

# SPIPS BULLETIN



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**St. Peter's**  
Institute of Pharmaceutical Sciences  
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*Where brilliant minds converge to transform the future of pharmaceutical sciences*



### FAST FACTS

- Invested 1500 crores
- Grants of \$ 165 M for Clinical Research (indirect)
- # of Employees - 1700
- R&D and Process Development
- # of Global Patents: >100
- Largest Technology Transfer Partner
- Ranked 2<sup>nd</sup> in Private Sector
- FOUR vaccines WHO prequalified

## **VISION**

St.Peter's is committed to generate, disseminate and preserve knowledge and work with pioneers of this knowledge, and to be the most sought after institute globally in the field of pharmaceutical sciences by creating world class pharmacy professionals and researchers.

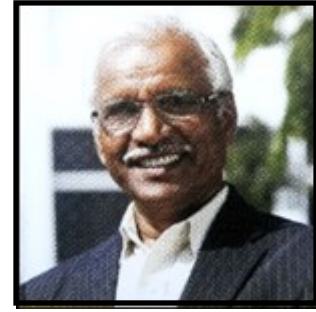
## **MISSION**

To achieve academic excellence with integrity and creating opportunities for leadership and responsibilities through groundbreaking performance in the field of Pharmaceutical Sciences by educating students with pharmaceutical needs of the society and to advance the knowledge through research and to serve the profession and community.

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## INDEX

<b>S. No</b>	<b>Title</b>	<b>Pages No</b>
1	Workshop on “ QUALIFICATION & VALIDATION ”	1
2	Guest Lecture on “Understanding Brain Stroke”	2
3	Guest Lectures	3
4	IACP– Pharmaceutical Sciences Congress 2019	4-15
5	Drug Master File and eCTD by Dr. Ashuthosh Dikshith	16
6	Orientation Programme	17
7	Work Shop on Precision Medicine and Drug Response, Pharmacogenomics	18

# Workshop on “ QUALIFICATION & VALIDATION “

One day workshop on “ QUALIFICATION & VALIDATION “ was held at St. Peter's Institute of pharmaceutical sciences by Dr. Ashutosh Dikshit, Head - Quality, Regulatory and compliance, Almelo Pvt. Ltd., Hyderabad. In his session he addressed about critical and non critical parameters during process validation.

He emphasized on qualification of equipment, facilities, utilities and systems from stages of developmental study to optimization. Scope of understanding the process of retrospective concurrent and prospective validation is mandatory to maintain and approve quality. Traditional process validation with respect to number of batches must be assessed to demonstrate a high level quality in every batch with ongoing process verification is highly essential. Critical quality attributes are to be following specifications. Methods to record and evaluate the results are to be made mandatory for continuous verification.

Hybrid of traditional and continuous process verification can be used when substantial amount of knowledge and understanding of product and process is available. Attended by all B Pharm & M Pharm students.



## Guest Lecture on “Understanding Brain Stroke”

ISPOR Telangana chapter and IPA, Hanamkonda branch organized a guest lecture on “**Understanding brain stroke**” at St.Peter’s Institute of pharmaceutical sciences, Hanamkonda. on December 5th 2019. The speaker of the session Dr.Ramakrishna Telugu, MD, DNB-Neurology (KIMS, Hyderabad), Assistant professor KMC, MGM, Warangal, T.Jayapal Reddy Chairman, Dr. P. Rajashekar Principal, and Dr. Devender Kodati HOD of PharmD have inaugurated session.

Dr.Ramakrishna Telugu conducted session on brain stroke AHA/ASA 2018 guidelines. The contents in his lecture included neuro anatomy, pathogenesis, types of stroke, symptoms, and risk factors for stroke. He also explained the stroke risk calculator and role of telemedicine whatsapp to support the patient for early diagnosis. He gave detailed information about evidence based medicine and experience based medicine in his lecture.

He described how to prevent errors and time window for treatment. He also gave live examples which he encountered during his study and practice with a note on co-morbidities associated with administration of hormonal drugs like estrogen and progesterone. As they are becoming the most important risk factor for cerebral sinus venous thrombus (CSV) along with smoking, alcohol, BP, Diabetes, and stress. He also mentioned about the guidelines for BP management and also recommendations for maintaining BP.

All the PharmD students i.e. 1<sup>st</sup> to 6<sup>th</sup> years attended the session. It was an interactive session where students whole heartedly participated in the discussion. The programme was ended by a key note and felicitation of Dr.Ramakrishna Telugu.



## Guest Lectures

St.Peter's Alumnus student A. Mrudula Naidu from New York University of Health , USA has delivered an Interactive session with the students and sharing importance of Networking and global connect w.r.t opportunities on November 20 2019. She emphasized mainly on word dictions and various approaches into research in World Class Universities and Research Center's.



Dr. Diwakar Goli, ex principal at Acharya & BM Reddy College of Pharmacy took sessions on 18th & 19th of November 2019 for Students of St.Peter's on how to design a career. He had over 3 hours of Interactive session with the students.





## IACP– Pharmaceutical Sciences Congress 2019

Indian Association of College of Pharmacy (IACP), a National Organisation has hosted a Two Day Pharmaceutical Sciences Congress – 2019 on 1<sup>st</sup> And 2<sup>nd</sup> November At St. Peters Institute of Pharmaceutical Sciences, Warangal, Telangana.

The theme of the event was “Connecting Pharmaceutical Sciences and Knowledge and Advancement”.

Dr. V G Somani, Drug Controller General of India (DCGI) New Delhi, Dr. B. Suresh, President, Pharmacy Council of India, New Delhi, Dr. B. Janardhan Reddy IAS, Principal Secretary, Education Govt. of Telangana & Vice Chancellor, KU. Eminent speakers from the pharmaceutical industry like, Sri. Madan Mohan Reddy, Managing Director, Aurobindo Pharma, Dr. Krishna Ella Chairman & Managing Director, Bharat Biotech International Ltd., Hyderabad, Dr. M U R Naidu, Director, Natco Pharma India, Sri. Ch. Bharath Reddy, Managing Director, MSN Labs, Hyderabad, Dr. N. Hemanth, Managing Director, Virchow Biotech Pvt., Ltd., Hyderabad, Dr. M U R Naidu, Director Natco Pharma India, Sri. Ch. Bharath Reddy, Managing Director, MSN labs, Hyderabad, Dr. P. Deshpande, Deputy Managing Director, Indian Immunologicals Ltd., Dr. S.D. Sinha, Sr. Vice President, and Hetero drugs Ltd., Sri Y. Venkat Reddy, Managing Director, Genesys Biologicals Pvt. Ltd. Hyderabad, Dr. A. Ramkishan, Dy. Drugs Controller of India, New Delhi, Dr. T. V. Narayana, President Indian Pharmaceutical Association has attended the pharmaceutical congress.



## IACP– Pharmaceutical Sciences Congress 2019

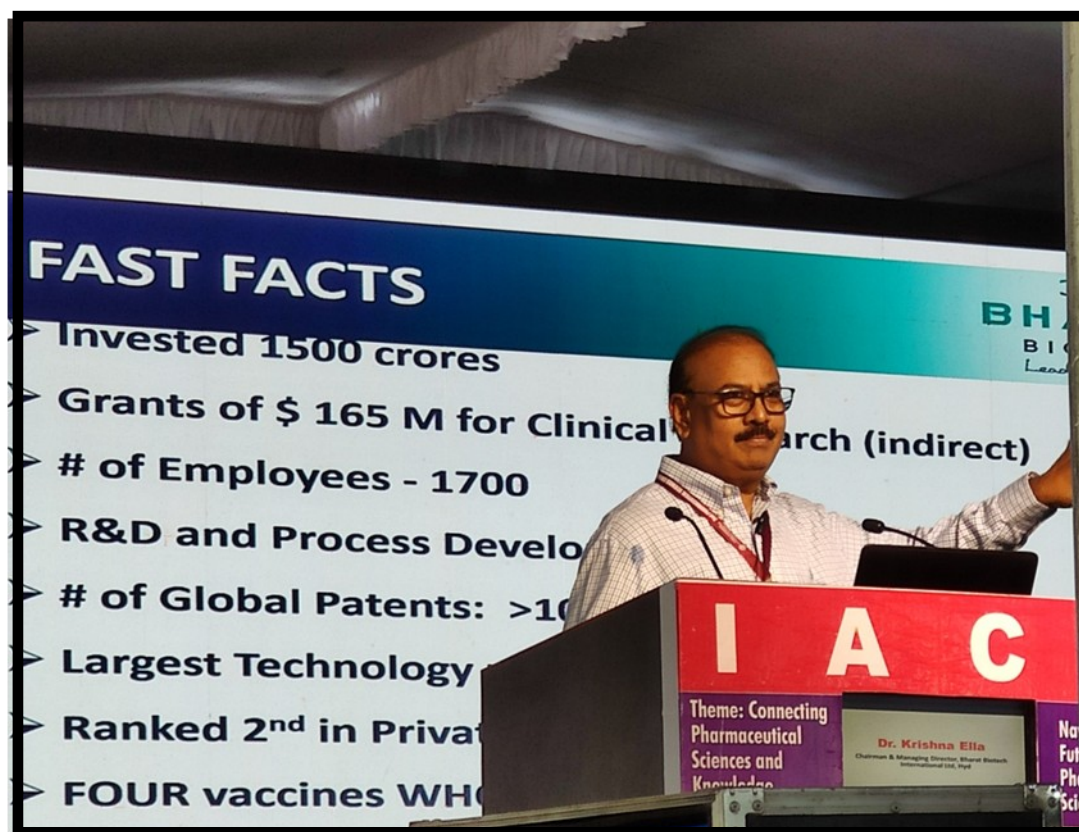
The first speaker **Dr. V. G Somani, Drug controller General of India (DCGI) New Delhi**. He addressed on Good Regulatory Practices (GRP) – Current challenges and gaps to achieve patient safety. Session was chaired by Dr. J.A.S. Giri, Chairman, Telangana state chapter of the Andhra chamber of commerce and Shri. J.Jayseelan, Managing Director, Delvin Labs Hyderabad. He described Patient safety is a fundamental element of health care and is defined as a freedom for a patient from unnecessary harm or potential harm associated with provision of health care. He gave an overview in recent years, there is growing recognition that patient safety and quality of care are critical dimensions of Universal Health Coverage (UHC). Legal rights of the patients are set out in the Clinical Establishment Act (CEA), but the CEA is not being implemented across India. National Pharmaceutical Pricing Authority (NPPA) and Drugs Controller General of India (DCGI) have mechanisms to see that patients' rights in terms of medication and device are protected and they are not overcharged. National Health System Resource Centre (NHSRC) has been designated as nodal agency at national level for implementing Quality Assurance program in public health facilities.



**Dr. V. G Somani, Drug controller General of India (DCGI) New Delhi during his speech**

## IACP– Pharmaceutical Sciences Congress 2019

The next delegate **Dr. Krishna Ella Chairman & Managing Director, Bharat Biotech International Ltd., Hyderabad**, addressed on human resource and innovation. Session was chaired by Dr. A. Ramkishan Dy, Drug Controller of India, New Delhi and Dr. K. Buchi Reddy, Chairman Rohini Super speciality Hospital. In his talk, he mentioned that India has not done enough on novel innovations that could create affordable solutions to benefit larger chunk of its population. India ranks 46th on the world's innovation map. Not an encouraging thing,” remarked Dr Ella, adding further “Challenge is that the society doesn't respect science. He said instead of following the West blindly, we should rather have an own model for India,” Dr Ella said adding, “Let us not compare our startup ecosystem with the Silicon Valley. We need to find our own indigenous model.”He advised the startups to update their regulatory knowledge when they are developing the products.



**Dr. Krishna Ella, during his session**

## IACP– Pharmaceutical Sciences Congress 2019

The next delegate was **Dr. B. Suresh, President, Pharmacy Council of India, New Delhi** addressed on Innovation and Entrepreneurship – a Way Forward. He was explaining how why individuals engage in entrepreneurial ventures with uncertain and risky outcomes. Sometimes there are classified according to the level of aggregation, starting the macro level and working their way down to industry – related factors, micro economic incentive structures and cognitive abilities of individuals. He briefly surveys the most frequent explanations to entrepreneurial activities, zeroing in at the empirical findings concerning the role of institutions and access to knowledge. The idiosyncrasies pertaining to the definition and production of knowledge are likewise addressed.



**Dr. B. Suresh addressing the gathering**

## IACP– Pharmaceutical Sciences Congress 2019

The next delegate was **Sri. Madan Mohan Reddy, Managing Director, Aurobindo Pharma**, addressed on Indian Drugs Export Opportunities to ICH countries. Session was chaired by Dr. B. Suresh, President, Pharmacy Council of India. In this talk he said that the Indian pharmaceuticals industry is the third-largest in terms of volume and thirteenth-largest in terms of value. It has established itself as a global manufacturing and research hub. India is expected to rank amongst the top three pharmaceutical markets in terms of incremental growth by 2020. As regards the regulatory issues, Sri Madan Mohan Reddy said most of the companies have addressed them. There is also a lot of improvement in their way of working. He expressed confidence that the global business will be retained in India because of competitive cost of production. He complemented the commerce and industry ministry for taking several measures to make India the main source of global manufacturing in pharmaceuticals.



**Sri. Madan Mohan Reddy, Managing director, Aurobindo**

## IACP– Pharmaceutical Sciences Congress 2019

**Dr. MU R Naidu, Director, Natco Pharma India**, his session was on Technological Advances in Implications for Drug Discovery and Development. Session was chaired by Dr. B. Jayakar, Registrar, Vinayaka Mission's University, Salem, Tamilnadu and Mr. Mujeebuddin C.S Founder and CEO, Clinisol Research Pvt. Ltd. The process of developing a new drug to treat an illness is long, costly and uncertain. He mentioned that the most difficult problem associated with new drug discovery was the identification and characterization of the most appropriate target within a disease pathway. The last decade has seen rapid technological progress but with increasing demands for safe and efficacious drugs. He expressed that no more than 1% of drugs in the discovery and development pipeline will reach the marketplace. Failure rates are too high, and all too often drug candidates fail relatively late in development, having already consumed substantial time and resources. Better information relative to disease pathophysiology is needed to improve target selection and validation; more predictive, biologically-relevant high throughput screens are essential; and, more emphasis must be placed on acquiring good ADME/Tox data earlier in the discovery process

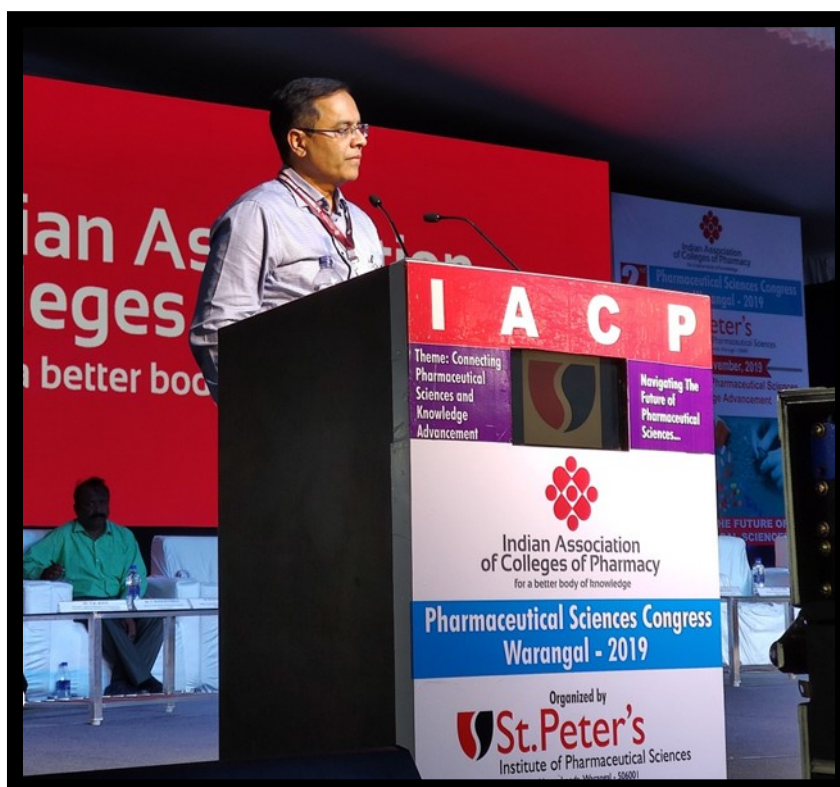


**Dr. MU R Naidu, Director, Natco Pharma India, delivering talk**

## IACP– Pharmaceutical Sciences Congress 2019

The next delegate was **Sri.CH.Bharath Reddy, Managing Director, MSN Labs, Hyderabad**, addressed on current pharmaceutical industries and opportunities. Dr. V. Ravichandran.

Director, National Institute of Pharmaceutical Education & Research, Kolkata and Dr. Ranganayakulu, Principal, Sri Padmavathi School of Pharmacy, Tirupathi,. Sri. Bharat Reddy said that the country has an established domestic pharmaceutical industry, with a strong network of 3000 drug companies and about 10,500 manufacturing units. The pharmaceutical industry in India produces a range of bulk drugs, which are the key acting ingredients with medicinal properties that form the basic raw materials for formulations. He was emphasizing that pharma industry should train students as per their need. Industries should contact Indian academic institutions to get qualified students who have the knowledge and aptitude for research and development in Pharma. He concluded that this will also help overcome the problem of unemployment for pharmacists and promote entrepreneurship in the nation. The industry can hire a team from academic institutions to participate in healthcare activities across the country for their promotional activities.



**Sri. CH. Bharath Reddy, Managing Director, MSN Labs during his session**

## IACP– Pharmaceutical Sciences Congress 2019

The next delegate was **Dr.N.Hemanth**, Managing Director, Virchow Biotech Pvt. Ltd Hyderabad, addressed on An SME Perspective on Pharma Development. His session was chaired by Dr. C. Gopal Krishnamurthy, Former Drugs Controller of AP and Ex-President IPA and Dr. P. Rajasekhar Reddy, Principal, St.Peter's. Indian pharma SMEs can definitely see a good future if these companies are willing to accept change and take over an accommodative move towards with the government and the other major industry players. There is a dire need to review many of the recent amendments in the related laws affecting pharma industry from India centric point of view, for survival of SMEs in India it is important to keep in mind that per-capita income in India is much low, per capita health expenses are negligible. The multinational are achieving their objectives by painting the Indian industry, specifically SMEs, black and everybody went all out to change the regulations forgetting the interest are safe guard of legitimate and genuine SMEs in India SMEs have not been able to project at the right places and right time the exact design and exact changes in the regulations which are totally in favour of multinational companies and which will result it into closure of many pharma SMEs



**Dr.N.Hemanth,Managing Director, Virchow Biotech Pvt. Ltd during his session**



## IACP– Pharmaceutical Sciences Congress 2019

**Dr. T. V. Narayana**, addressed on the Indian Pharma Industry : Now low cost generic medicines produced in India are helping millions of people across the world to get affordable high quality medicines and is likely to be in the top 10 global markets in value term by 2020. All these factors made Indian Pharmacy grow in the world and explained about the challenges of 21st century , as the world grows smaller present and future professional including technocrats managers administrators need to plan out careers on global lines rather than regional or national lines demanding the human resources to be sharper than ever to survive and exceed. His session was chaired by Prof. V. Kishan, Principal and HOD, UCPSc, Kakatiya University and Dr. K. Devender Rao, HOD, St.Peter's.



**Dr. T. V. Narayana, President IPA delivering speech**

## IACP– Pharmaceutical Sciences Congress 2019

**Dr. P. Deshpande, Deputy Managing Director**, Indian Immunologicals Ltd. told about Increasing Vaccination coverage in India. His session was chaired by Dr. Rao Vadlamudi President, Commonwealth Pharmacy Association India and Mr. Krishna Dev. IIL company is the major supplier of DPT, TT, Hepatitis-B vaccine, Papilloma virus vaccine and pneumococcal vaccine. It offers FMD vaccines to farmers at affordable prices. The company is also emphasizing on the development of diagnostic methods against TB, Para TB and brucellosis. Novel vaccines against animal diseases continue to be a major focus area for the research and development. OIL exports it's products more than 45 countries across the world and we are working towards expanding the business are towards South Americans market, USA and Europe.



**Felicitation of Dr. P. Deshpande, Deputy Managing Director, Indian Immunologicals Ltd**

## IACP– Pharmaceutical Sciences Congress 2019

**Dr. S. D. Sinha, Senior Vice President, Hetero Drugs Ltd,** said about the Biosimilar Drug Development Challenges and Opportunities. His session was chaired by Dr. Rao Vadlamudi President, Commonwealth Pharmacy Association India and Dr. A. Ramesh, Principal, Viper, Hyderabad. He started the session with development of a Biosimilar and its importance and also included the challenges faced in manufacturing of Biosimilars.



**Sri Y. Venkat Reddy Managing Director, Genesys Biologicals Pvt. Ltd. Hyderabad** shared his views on My Journey: Corporate to Entrepreneur his session was chaired by Dr. Divakar Goli, Campus Director, Acharya B.M Reddy College and Prof. G. Achaiyah, Department of Pharmacy, UCPSc, Kakatiya University. He explained about the concept of entrepreneurship and what is the need for a corporate entrepreneurship. He told about the key factors that can lead to successful entrepreneur such as right attitude, passion, proactiveness, resilience and perseverance.

## IACP– Pharmaceutical Sciences Congress 2019

**Dr. A. Ramkishan, Deputy Drugs Controller of India, New Delhi.** He addressed on role of pharmacist in Rare Disease- Drug Discovery also mentioned about IACP importance in his session. His session was chaired by Dr. T. K. Ravi Principal, Sri Ramakrishna Institute of Paramedical. He also mentioned that earlier there was no association of pharmacy colleges and this 2<sup>nd</sup> IACP really boosts the students to study pharmacy. He started his session with how a pharmacist can lead with respect to hospital service, community services. He also vocalised that patients are very sensitive with respect to medicinal products and care should be taken. The main role of a pharmacist is to promote circulars, guidelines to the society which were amended by the government.



**Dr. A. Ramkishan, Deputy Drugs Controller of India, New Delhi during his session**

# Drug Master File and eCTD by Dr. Ashuthosh Dikshith

One day work shop on Drug Master File and eCTD in Pharmaceuticals was conducted at St. Peters Institute of Pharmaceutical Sciences, Hanamkonda on September 13th 2019. The session was inaugurated by Dr. Ashuthosh Dikshith Head Quality Control & compliance at Almelo Pvt. Ltd., T. Jayapal Reddy, Chairman and Principal Dr. P. Rajashekar, St. Peters Institute of Pharmaceutical Sciences

Dr. Ashuthosh Dikshith explained basic terminology used in DMF filing. He gave a detailed information about various types of Drug Master Files like Type I which explains about Manufacturing Site, Facilities, Operating Procedures, and Personnel, Type II: Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product, Type III: Packaging Material, Type IV: Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation, Type V: FDA Accepted Reference Information. Each DMF should contain only one type of information and all supporting data. Earlier manufacturer used to submit DMF in paper format to central document room and now a days electronic common technical documents (eCTD) are used to submit DMF. He gave a note on Laws which are regulating DMF like, Food and Drug Administration Act, Food and Drug Administration Safety and Innovation Act, Generic Drug User Fee Amendments, Prescription Drug User Fee Act.

All the B.Pharmacy students i.e., 2<sup>nd</sup>, 3<sup>rd</sup>, 4<sup>th</sup> attended the session. It was an interactive session, where students whole heartedly participated in the discussion. The program was ended by a key note and by felicitation of Dr. Ashuthosh Dikshith. Chairman .



## Orientation Programme

Orientation Programme was conducted at St. Peter's Institute of Pharmaceutical Sciences on September 5th 2019. One of the chief guests Dr. J. Sudhakar reddy preceded the gathering regarding pharmacist role in healthcare system with duties of pharmacist. He discussed about job opportunities like community pharmacist, hospital pharmacist and clinical pharmacist and various pharmacy opportunities in medical department, synthetic R&D and analytical R&D.

The session was next addressed by Mr. T. Jaypal Reddy, chairman of St. Peter's Institute of Pharmaceutical Sciences, he spoke about future industrial training programs provided by management. Various industrial personnel's and experienced academic guest lecturers are invited to conduct workshops and seminars. Our chief guest Dr. B. Prabhaskar gathering regarding his 45 years of experience in pharma industry. He students must be trained for their technical skills, communication skills. He quoted, "Every day is a learning day, which is never ending". He advised faculty to experience industrial knowledge by regular industrial visits.

Session was ended with cultural activities like skit and dance by our students. Program was concluded by felicitation of chief guests Dr. B. Prabhaskar, Dr. J. Sudhakar reddy by college management.



## Work Shop on Precision Medicine and Drug Response, Pharmacogenomics

One day workshop was conducted by St. Peter's Institute of Pharmaceutical Sciences on 24th July 2019 on Precision medicine and drug response, Pharmacogenomics by Dr. Krishna Deverakonda President, ARCay Scientific LLC, USA.

He stated that Precision medicine aims to customize health care, with decisions and treatments tailored to each individual in every way possible and Pharmacogenomics is part of precision medicine.

Dr. Krishna Deverakonda stated that even though genomic testing is still a relatively new development in drug treatment, this field is rapidly expanding. Currently, more than 200 drugs have label information regarding pharmacogenomic biomarkers — some measurable or identifiable genetic information that can be used to individualize the use of a drug and he clearly explained that pharmacogenomics has great promise and has made important strides in recent years, it's still in its early stages. Clinical trials are needed not only to identify links between genes and treatment outcomes but also to confirm initial findings, clarify the meaning of these associations and translate them into prescribing guidelines.



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