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Kamla Nehru College of Pharmacy

Borkhedi (gate), Butibori, Nagpur-441 108 (M.S.)

One Day Seminar on "Quality by Design" organized by Kamla Nehru College of Pharmacy, Butibori, Nagpur

One day seminar on "Quality by design" organized by Kamla Nehru College of Pharmacy, Butibori, Nagpur on February 8th, 2016. The seminar was organized for teachers and PG students.

The seminar was inaugurated by Dr. Sudhir N. Umathe, Principal, Kamla Nehru College of Pharmacy, Butibori, Nagpur. The welcome address was delivered by Mr. Mangesh D. Godbole , Assistant Professor and preamble was given by Ms. Disha M. Dhabarde, Assistant Professor, Kamla Nehru College of Pharmacy, Nagpur.

The inaugural function was followed by two long sessions conducted Dr. Sunil V. Gupta, Research and Development Manager, Zim Laboratories Pvt. Ltd., Kalmeshwar, Nagpur.

In a two long sessions, Dr. Sunil V. Gupta focuses on following points:

- A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management.
- The successful implementation of a QbD approach requires a good understanding of its key elements - Quality target product profile (QTPP), Critical quality attributes (CQAs), Risk assessments, Critical material attributes (CMAs), Critical process parameters (CPPs), Design space, Comprehensive control strategy, and Lifecycle management.
- ANDA applicants can implement QbD to develop generic product that are therapeutically equivalent to the RLD. Initially QTPP is defined based on the properties of the drug substance, characterization of the RLD product and consideration of RLD label and intended patient population.
- Identification of CQAs is based on the severity of harm to a patient (safety and efficacy) resulting from failure to meet that quality attribute of the drug product. Usually the CQAs comprise of assay, content uniformity, dissolution and degradation products.

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- If the drug is poorly soluble efforts are focussed on Dissolution method development that would be able to predict in vivo performance in pilot bioequivalence studies.
- Pre-formulation studies of drug product comprise of analysing drug substance properties, excipient compatibility studies and excipient grade selection. Drug product studies include formulation development and evaluation of properties on one hand and Manufacturing process development and risk assessment on the other hand. The process is scaled-up from lab to pilot scale (to demonstrate bioequivalence in the pivotal BE study) and commercial scale. The updated risk assessment of the drug product manufacturing process, operating ranges for CPPs at the commercial scale are proposed and qualified during routine commercial manufacture.
- Risk assessment is used throughout development to identify potentially high risk formulation and process variables and to determine which studies are necessary to develop a control strategy.
- The proposed control strategy includes material attributes and CPPs. The control strategy also includes in-process controls and finished product specifications. The process is monitored during the product life cycle and additional knowledge gained is utilized for management and continuous improvement.

The seminar was anchored by Ms. Kavita R. Pandey, Assistant Professor, Kamla Nehru College of Pharmacy, Butibori, Nagpur and the vote of thanks proposed by Ms. Seema Wakodkar, Assistant Professor, Kamla Nehru College of Pharmacy, Butibori, Nagpur. There was an overwhelming response to attend the seminar and 63 delegates registered for the conference. Mrs. Suhasine G. Wanjari, President, Amar Sewa Mandla, Nagpur and Adv. Abhijit G. Wanjari, Secretary, Amar Sewa Mandal, Nagpur congratulated Dr. S. N. Umathe, the Convenor and Mr. Mangesh D. Godbole, the Organizing Secretary and all teaching and non-teaching staff for the grand success of the programme.

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