SHREE NARANJIBHAI LALBHAI PATEL COLLEGE OF PHARMACY, UMRAKH

International Webinar Report

Date: 06-06-2020

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

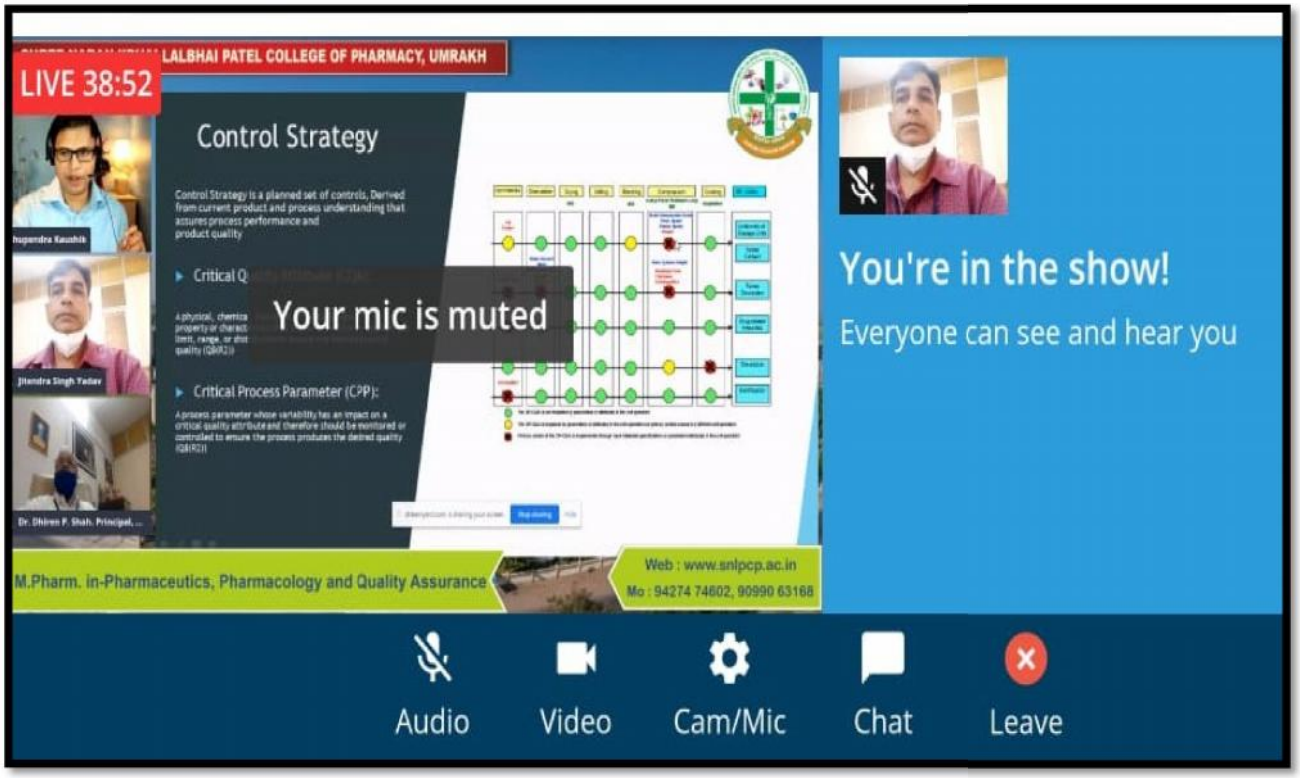
Guest Speaker: Mr. Bhupendra Kaushik, New Product Development Manager, Martindale Pharmaceuticals, London, UK

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 problemsof 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 anddetermine the benefits of QbD. At last, we had taken feedback form from participants and got 437 responses.


LIVE 38:52
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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 Q
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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 (QbR2)
M.Pharm. in-Pharmaceutics, Pharmacology and Quality Assurance
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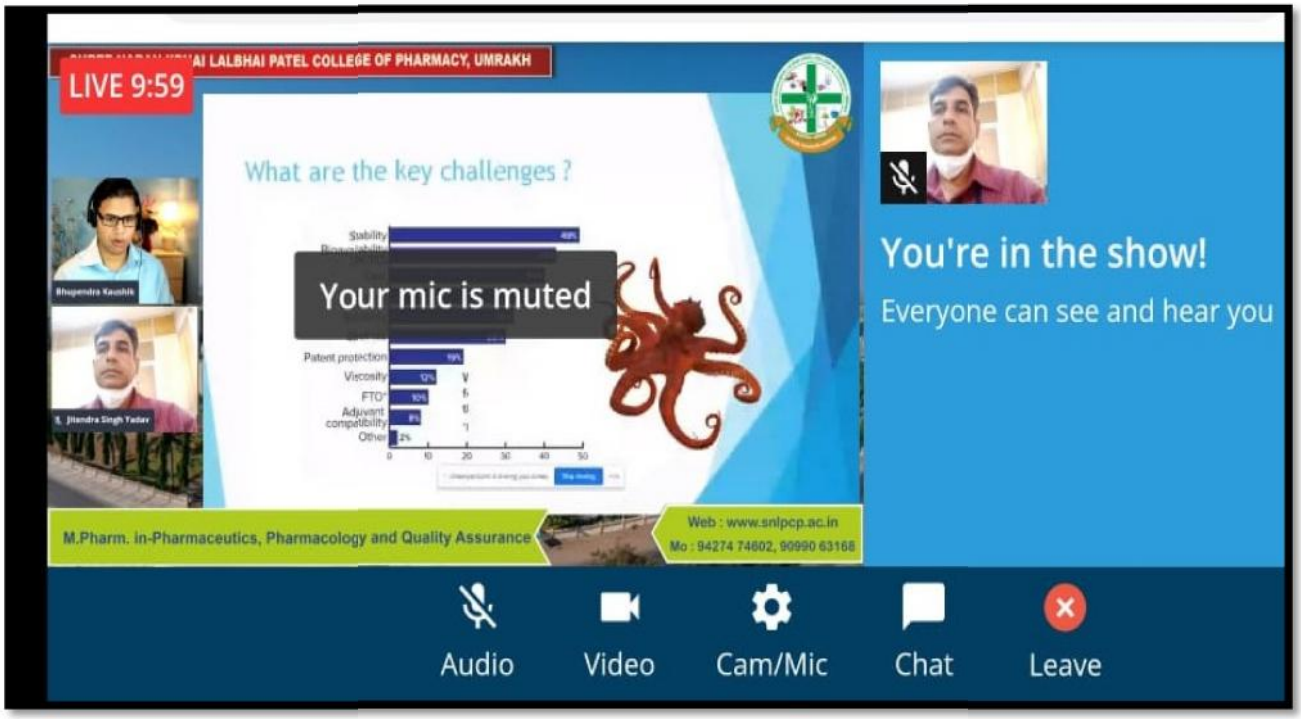
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What are the key challenges ?
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Patent protection
Viscosity
FTC*
Adjuvant compatibility
Other
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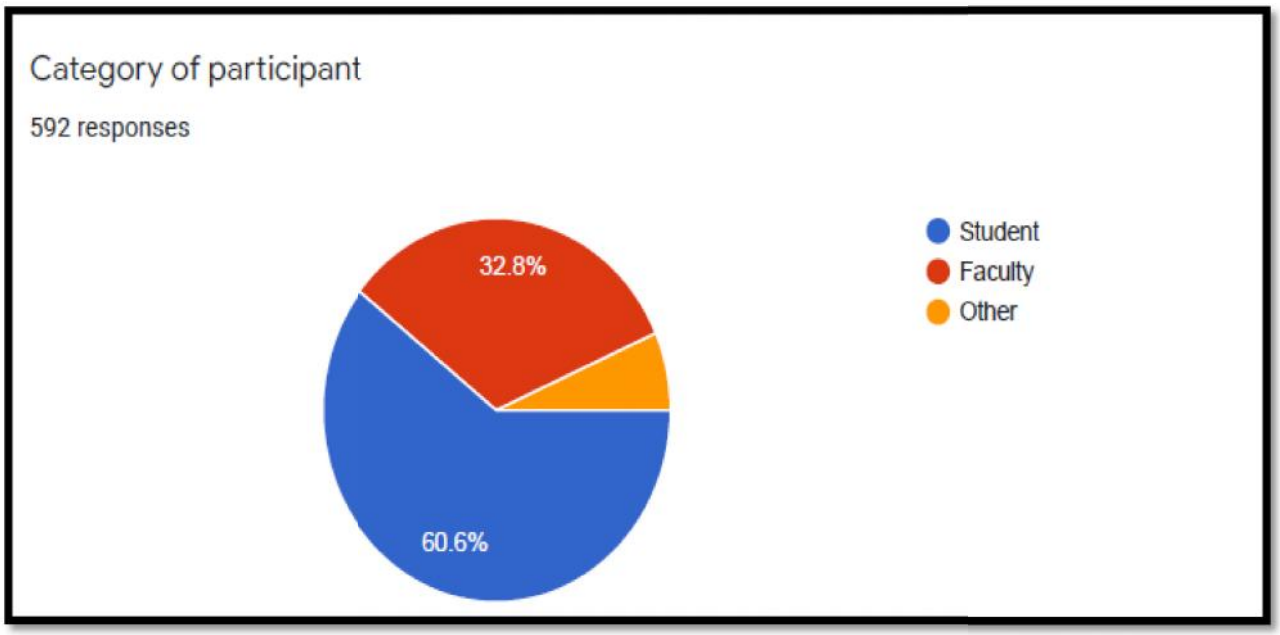
- **Total Participants**



- **Participants Feedback Forms**