties of Materials<br>**H:** Sample Selection and Preparation (ISO-10993-12)<br>**When the drug component is the Principal Mode of Action in a Combination Product** |
| 19:00 - 21:00 | **Social Hour for Networking and Dinner** |
| | **18 Feb 2014 Tuesday** |
| 8:00 - 10:00 | **I:** Acute Systemic Safety Tests (ISO-10993-11)<br>**J:** Cytotoxicity (ISO-10993-5)<br>**K:** Hematocompatability (ISO-10993-4) |
| 10:00 - 10:30 | **Tea** |
| **10:30 - 11:00** | **Medical device regulations in India: Dr. S Eswara Reddy** Deputy Drugs Controller (India), CDSCO, HQ, New Delhi |
| 11:00 - 12:00 | **L:** Local Tissue Tolerance: Irritation & Pyrogenicity (ISO-10993-6), (ISO-10993-10)<br>**M:** Immunotoxicity (ISO-10993-20) |
| 12:00 - 13:00 | **Lunch** |
| 13:00 - 15:00 | **N:** Genotoxicity (ISO-10993-3)<br>**O:** Implantation Studies (ISO-10993-6), (ISO-10993-8) |
| 15:00 - 15:30 | **Tea** |
| 15:30 - 17:00 | **P:** Subchronic and Chronic Toxicity Studies Under New FDA Interpretation<br>**Q:** Reproductive & Developmental Toxicology (ISO-10993-3) |
| 17:00 - 18:30 | **Evening Session:**<br>Case Histories and Problem Resolution |
| 19:00 - 21:00 | **Dinner** |
| | **19 Feb 2014 Wednesday** |
| 8:00 - 10:00 | **R:** Carcinogenicity (ISO-10993-3)<br>**S:** Toxicokinetics for Medical Devices (ISO-10993-16)<br>**T:** Contracting Studies to Outside Laboratories<br>**U:** Risk Assessment for Medical Devices (EN 14971) |
| 10:00 - 10:30 | **Tea** |
| **10:30 - 11:00** | **Good Laboratory Practice: Chemicals Vs Medical Devices** |
| 11:00 - 12:00 | **V:** Safety Considerations for Combination Products<br>**W:** Leachable and Extractable (L&E) Studies and Associated Risk Assessment |
| 12:00 - 13:00 | **Lunch** |
| 13:00 - 14:00 | Leachable and Extractable Studies and Notified Bodies (EU) and the SFDA (China) |
| 14:00 - 15:00 | **AA** - Special Studies<br>**AB** - Clinical Safety Trials and Epidemiology Studies for Medical Devices |
| 15:00 - 15:30 | **Tea** |
| 15:30 - 17:00 | **AC** - FDA Regulatory Submissions: IDEs, INDs, 510(k)s, PMAs, and NDAs |

### Course Director

**Dr. Shyane Cox Gad, USA**

Whittier College, Chemistry and Biology (1970) and Ph.D. in Pharmacology/Toxicology (Texas, 1977) DABT, ATS, is the principal of Gad Consulting Services, a seventeen year old consulting firm with six employees and more than 500 clients (including 50 medical device companies in the US and 20 overseas). Prior to this, he served as director-level and above positions at Searle, Synergen and Becton Dickinson.

He has authored or edited more than 44 published books and more than 350 chapters, articles and abstracts in the fields of toxicology, statistics, pharmacology, drug development and safety assessment. He has more than 35 years of broad based experience in toxicology, drug and device development, statistics and risk assessment. He has specific expertise in neurotoxicology, in vitro methods, cardiovascular toxicology, inhalation toxicology, immunotoxicology, and genotoxicology. Past President of the American College of Toxicology, the Roundtable of Toxicology Consultants and three of SOT's specialty sections, and recipient of the American College of Toxicology Lifetime Contribution Award. He has direct involvement in the preparation of INDs (93 successfully to date), NDA, PLA, ANDA, 510(k), IDE, CTD, clinical data bases for phase 1 and 2 studies, and PMAs. He has consulted for FDA, EPA and NIH, and has trained reviewers and been an expert witness for FDA. He has also conducted the triennial toxicology salary survey as a service to the profession for the last 22 years.

### Faculty

**Dr. Rajiv Tayal**

*Advisor, Department of Science & Technology, New Delhi*

Rajiv Tayal has a basic background in Chemical Engineering. In the beginning of his professional career, he worked in industrial R&D dealing with various facets of technology development, viz., process engineering, design, scale up and project appraisal, implementation and management.

He is currently working in the Department of Science & Technology (DST) for the last twenty five years, dealing with policy framework and direct interventions through a vast range of schemes and programmes related to promotion of scientific research and capacity building, particularly in the area of engineering sciences. Over the years, he has presided over some of the best and most efficiently managed R&D programmes in DST and elsewhere, receiving wide acclaim from the research community.

**Dr. S Eswara Reddy**

*Deputy Drugs Controller (India), CDSCO, HQ, New Delhi.*

Dr. S. Eswara Reddy has obtained his Masters Degree in Pharmacy from College of Pharmaceuticals Sciences Manipal in 1994 and Ph.D from J.N.T.U, Hyderabad in 2009. He has experience in manufacturing of pharmaceuticals, academic and in regulations.

He started his carrier as a Drugs Inspector in CDSCO, West Zone, Mumbai in 1998 and has good experience in GMP, GCP and GLP audits and promoted as a Assistant Drugs Controller of India in 2009. He participated in many national and international seminars/workshops/meetings on various areas of Drugs regulations and undergone training from USFDA, KFDA, South Korea and WHO, Geneva. He got Best Drugs Inspector award in 2005 and Distinguished Alumni Award from Manipal Academy of Higher Education, Manipal. Dr. Reddy has been awarded with appreciation letters from his superiors for effective implementation of Drug Regulations. He also published articles in various journals. At present Dr.Reddy is working as a Deputy Drugs Controller of India at CDSCO HQs, New Delhi to assist DCGI in implementation of various provisions of Drugs And Cosmetics Act and Rules including Import Registration of Medical Devices and Diagnostic Kits and other activities.

All lectures with the exception of India specific talks will be offered by Dr. Gad, who is a world renowned expert in the field.

### Contact Address


**Dr. PV Mohanan**

Organizing Secretary, RTPMED-2013

Scientist & Head, Toxicology Division

Biomedical Technology Wing

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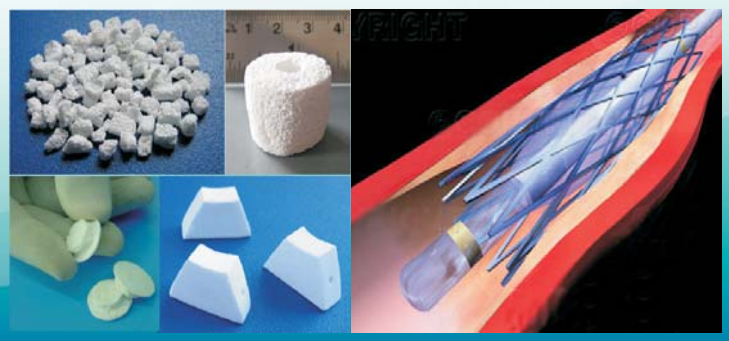

**REGISTRATION FORM**

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**'Toxicity, Safety, Biocompatibility Evaluation of Materials, Medical devices and Combination Products'**

1. Name :
2. Sex :
3. Designation :
4. Organization :
5. Address :
6. Email :
7. Mobile and Land Phone Number :
8. Registration with accommodation (shared accommodation) : Yes/No
9. Mode of Pay :
10. Signature :

**Address for communication:**

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