

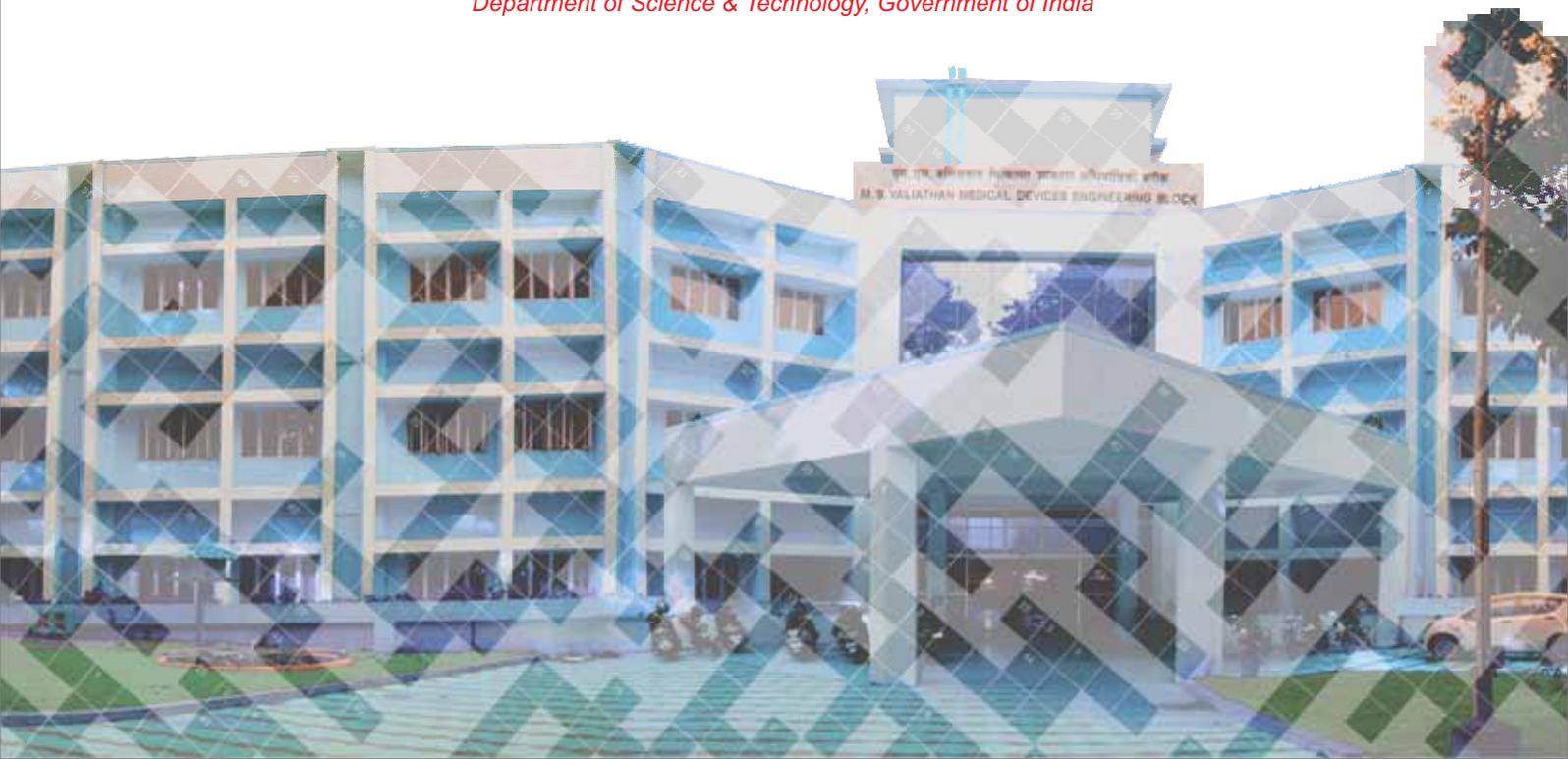
Biological Safety & Efficacy Evaluation of Medical Devices

19-21 March 2018



**Industry Institute Partnership Cell
Sree Chitra Tirunal Institute for
Medical Sciences & Technology**

*an institute of national importance under
Department of Science & Technology, Government of India*



Sree Chitra Tirunal Institute for Medical Sciences & Technolog (SCTIMST) has played a pioneering role in the development of medical devices industry in India by developing and successfully commercializing a wide range of biomedical devices and implants such as the Heart Valve, Blood Bag, Oxygenator, Vascular Graft, Hydrocephalus Shunt, Haemoconcentrator, Dental Composites, Bioactive Composites for Orthopedics, Emily IUS etc.

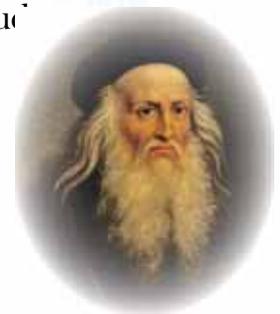
The Biomedical Technology Wing of the SCTIMST has been engaged in the research and development of medical devices and biomaterials and has built up extensive expertise and facilities. Its laboratories are now accredited by COFRAC, France under ISO/IEC 17025 for testing of medical devices and materials.

The process of medical device development is complex and need inputs from varied disciplines of science and technology. The process of medical device development and associated aligned areas of biomedical technology therefore requires extensive learning.

Biomedical Technology Wing of SCTIMST has traveled through this arena for more than thirty years now. The medical device industry being at a budding stage in India and various start ups emerging, the Institute recognizes that the expertise and experience that has been gained through the years are to be shared with the medical device industry, the researchers and stu

**“Learning is the only thing the
mind never exhausts, never fears,
and never regrets”**

..... Leonardo da Vinci



The Institute has its Industry Institute Partnership Cell (IIPC) with focus on services like training, problem solving and consultancy in existence for more than a decade now. To support the medical device industry and the start ups in enhanced learning of Biomedical Technology, the IIPC now launches a series of training programs which shall be pre-scheduled for the entire year on various selected topics.

The participants are free to register to any of the programs of IIPC before the last date of registration.

Payment can be send as cheque/DD in favour of "The Director, SCTIMST" payable at Thiruvananthapuram or can be transferred online by giving due intimations. Please note that the GST rates as applicable are to be paid extra.

If any custom made training programs are to be arranged, the same shall be entertained by IIPC subject to the mutual convenience. You may convey the same to us through our email.



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Supported By
Association of
Medical Device Industry



Course Objective

- ✕ The course provides learning experience on:
- ✕ The importance and use of biological evaluation for medical devices.
- ✕ Classification of medical devices.
- ✕ A risk management process for biological evaluation.
- ✕ Tests for cytotoxicity.
- ✕ Toxicological evaluation
- ✕ Histopathological evaluations.
- ✕ Selection of tests for interactions with blood.
- ✕ In vivo safety / performance evaluations.
- ✕ Biological evaluation matrix for medical devices.
- ✕ Regulatory submissions on biological evaluation.

Course Outcome

The course shall provide the skill to the participant to:

- ⊙ Classify the medical devices.
- ⊙ Select the tests required for medical devices.
- ⊙ Develop a biological evaluation matrix.
- ⊙ Understand the technicalities involved in the biological evaluation.

Target Audience

The course is intended for professionals who are in the Preclinical, Regulatory, Quality Assurance related activities. R&D professionals /Research scholars in Medical Device Development shall also register. The maximum intake for the course is 50.

Registration

Participants are to register by filling the form available at the website and paying the course fee. Last Date of registration is 12th March 2018.

Course fee

Option A: Rs 15,000 (18% GST included) (For Medical Device Industry)

Option B: Rs 12 500/- (18% GST included) (for AIMED members and Start ups)

Sessions

- ★ Medical Device Classification as per Regulatory Norms
- ★ Systematic Approach to Biological Evaluation
- ★ Physiocochemical Characterisations
- ★ Evaluation and Testing within Risk Management Process - ISO 10993
- ★ Tests for In vitro cytotoxicity, Toxicological Evaluation of Medical Devices, Blood Compatibility of Medical Devices as per ISO 10993 and Data Evaluation
- ★ Biocompatibility and Preclinical Evaluation of Medical Devices - Histopathology
- ★ In vivo Safety and Performance Evaluation of Medical Devices
- ★ Device Regulations and Regulatory Submissions

Course kit

The course kit shall contain the course materials and white papers related to the course in USP and other amenities.

Attendance

The attendance on the three days is compulsory for the course. Certificates will be issued to the delegates on the final day of the program.

Visit to the testing facility

A one day visit to the testing facility of Biomedical Technology Wing shall be part of the course.



Bank details of the Institute: SCTIMST

PAN Number: AAAJS0437M
Account Number: 57001148263
IFSC Code: SBIN0070032
GST No: 32AAAJS0437M1Z4

Demand draft in favour of

“The Director, SCTIMST”
payable at Thiruvananthapuram

For further enquiries

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The Industry Institute Partnership Cell (IIPC) was initiated with an approval and funding from AICTE, New Delhi and subsequently encouraged and stabilized by SCTIMST with a mandate to develop awareness and relevance of quality consciousness in the development of biomedical technology in the minds of Industrial personnel in India. The IIPC intends to do this through a series of structured symposiums and appropriate workshops. Participants are offered an opportunity to learn from and share the expertise built by the institute. They can interact with the faculty, have laboratory visits and exposure to the facilities and expertise available and explore future collaborative programmes.

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