

JSS ACADEMY OF HIGHER EDUCATION & RESEARCH, MYSURU

(Deemed to be University – Accredited 'A+' Grade By NAAC)

JSS COLLEGE OF PHARMACY, OOTY, TAMILNADU, INDIA

(An ISO 9001:2015 Certified Institution)

(Ranked 8th in India by NIRF - 2019)

(QS 3Star in Pharmacy & Pharmacology)



AICTE Sponsored
International Conference on Current Regulations
for Medical Devices & *In Vitro* Diagnostic
18th & 19th October 2019

JSS Academy of Higher Education & Research, Mysuru

JSS Academy of Higher Education & Research (JSS AHER), formerly known as JSS University is located in Mysuru, Karnataka. It was established in 2008 under Section 3 of the UGC Act 1956 and is part of JSS Mahavidyapeetha, which runs a diversity of educational institutions. This deemed-to-be university is recognized by MHRD and re-accredited by NAAC with "A+" Grade. The Academy has been focusing more on teaching, research and service from its inception. Under the leadership and gracious Patronage and blessings of His Holiness Jagadguru Sri Shivarathri Deshikendra Mahaswamiji, the Chancellor of JSS Academy of Higher Education & Research and Pro Chancellor, Dr.B.Suresh, a noted multifaceted leader of repute, the academy has made great progress in grooming graduates, postgraduates, and PhD researchers by providing effective value based education across our institutions by focusing on overall development of an individual through state-of-art facilities to make the learner a responsible citizen to the society.

JSS Academy of Higher Education & Research is focused on medical and health related studies, and comprises JSS Medical College, JSS Dental College and JSS College of Pharmacy at the campus in Mysuru as well as another pharmacy college in Udhagamandalam (Ooty), Tamil Nadu.

The Academy has also played a pivotal role in ensuring benefit for the students and faculty through wide-ranging international tie-ups. The institutions have collaborations with reputed universities, industrial and research organizations. These include international collaboration with La Trobe University, Australia; KhonKaen University, Thailand; University of Southern Nevada, USA; Long Island University, USA; AIMST University, Malaysia; Howard University, Washington DC; University of Illinois, Chicago, USA; AlfaGene Biosciences Inc, USA; National Institutes of Health, USA; and Oman Medical College, Oman, etc.

The research outputs have supported with high impact publications in peer reviewed scientific journals and have contributed "new knowledge to the understanding of newer drugs", therapy and treatment through innovations and patents. There is a wealth of knowledge that is being generated every single day in the field of molecular biology through the centre of excellence of Molecular Biology and Natural Product Research to address important societal problems. The academy combines leading medical research and compassionate patient care to face the world's most pressing medical challenges. Major Research Grants from National Funding Agencies reveal the quality of the University/Programs offered as a whole and Colleges in particular.

JSS College of Pharmacy, Ooty

JSS College of Pharmacy was established in 1980 with a view to provide job oriented professional courses in Pharmacy. The College and the JSS AHER are accredited by the National Assessment and Accreditation Council (NAAC) with 'A+' Grade. The infrastructure available makes the college a conducive place for academic learning that provides students with quality education in a clean and comfortable environment.

JSS College of Pharmacy, Ooty offers D.Pharm., B.Pharm., M. Pharm., Pharm. D., Pharm. D (PB), PG Diploma and PhD programmes. The college is affiliated to the JSS Academy of Higher Education and Research, Mysuru and approved by the All India Council for Technical Education (AICTE), Pharmacy Council of India (PCI), Govt. of Tamil Nadu and recognized by other statutory bodies.

The college is working towards becoming a Centre of Excellence in Pharmaceutical Education and Research and will be world leader in the field of pharmaceutical sciences and pharmacy practice with a vision of strengthening the healthcare of the country. In the last three decades, more than 1300 research papers have been published and presented at various national and international conferences. The college has received research grants from DST, DBT, CSIR, ICMR, UGC, TNSPWT, AICTE and pharmaceutical Industries.

Objective

To provide direct, relevant and valuable information on key aspects of Medical Devices & in vitro Diagnostic Kits including its regulations in India. This seminar brings together some of the renowned R & D Experts and Regulators to share information regarding best practices and challenges in medical device & IVD kits regulation in the country

The Program

The term medical devices cover a vast range of equipment, from simple tongue depressors to hemodialysis machines. Like medicines and other health technologies, they are essential for patient care – at the bedside, at the rural health clinic or at the large, specialized hospital. Medical devices also cost governments a substantial amount of money. In 2017, the estimated different medical devices available on the market represented over US\$319 billion. With innovation and the rapid advancement of technologies, medical devices are currently one of the fastest growing industries. Yet many countries lack access to high-quality devices and equipment that are appropriate for their specific epidemiological needs. This is particularly true in developing countries, where health technology assessments are rare and where little regulatory controls exist to prevent the importation or use of substandard devices. With the vast majority of

devices in developing countries being imported, this leaves them prey to unscrupulous market influences and puts patients' lives at risk. Governments need to put in place policies that will address all elements related to medical devices, ranging from access to high quality, affordable products, through to their safe and appropriate use and disposal. In the light of escalating use of medical devices, stringent regulatory standards are required to ensure that the devices are safe, well studied and have least adverse reactions. Recently introduced guidelines and the amendment in the law will provide adequate guidance for both the manufacturers and competent authorities to manage cases efficiently and appropriately. The public expects that medical devices meet the highest safety standards.

Pharmacy personnel can certainly play an important role in the regulation of medical devices. Safety, risks, effectiveness and performance of the medical devices need to be well established and regulated properly. It is hoped that the guidelines are implemented and regulated properly with effective outcome.

Proposed Topics to be delivered

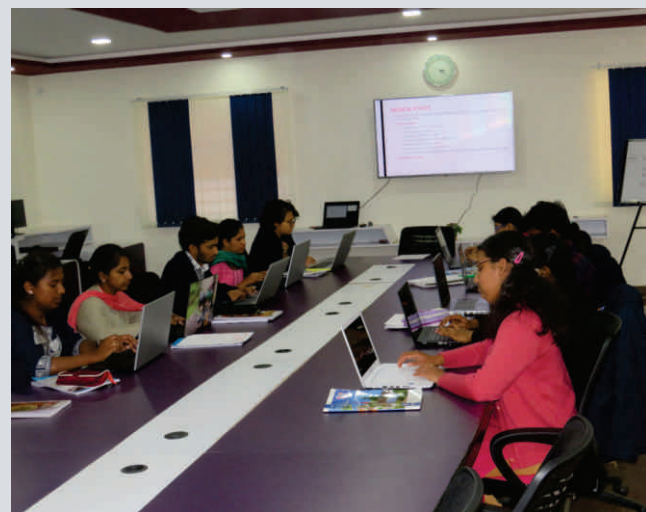
- Key changes in new medical device regulation
- Medical Devices – Indian Regulatory scenario
- Classification of medical devices – Comparative analysis
- Clinical trial of medical devices
- Design and development of medical devices
- Safety assessment of medical devices
- Regulations for *In Vitro* Diagnostics kits



Expected Program Outcomes

This seminar brings together some of the renowned R & D Experts and Regulators to share information regarding best practices and challenges in medical device & IVD kits regulation in the country at the end of seminar delegates can understand the following key aspects of medical device

- Updation and definition of certain medical devices and in vitro diagnostics
- Clearly defining and systematizing device import requirements
- Clarifying existing regulatory requirements for medical devices
- Establishing a Medical Devices Technical Advisory Board
- Updating India's Good Manufacturing Practices



Key Activities

- Invited Lectures
- e-Poster Presentation
- Panel Discussion



Resource Person

Experts from Industry, Government Regulatory Bodies, Indian Drug Manufacturers Association and Academia

e-Posters:

Scientific abstracts with a maximum of 250 words are invited for e-poster presentation. Title and abstract of the presentation should be sent on or before 30th September 2019 to narayana.reddy@jssuni.edu.in. Template can be downloaded from JSS AHER website- www.jssuni.edu.in

Registration

Workshop Registration Fees

Seminar	On or Before 30th Sep	Spot Registration
Academia	INR 1200/-	INR 1500/-
Industry	INR 2000/-	INR 2500/-

(Incl. GST)

Amount paid towards registration and accommodation is non-refundable and non-transferable

Accommodation is based only on pre-request

Kindly complete the registration form along with a DD in favor of "JSS College of Pharmacy, Ooty", payable at Ooty towards registration Charges or by NEFT (Details in registration form).

Scanned copy of the application form and DD should be mailed to ipprmd2019@gmail.com and the hard copy of the same should be shown during registration on the day of the conference. The last date for registration is **30th September 2019**.

For further information regarding registration contact : **V. Senthil, 9842650602**
ipprmd2019@gmail.com

For accommodation kindly contact the organising secretary.

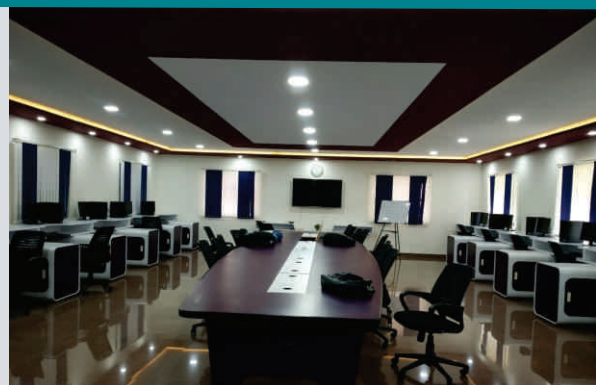
Day 1 (Friday, Oct 18, 2019)

9.00	–	10.30 am	:	Registration
10:30	–	11:45 am	:	Inauguration and Keynote address
11:45	–	12:00 noon	:	Refreshment break
12:00	–	1:30 pm	:	Scientific Session I
1:30	–	2:30 pm	:	Lunch
2:30	–	3:45 pm	:	Scientific Session 2
3:45	–	4:00 pm	:	Refreshment break
4:00	–	5:30 pm	:	Scientific session 3 (e-posters)



Day 2 (Saturday, Oct 19, 2019)

9:30	–	10:45 am	:	Scientific session 4
10:45	–	11:00 am	:	Refreshment break
11:00	–	1:30 pm	:	Scientific session 5
1.30	–	2.30 pm	:	Lunch
2.30	–	3.00 pm	:	Panel Discussion
3.00	–	3.30 pm	:	Closing ceremony
4.00	–	5.30 pm	:	Refreshments and Safe journey home



Who can participate?

1. B.Pharm, M.Pharm, Pharm.D. graduates.
2. Research Scholars (Pharmacy)
3. Academicians, Pharmacists, Industrial executives and Drug Inspectors.

Chief Patron

Dr. B. Suresh

Pro- Chancellor, JSS AHER, Mysuru

Patron

Dr. H. Basavana Gowdappa

Vice-Chancellor, JSS AHER, Mysuru

Chairman

Dr. S.P. Dhanabal

Principal, JSS College of Pharmacy, (Ooty) Udhagamandalam.

Convenor

Dr. K. Gowthamarajan

Professor & Head, Department of Pharmaceutics,
JSS College of Pharmacy, Ooty

Organising Secretary

Dr. GNK Ganesh

Co-ordinator, Pharmaceutical Regulatory affairs, JSS College of Pharmacy,
Rocklands, P.B. NO: 20, Ooty – 643001, The Nilgiris, Tamil Nadu.

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Organising Committee

Dr. V. Senthil

Dr. R. Suresh Kumar

Dr. D. Nagasamy Venkatesh

Dr. N. Jawahar

Dr. K.V.V.S. Narayana Reddy

Mr. R. Arun

Registration Form

**AICTE Sponsored
International Conference on Current Regulations
for Medical Devices & *In Vitro* Diagnostic**

18th & 19th October 2019

(Fill the form in CAPITAL LETTERS only)

Name

Age Gender

Designation

Institution

Official address

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Mobile Email

Please ✓

1. Seminar

Yes

No

2. Accommodation

Yes

No

Mode of Payment

DD should be taken in favor of The Principal, JSS College of Pharmacy, Ooty

DD No Amount

Drawn On Bank

(OR)

For online payment (NEFT/RTGS/IMPS)

A/C name: JSS College of Pharmacy, A/C No. 4390000100099542

Bank: Punjab National Bank, Branch: Ootacamund

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JSS College of Pharmacy,

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of Head of the Institute

Date: