Report of Workshop on

Preclinical & Clinical Studies: Challenges and Walkover to Drug Development

&

Importance of Quality Assurance in Different Pharmaceutical Areas

9th-11th April 2012

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PARUL INSTITUTE

• Jointly Organized by •

Baroda College of Pharmacy

&

Parul Institute of Pharmacy

A Report on "Preclinical & Clinical Studies: Challenges And Walkover To Drug Development."- Workshop 2012

A three days workshop titled "Preclinical & Clinical Studies: Challenges and Walkover to Drug Development." was jointly organized by Baroda College of Pharmacy & Parul Institute of Pharmacy between 9th april 2012 to 11th April 2012.The **inaugural function of the same was organized on** 9th April 2012 at the Auditorium of Parul Arogya Seva mandal, Dr,Vinod Burade , DGM, Pharmacology, from Sun Pharma Advanced Research Company Ltd.,Vadodara graced the occasion as Chief Guest.

13 speakers were invited for the workshop from different industries like Sun Pharma Advanced Research Company Ltd., Vadodara, Ethicare Clinical Trial Services, Ahmedabad, Synergicus Research Pvt. Ltd., Ahmedabad, Quintiles Research Center,Ahmedabad,Veeda Clinical Research,Ahmedabad, Sahjanand Medical Technologies Pvt. Ltd., Surat, Torrent Research centre,Ahmedabad, etc.

The first day of the workshop aimed for the preclinical aspects of drug discovery and covered topics viz.,How are drugs discovered and developed ?, Drug Development for Multiple Sclerosis with respect to S1PR1, Oncologic Preclinical Research: Role of Human Tumor Xenografts, Demonstration on Male Rat-Orchiedectomy Female Rat-Ovariectomy ,Rabbit-Surgical procedure for collection of different tissues from eye etc. The second day of the workshop(10th April 2012) encompassed the clinical aspects and included topics viz.,Fundamentals of Clinical research and conduct and management of clinical trials, Ethical concerns and human subject protection in clinical trials, Regulatory issues in clinical research.,Quality assurance in clinical trials, Clinical research for medical Devices. The third day (11th April 2012) of the workshop was based on toxicological aspects viz., Toxicological study procedures for regulatory requirements, Preclinical toxicological studies from concept to market, Toxicology and preclinical evaluation of medical devices, Indian drug Discovery: Pharmacology and you etc.

A total of 46 M. Pharm students participated in the workshop from different pharmacy colleges throughout Gujarat State.

Keynote Address by Dr Vinod Burade,
DGM, Pharmacology,
Sun Pharma Advance Research Center,
Vadodara.

Dr Milan Satia
MD, Ethicare Clinical Trail Services, Ahmedabad
"Fundamentals of Clinical
Research and Management of Clinical Trials"

Dr Shailendra Goswami
MD & CEO, Synergius Research Pvt. Ltd., Ahmedabad
"Highlighting Ethical Concerns"

Dr Ramila Mandal
Scientist, Sahajanand Medical Technologies Pvt. Ltd.,
Surat
"Toxicology &
Preclinical evaluation of Medical Devices"

Audience

A Report Of Three Days Workshop On "Importance Of Quality Assurance In Different Pharmaceutical Areas" - Workshop 2012

A three days workshop on "Importance of Quality Assurance in different Pharmaceutical Areas" was jointly organized by Baroda College of Pharmacy and Parul Institute of Pharmacy from 9/04/12 to 11/04/12 at Auditorium Hall, Parul Campus, Limda, Vadodara.

The workshop was given different themes for different days. The talk of first day was based on Importance of QA in F & D, Second day was focused on Importance of QA in RA and Corporates, Third day was aimed on Importance of QA in Clinical Research. There were around 208 participants/delegates from our institutes and other colleges of Gujarat.

The programme was inaugurated on 9th april 2012 at 10.00 a.m. by the Chief Guest, Dr. Vinod Burade, DGM, Pharmacology, Sun Pharma Advance Research Center, Vadodara in the presence of Dr. Archana Paranjape, Principal, Baroda Pharmacy College, Dr. Rajesh K.S., Principal, Parul Institute of Pharmacy, Dr. Suresh Jain, Chief Co-ordinator of the event and other dignitaries. Dr. Vinod Burade ,delivered a keynote on "How the drugs are discovered and developed."

After inauguration and tea break, the first deliberation was on "An overview of QbD, Quality by design" by Dr. Jayvaden K Patel, Principal, Nootan Pharmacy College, Visnagar (Guj.). The other speakers of the day were Mr Laxmikant Patil, Manager R and D, S Kant Healthcare, Vapi (Guj.), who delivered his talk on "Role of QA in Formulation and Development ; a general talk.." .

After Lunch the session was started with a talk by Mr. Nitesh Patel, Research Scientist, Alembic Ltd, Vadodara. Who delivered on "SUPAC guidelines: Emphasis on IR Tablet ". The last speaker of the first day was Dr. J. B. dave, Director, Shri Sarvajanik Pharmacy College, Mehsana (Guj.). His talk was on "Overview of ICH Q9 and Q10 with special reference to product development".

The session of second day was started sharp at 10.30 a.m. and the first talk was by Mr. Manish Bajaj, Group Leader, Regulatory Affairs, Astron Research Lab., Ahmedabad (Guj.). He delivered his talk on "Regulatory affairs ; an overview". The second talk was by Mr. Inderr B sharma, Manager- Regulatory Affairs, Veeda Clinical Research Pvt., Ltd., India on "Regulatory affairs in clinical trials; Indian prospective". After lunch third talk was delivered by Dr. Priyanka Pawar, Assist. GM, Amneal Pharmaceuticals, Ahemdabad. She delivered her talk on, "Role of Regulatory Affairs in a Pharmaceutical Company" , followed by a brief discussion on, "Drug Master File". The last lecture of second day was delivered by Mr. Keyur G Shah, Sr. Executive, CQA, Alembic Ltd, Vadodara. He delivered his talk on "Core concepts of CTD and eCTD".

The third day session was started sharp at 10.30 a.m. The first talk was delivered by Mr. Diken A Panchal, Research Associate, TRC, Ahemdabad. He delivered on, "Importance of QA" in clinical research. Second talk was delivered by Dr. S. K. Goswami, MD and CEO Synergicus research Pvt. Ltd., Ahmedabad. He delivered his talk on "Quality Aspects in clinical research". After lunch the third talk was of Mr. Deepak Kheni, Scientist II, TRC , Ahemdabad. He delivered his talk on, "Quality issues in Formulation development". The last talk was Mr. Paresh Mistry, General Manager, Clinical trial and Bioequivalence, Accutest Research Lab, Ahmedabad (Guj.). He delivered his talk on, "Role of QA Clinical trials". After the success of three days eminent talks the session was ended by 4.30 p.m. with vote of thanks, Group Photo and high tea.

Inauguration by Dr. Vinod Burade,
DGM, Pharmacology , Sun Pharma Advance Research Center, Vadodara.

Ma Saraswati Vandana

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DGM, Pharmacology, Sun Pharma Advance Research Center, Vadodara,
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Mr. Laxmikant Patil,
Manager R & D, S Kant Healthcare, Vapi (Guj.),
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Dr. J. K. Patel,
Principal, Nootan Pharmacy College,
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Mr. Paresh Mistri,
General Manager, Clinical trial and Bioequivalence,
Accutest Research Lab, Ahmedabad,
"Role of QA Clinical trials"

Audience

Dr. S. K. Goswami,
MD and CEO,
Synergicus research Pvt. Ltd., Ahmedabad,
"Quality Aspects in clinical research"

Mr. Inderr B Sharma,
Manager- Regulatory Affairs,
Veeda Clinical Research Pvt., Ltd,
"Regulatory affairs in clinical trials; Indian prospective"

Mr. Diken Shah,
Research Associate, TRC, Ahemdabad,
"Importance of QA in clinical research"

Dr. Priyanka Pawar,
Assist. GM, Amneal Pharmaceuticals, Ahemdabad,
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