



स्वामी रामानंद तीर्थ मराठवाडा विद्यापीठ

नांदेड- ४३१६०६ (महाराष्ट्र)

SWAMI RAMANAND TEERTH MARATHWADA UNIVERSITY

NANDED-431606, MAHARASHTRA STATE, INDIA.

Established on 17th September 1994 - Recognized by the UGC U/s 2(f) and 12(B), NAAC Re-accredited with 'A' Grade



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परिपत्रक / कार्यशाळा / चर्चासत्र / परीषद / 2015-2016

या परिपत्रकान्वये सर्व संबंधितांस कळविण्यात येते की, Channabasweshwar Pharmacy College, (Degree), Kava Road, Basweshwar Chauk, Latur यांच्या वतीने -Current Regulatory Scenario & Challenges for Food & Pharmaceutical Industry या विषयावर दि.२७/०२/२०१६ रोजी One Day National Seminar चे आयोजन करण्यात आले आहे.

सदरील National Seminar ला प्रस्तुत विद्यापीठाशी संलग्नित सर्व महाविद्यालयातील संबंधित विषयाच्या सहभागी होणाऱ्या इच्छुक शिक्षकांना त्यांच्या महाविद्यालयाच्या वतीने कर्तव्य रजा (Duty Leave) मंजूर करण्यात यावी. ही विनंती.

“ज्ञानतीर्थ” परिसर विष्णुपूरी, नांदेड.

जा.क्र.शै.नि.वि.वि. / परिपत्रक / कार्यशाळा /

२०१५-१६ / ४४२६

दिनांक : १८/०२/२०१६

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स्वा/-

संचालक

महाविद्यालय व विद्यापीठ विकास मंडळ

प्रत :

1. मा. प्राचार्य, Channabasweshwar Pharmacy College, (Degree), Kava Road, Basweshwar Chauk, Latur, यांना या परिपत्रकाची प्रत देऊन कळविण्यात येते की, उक्त कार्यक्रमात सहभागी होणाऱ्या संबंधितांना आपल्या स्तरावरून स्वतंत्रपणे कळविण्यात यावे. ही विनंती.

2. श्री. अजय दर्शनकार, यु.जी.सी., सिस्टीम एक्सपर्ट, प्रस्तुत विद्यापीठ, यांना प्रत देवून कळविण्यात येते की, सदरील परिपत्रक व माहिती पत्रिका विद्यापीठाच्या सांकेतिक स्थळावर प्रकाशित करावे.

## Registration Form

Name: Dr/Mr./Ms. \_\_\_\_\_

Sex: Male/Female \_\_\_\_\_

Qualification: \_\_\_\_\_

Designation: \_\_\_\_\_

Organization: \_\_\_\_\_

Address for Correspondence: \_\_\_\_\_

Mobile No: \_\_\_\_\_

Phone No: \_\_\_\_\_

E.mail: \_\_\_\_\_

Date: \_\_\_\_\_

Registration Fees : Rs. 250/- for student and research scholar  
Rs. 400/- for Academic / Industrial person

Payment Mode : Demand Draft / Cheque to be made in favour of  
"Principal, Channabasweshwar Pharmacy College  
(Degree), Latur" Payable at Latur to be sent by courier or mail scan  
copy of receipt to channaseminar@gmail.com

(Cash/DD/Cheque) \_\_\_\_\_

DD/ Cheque No. \_\_\_\_\_

Bank \_\_\_\_\_

Date \_\_\_\_\_

Signature of Participant

Accommodation Details : Accommodation will be arranged by the  
organizer in nearby hotels on prior intimation. Payment will have to be  
made by the participant on arrival during seminar.

### PATRONS

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### PROGRAM CO-ORDINATOR

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ONE DAY

## NATIONAL LEVEL SEMINAR

Current Regulatory Scenario & Challenges  
for Food & Pharmaceutical Industry

Saturday, 27<sup>th</sup> February, 2016



Sponsored & Supported By

Indian Pharmaceutical Association (IPA)  
Association of Pharmaceutical Teachers of India (APTI)  
Swami Ramanand Teerth Marathwada University, Nanded.

Organised by



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### CHANNABASWESHWAR PHARMACY COLLEGE

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#### ABOUT COLLEGE

Panchakshari Shivacharya Trust is a charitable trust registered under Bombay Public Trust Act 1950. It undertakes religious and social activities. The trust is actively engaged since 1973 in promoting quality education in technical education. This trust has started Channabasweshwar Polytechnic (D. Pharmacy), Latur in the year 1980. Channabasweshwar D. Pharmacy Institute is one of the reputed Diploma Pharmacy institute in the state of Maharashtra. After realizing the prospects and potential of the course in the emerging scenario of the global pharmaceutical industry and education the trust has started degree course (B. Pharm) since from 2010 and post graduate course (M.Pharm) 2012. The trust also conduct course such as Post Graduate Diploma Course in Medical Laboratory Technology (PGDMLT) and Junior College. Institute is having its own constructed precious building well equipped laboratories library with number of reference books national international journals with e-library, good computing facility and research laboratory.

#### ABOUT THE SEMINAR

A set of norms, standards, and code of conduct govern the pharmaceutical industries across the globe to ensure a safe and secured healthcare system to all. These laws are varying from country to country. The dynamics in the regulatory affairs demands constant research, as the pharmaceutical industry should have to comply with the changes in technology, market and legal aspects in order to survive in the competitive markets.

Regulatory affairs is a comparatively new profession which developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, food industry, agrochemicals, cosmetics and complementary medicines.

Regulatory affairs is involved in the development of new medicinal products from early on, by integrating regulatory principles and by preparing and submitting the relevant regulatory dossiers to health authorities and it actively involved in every stage of development of a new medicine and in the post-marketing activities with authorized medicinal products also it is an important part of the organizational structure of pharmaceutical companies.

A regulatory-science driven regulatory strategy is essential as part of today's biopharmaceutical product early development planning. A well-prepared regulatory strategy

will align the proposed clinical development plan with business objectives, and pre-emptively identify challenges, as well as, proposed alternative/innovative approaches to new product development which leverage new standards for evidence generation supporting continuing development and global market authorization. A regulatory strategy helps to define key issues/challenges to proactively discuss with Regulatory authorities and also defines key program milestones that are often considered business catalysts driving investor interest and financing. Most importantly, a timely, well-prepared and well-maintained regulatory strategy, with proactive and collaborative interaction with regulatory authorities, is often a differentiating factor for industry leaders bringing commercially successful and innovative products to market in today's competitive marketplace. Regulatory strategy is a major component of successful biopharmaceutical product development. Covance global regulatory affairs prepares and maintains regulatory-science driven and product-specific global regulatory strategies for many product types, e.g., drugs, biologics, drug-device combinations, vaccines, gene-therapies, cell-therapies, across a range of therapeutic areas and full regulatory strategy support for product development initiatives. This one day national seminar focuses on knowledge development of young student, researchers and faculty about current expertise in regulatory practices, its requirement and challenges for food and pharmaceutical industry.

#### OBJECTIVES

To offer and tone up the regulatory knowledge required for food and Pharmaceutical Industry.

**To addresses current trends, importance, challenges and opportunities with regulatory requirements for mfg. of food and drug products.**

To build industry-institute partnership and strengthen relationships with industry to better understand and address regulatory requirements.

To boost existing interest for the development of student, researchers and academicians as per the demands of corporate industry.

To inculcate importance of ethics and morality in implementation of regulatory guidelines.

#### THEMATIC AREAS COVERED DURING SEMINAR

- \* Current Regulatory Guidelines
- \* Regulatory trends & challenges for domestic Market
- \* Regulatory trends & challenges for export Market
- \* Dossier Requirement and Guidelines (Quality Part)
- \* Biowaiver Implementation
- \* Regulatory intelligence

#### WHO CAN ATTEND ?

All the PG students and faculty members of Pharmacy, Medicine, Biotechnology, Food Science, Agriculture Colleges: Industry aspirants from edible Oil Industry and all food and drug industry.

#### ABSTRACT FOR POSTER

Student should send the abstract (250words) related to the theme and advances in pharmaceutical science which includes scope of review/Research work, various presenting Parameters, conclusion and references. Abstract will be published in e-abstract book bearing ISBN number. Please note that abstract of those authors the registration fees before 23 Feb 2016 can be include in the e-abstract book.

**Abstract mailed to:** channaseminar@gmail.com before 23<sup>rd</sup> Feb 2016. Acceptance of abstract will be confirmed by e-mail

**Abstract format:** The abstract should not exceed 250 words and should be in the font Times new roman (size-12)  
**Dimension for Poster:** The poster should be in dimension 1M X 1M.

**Award:** Best three Posters will be awarded by medal and certificate.

#### PROGRAMME DETAILS

Date: 27/02/2016

Time	Schedule
08:00 am - 10:00 am	Registration & Breakfast
10:00 am - 11:00 am	Inauguration & Key Note Address
11:00 am - 12:00 pm	Plenary Lecture-1
12:00 pm - 01:00pm	Plenary Lecture 2
01:00 pm - 01:45pm	Lunch
01:45 pm - 02:30pm	Inauguration of Poster Session
02:30 pm - 03:30pm	Plenary Lecture-3
03:30 pm - 04:30pm	Plenary Lecture-4
04:30 pm - 04:45pm	High Tea
04:45 pm - 05.30pm	Valedictory Function



#### VENUE

**HOTEL VITS GRAND**  
Barshi Road, Latur,  
Maharashtra - 413531

