

**SHREE NARANJIBHAI LALBHAI PATEL COLLEGE OF
PHARMACY, UMRAKH**

International Webinar Report

Date: 06-06-2020

Topic: “Quality by Design (QbD) Implementation: An Industry Perspectives”

Guest Speaker: Mr. Bhupendra Kaushik, New Product Development Manager, Martindale Pharmaceuticals, London, UK

Number of Participants: 592

Summary of Lecture:

S.N.L.P. College of Pharmacy has arranged International Webinar on “**Quality by Design (QbD) Implementation: An Industry Perspectives**” for B. Pharm and M. Pharm Students, Faculty members and Industrial Person on 06th June 2020. “**QbD is understanding the manufacturing process and identifying the key steps for obtaining and assuring a pre-defined product quality**”. The US FDA’s quality by design (QbD) initiative and associated ICH Q8, Q9, and Q10 guidance documents are increasingly embraced by the pharmaceutical manufacturing industry for ensuring consistent product quality and lower costs of development and manufacturing. Sir has explained critical problems of drug Stability, Bioavailability, Solubility, Shelf life, Patent protection, Viscosity, Safety, and Cost, which are overcome by applying QbD. Moreover, sir has described the benefits of QbD 1) Improved productivity (focusing resources on what is often a small number of key variables) 2) Fewer variables allowing real-time monitoring and timely release of product (a closer observation of key process parameters and quality outcomes). 3) Improved control strategies and robust risk assessments. 4) A valuable knowledge management system (people no longer spend substantial periods performing root-cause analysis). 5) Lower rates of production failure and scrap.

The teaching faculties of SNLPCP and 592 participants attended the session. Sir has also explained the various examples for the same. This lecture will enlightening for the students to how to implement and determine the benefits of QbD. At last, we had taken feedback form from participants and got 437 responses.

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Control Strategy

Control Strategy is a planned set of controls, Derived from current product and process understanding that assures process performance and product quality

Critical Quality Attribute (CQA):
A physical, chemical, biological, or microbiological property or characteristic that must be controlled to ensure the process produces the desired quality (CQAs)

Critical Process Parameter (CPP):
A process parameter whose variability has an impact on a critical quality attribute and therefore should be monitored or controlled to ensure the process produces the desired quality (CQAs)

Your mic is muted

Dr. Dhruv P. Shah, Principal, ...

M.Pharm. in-Pharmaceutics, Pharmacology and Quality Assurance

Web : www.snipcpc.ac.in
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Audio Video Cam/Mic Chat Leave

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What are the key challenges ?

Your mic is muted

Challenge	Percentage
Stability	48%
Patent protection	19%
Viscosity	12%
FTO	10%
Adjuvant compatibility	8%
Other	2%

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- **Total Participants**

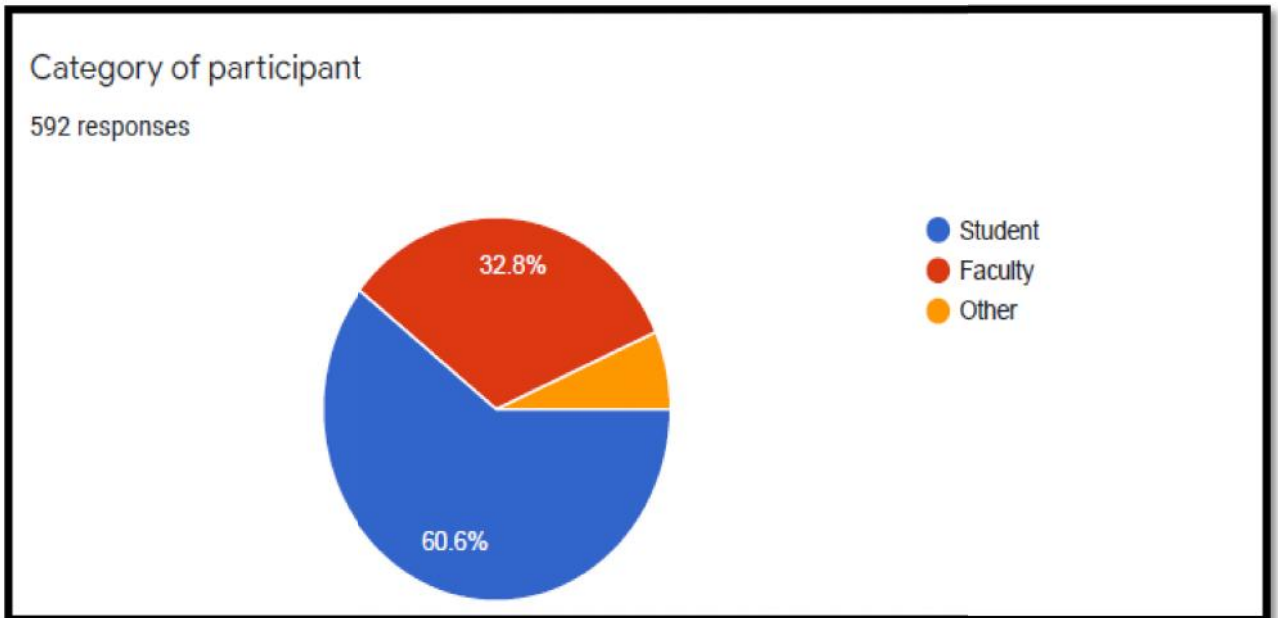
6/8/2020 Webinar Registration form - Google Forms

Webinar Registration form

Questions Responses 592

592 responses

Not accepting responses

A screenshot of a Google Forms interface. At the top left, it shows the date '6/8/2020' and the form title 'Webinar Registration form - Google Forms'. Below the title, there are icons for a document, a palette, a play button, and a vertical ellipsis. The main heading is 'Webinar Registration form'. Below that, it says 'Questions Responses 592'. A large box contains the text '592 responses' and a green plus icon with a vertical ellipsis. At the bottom right, there is a toggle switch labeled 'Not accepting responses' which is currently turned off.

- **Participants Feedback Forms**

6/8/2020 Mr. Bhupendra Kaushik webinar - Google Forms

Mr. Bhupendra Kaushik webinar

Questions Responses 437

437 responses

Accepting responses

Summary Question Individual

