

REPORT



Amar Sewa Mandal's
Kamla Nehru College of Pharmacy



Accredited by NAAC with (B⁺⁺) grade
Approved by PCI & DTE Maharashtra (DTE Code : 4206)
Affiliated to Rashtrasant Tukadoji Maharaj Nagpur University, Nagpur.

APTI (M.S. Branch)

Organize

National Conference

on

Application of QbD in Pharmaceutical Research

on

23rd May 2023

Resource Person

Dr. Sunil Gupta

Professor, School of Pharmacy,
Mangalayatan University, Aligarh, U.P.

Dr. Alok Sharma

Professor and Head Department of Pharmacognosy,
MIET, Meerut.

Dr. Vineet Kumar Rai

Project scientist II, DBT Builder Project
School of Pharmaceutical Sciences, Siksha O Anusandhan University,
Bhubaneswar, Odisha,

Convenor

Dr. Jagdish R. Baheti
Principal

Co-ordinator

Dr. Parimal P. Katolkar
Dr. Mahendra C. Gunde

Co-coordinator

Dr. Nitin N. Padole
Dr. Pankaj R. Dhapke

Patron

Dr. (Smt) Suhasini G. Wanjari
President

Amar Sewa Mandal, Nagpur

Adv. Abhijit G. Wanjarri

MLC, Maharashtra State,
Secretary, Amar Sewa Mandal, Nagpur

Dr. Smeeta A. Wanjarri

Treasurer
Amar Sewa Mandal, Nagpur



Association of Pharmaceutical Teachers of India (Maharashtra State Branch)

in Association With



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Organizes National Conference (Online)

on

Application of QbD in Pharmaceutical Research

on

Tuesday, 23rd May 2023

Schedule

Inauguration	10.30 AM – 11.00 AM	
Preamble of the Conference	Dr. Parimal P. Katolkar Coordinator	10.35 AM-10.40 AM
Welcome Address	Dr. Jagdish R. Baheti Principal and Convener	10.40 AM – 10.45 AM
Address by APTI Office Bearers	Dr. Swaroop Lahoti Vice-President, APTI (MS-Branch)	10.45 AM – 10.50 AM
	Dr. Rakesh Somani President APTI (MS-Branch)	10.50 AM – 10.55 AM
	Dr. Milind Umekar President APTI (India)	10.55 AM – 11.00 AM
Plenary Session I Dr. Sunil Gupta Professor School of Pharmacy Mangalayata University, Aligarh (UP).	Title: Application of QbD in Pharmaceutical Analysis	11.00 AM – 12.30 PM
Break	12.30 PM – 01.00 PM	
Plenary Session II Dr. Alok Sharma Professor and Head Department of Pharmacognosy, MIET, Meerut.	Title: Application of QbD in Herbal Extraction	01.00 PM – 02.30 PM
Plenary Session III Dr. Vineet Rai Project Scientist II DBT Builder Project School of Pharmaceutical Sciences Siksha O Anusandhan University Bhubaneswar (Odisha).	Title: Application of QbD in Phar- maceutical Product Development	02.30 – 4.00 PM
Vote of Thanks	Dr. Pankaj Dhapke	04.00 PM – 04.15 PM

Note:

Certificate will be issued after filling the feedback form within 3 days.

Kindly post your queries on You Tube comment Box; they will be address after scrutiny from organizer by the speakers during running session.

Conference Report

Introduction

Events around the world over the last few decades have emphasized the need for more detail elaborations on Applications of QbD in Pharmaceutical Research. QbD is a cost and time efficient approach in design and manufacturing, with DoE, risk assessment, and PAT as its tools to achieve a better understanding on the materials and processes, which make the QbD available and feasible to the pharmaceutical field.

One of the main benefits of using the QbD approach is that it gives the manufacturing team a clear understanding of the process parameters and how they work together. By doing so, it reduces the likelihood of unexpected reasons causing batch failure.

The purpose of pharmaceutical quality assurance is to ensure that the medication being manufactured will provide the desired effect to the patient. Quality assurance also guarantees that there are no contaminants present and that the medications will meet quality requirements and all relevant regulations.

The Program

To create awareness amongst pharma professionals including students, researchers, academicians, industry persons etc about the Application of QbD, Kamla Nehru College of Pharmacy organized this national conference in collaboration with Association of Pharmaceutical Teachers of India (Maharashtra Branch) in online mode.

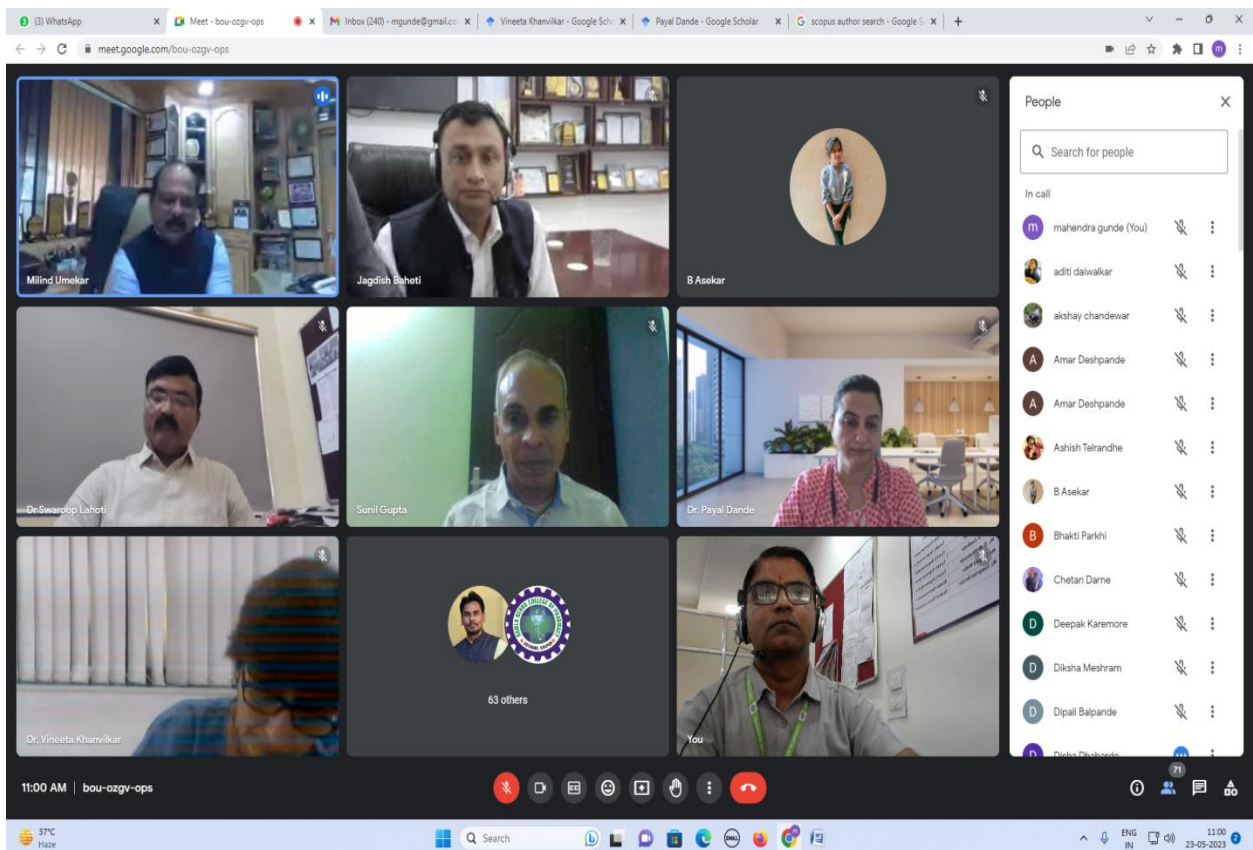
The Conference aimed at bringing the views of experts, researchers, academia and students to the forefront, with the purpose of creating substantial positive change in the Pharmaceutical industries regarding QbD.

Participation

The conference witnessed a participation of nearly 200 delegates including academicians and students from various Institutions around the country. The Conference created a lot of excitement in the research fraternity which was reflected in the form of interactive questions from the participants.

Inaugural Session

Dr. Milind Umekar, President APTI (Central) inaugurated the Conference, with Dr. Rakesh Somani, President APTI (Maharashtra Branch) and Dr. Swaroop Lahoti, Vice President APTI (Maharashtra Branch). Dr. Umekar Highlighted the achievement of APTI in small span of time and focused on collection of data of all teachers of pharmacy from country and explain the future plans for benefits of teachers. . Dr. Somani enlightened the various events organized by APTI Maharashtra branch and active participants of all stake holders. Dr. Lahoti explains how concepts of QbD can be apply in real life to live life happily. Principal and Convener Dr. Jagdish Baheti welcomed the dignitaries and greeted one and all and expresses thanks for giving opportunity to conduct this conference. Dr. Parimal Katolkar, Coordinator of the conference presented the theme of the conference in a lucid manner for the understanding of the audience. Anchoring was done by Prof. Disha Dhabarde and vote of thanks was given by Dr. Pankaj Dhapke



Session –I

Soon after the Inaugural session, the first technical session on “Applications of QbD in Pharmaceutical analysis” began. The Keynote Speaker for this session was Dr. Sunil Gupta, Professor, School of Pharmacy, Mangalyatan University, Aligarh, U.P. The moderator for this session was Prof. Kavita Pandey, she briefly introduced the speaker. Dr. Gupta gave a brief overview about the basics of QbD and elaborates on applications of QbD in Pharmaceutical Formulation by giving more emphasis on Analytical QbD. He describes how combining a focus on process understanding with a structured risk-assessment process can help develop control strategies that enhance process robustness. Similar concepts are also discussed in ICH Q8 Pharmaceutical Development and International Conference on Harmonization (ICH) Q9 Quality Risk Management. He also explains how the principles of QbD being developed for manufacturing processes can equally well be applied to ensure that analytical tests methods and process analytical technology (PAT) are robust, as defined by ICH Q2(R1).

The screenshot shows a Microsoft Teams meeting interface. The main window displays a presentation slide titled "What is QbD? – Our Definition". The slide content includes the following text and images:

- Title: **What is QbD? – Our Definition**
- Text: "The questions you must answer for every project"
- Text: "What does the Customer want?"
- Image: A cartoon of a man with a lightbulb idea.
- Text: "How exactly will you deliver the project?"
- Image: A cartoon of a man pointing at a sign that says "WRONGWAY".
- Text: "What can possibly go wrong?"
- Signature: Sunil Gupta

The meeting interface shows several participants in a grid view on the right, including Jagdish Baheti, Lokes Thote, Sunil Gupta, Disha Dhabarde, knpc pharmacy, kavitarajesh pandey, Parimal Katolkar, and 70 others. The bottom of the screen shows the Windows taskbar with the time 11:19 AM and date 23-05-2023.

Session-II

The Second technical session was on “Application of QbD in Herbal Extraction” The key note speaker for the session was Dr. Alok Sharma, Professor & Head, Department of Pharmacognosy, MIET, Meerut, U.P. The moderator for this session was Dr. Mahendra Gunde, he briefly introduced the speaker. Dr. Sharma introduced the topic for the session by explaining the application of QbD in extraction of phytoconstituents from plant materials. He further explains the concepts by giving his research case study examples like extraction of gallic acids from Amla fruit. He endeavors to highlight the applications of QbD in improving extraction process of potent bioactives from medicinal plants using modern extraction techniques. The objective, in a nutshell, is to show the real utility of systematic QbD tools for extraction processes of varied kinds with minimal expenditure of time, cost and other resources.

The screenshot displays a Microsoft Teams meeting interface. The main window shows a PowerPoint presentation slide titled "A Good Teacher is A Master of Simplification and A Good Researcher is Open-minded and Adopt A Critical Way of Thinking". The slide includes an image of a man wearing headphones and gesturing while speaking. The presentation is titled "Presentation Nagpur [Compatibility Mode] - Microsoft PowerPoint". The Teams interface shows a grid of participant avatars, including Alok Sharma, knop pharmacy, Swapnil Kale, k p, Shweta Dhole, Rashmi Khope, Deepika Modi, and 30 others. The bottom status bar indicates the time is 3:05 PM and the user is bou-ozgv-ops.

Session-III

The Third technical session was on “Application of QbD in Pharmaceutical Product Development ” The Keynote Speaker for this session was Dr. Vineet Kumar Rai, Scientist DBT Builder Project, School of Pharmaceutical Sciences, Siksha O Anusandhan University, Bhubaneswar, Orissa. The moderator for this session was Dr. Nitin Padole, he briefly introduced the speaker. Dr. Rai enlightened the participants with the importance of QbD in Pharmaceutical Product Development by explaining various parameters which affects the QbD. He emphasized the principles and applications of QbD in pharmaceutical development in their guidance for the industry.

He explain key elements of QbD viz., target product quality profile, critical quality attributes, risk assessments, design space, control strategy, product lifecycle management, and continual improvement are discussed to understand the performance of dosage forms within design space. Design of experiments, risk assessment tools, and process analytical technology are also discussed for their role in QbD. His talk underlines the importance of QbD in inculcating science-based approach in pharmaceutical product development.

The screenshot displays a Google Meet interface. The main window shows a PowerPoint presentation titled "Application of QbD in Pharmaceutical Product Development". The slide content includes the following text and logos:

- Application of QbD in Pharmaceutical Product Development**
- ICH QbD (R2)** logo with the tagline "QUALITY BY DESIGN International Council for Harmonization"
- Dr Vineet Kumar Rai**, Scientist, DBT BUILDER Project, School of Pharmaceutical Sciences, Siksha O Anusandhan University, Bhubaneswar

The presentation also features logos for the Department of Botany, Government of India, and Siksha O Anusandhan University. The Google Meet interface shows a grid of participants on the right, including Vineet Rai, Amar Doshpande, Swapnil Kale, Priyanka Boratwar, knpc pharmacy, Swapnil Kale, Dr. Nitin Padole, and 29 others. The bottom of the screen shows the system tray with the time 3:15 PM and date 23-05-2023.

The Conference ended with these probable outcomes and conclusions:

- The conference was highly applauded for bringing together great minds from different fields of QbD. Their views and discussions made the audience see how application of QbD is important in Pharmaceutical industry.
- There was also an emphasis, especially in the plenary session discussions, to make the audience realise how the whole idea of QbD is changing with the changing perception of Pharmaceutical industry worldwide.
- The conference also provided an active platform to discussions on the user centric nature of QbD that apparently becomes a cost effective medium for Pharmaceutical industry.
- The Conference has shown the way as to what can be achieved through such events that are supported by organizations like APTI and have the active participations from students and academics.