



Vishnu Waman Thakur Charitable Trust's  
**VIVA Institute of Pharmacy**

Approved by PCI, AICTE (New Delhi), DTE (Government of Maharashtra),  
and Affiliated to University of Mumbai

**Overview of quality assurance & regulatory affairs in pharmaceutical  
Industry**

VISHNU WAMAN THAKUR CHARITABLE TRUST'S  
**VIVA INSTITUTE OF PHARMACY**  
SHIRGAON, VIRAR EAST - 401305

NATIONAL SEMINAR  
ON  
**Overview of Quality Assurance and  
Regulatory Affairs  
In  
Pharmaceutical Industry**

DATE : 8<sup>TH</sup> APRIL, 2022 TIME : 10.45AM TO 1.00 PM

**RESOURCE PERSONS :**

❖ **SANDHYA GAWAI**  
( ASSISTANT MANAGER - REGULATORY AFFAIRS AT  
AUROCHEM LABORATORIES Pvt. Ltd )  
TOPIC : PHARMACEUTICAL REGULATORY AFFAIRS  
(10.45 AM - 11.45 PM)

❖ **SUNIL GULHANE**  
( ASSISTANT MANAGER - QUALITY ASSURANCE AT  
AUROCHEM LABORATORIES (I) Pvt. Ltd )  
TOPIC : QUALITY ASSURANCE IN PHARMACEUTICAL INDUSTRY  
(12.00 PM - 1.00 PM)

**CONVENER :- DR.SUNITA OGALE (PRINCIPAL)**  
**CO-ORDINATOR :- PROF. SUSHRUTA MULAY**  
(+919594374489)





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## Report :

Webinar – Overview of quality assurance and regulatory affairs in pharmaceutical industry

Venue – Google

Date and Time – 8<sup>th</sup> April 2022 Time: 10:45am to 1:00pm

Speaker – 1) Sunil Gulhane

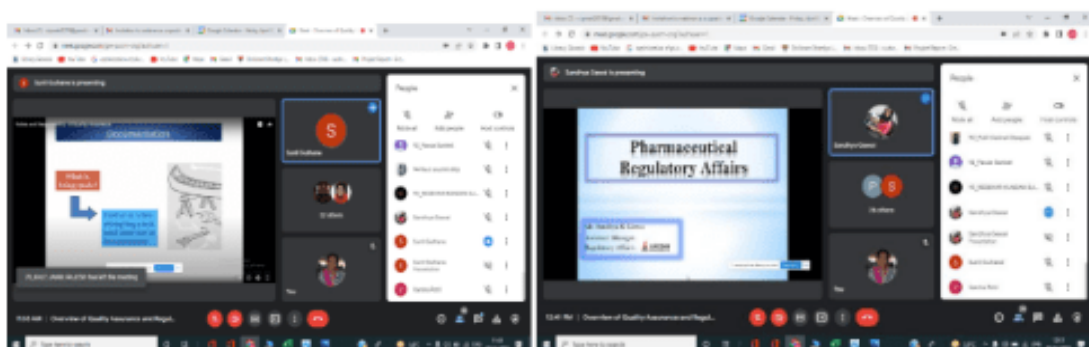
(Assistant Manager – Quality Assurance at Aurochem Laboratories Pvt.Ltd)

2) Sandhya Gawai

(Assistant Manager- Regulatory Affairs at Aurochem Laboratories Pvt.Ltd)

VIVA Institute of Pharmacy, Virar coordinated the virtual webinar on quality assurance and regulatory affairs in pharmaceutical industry. Prof. Sushruta Mulay started the webinar by hosting and welcoming everyone including the speakers. Nitisha Patil student of final year introduced the first speaker to everyone i.e. Mr.Sunil Gulhane. The first speaker explained various things related to quality assurance such as definition and principle of QA, system of QA, types of documents used, SOP's, master formula and batch process records. He also explained training files, validation, environmental monitoring trends and annual product review.

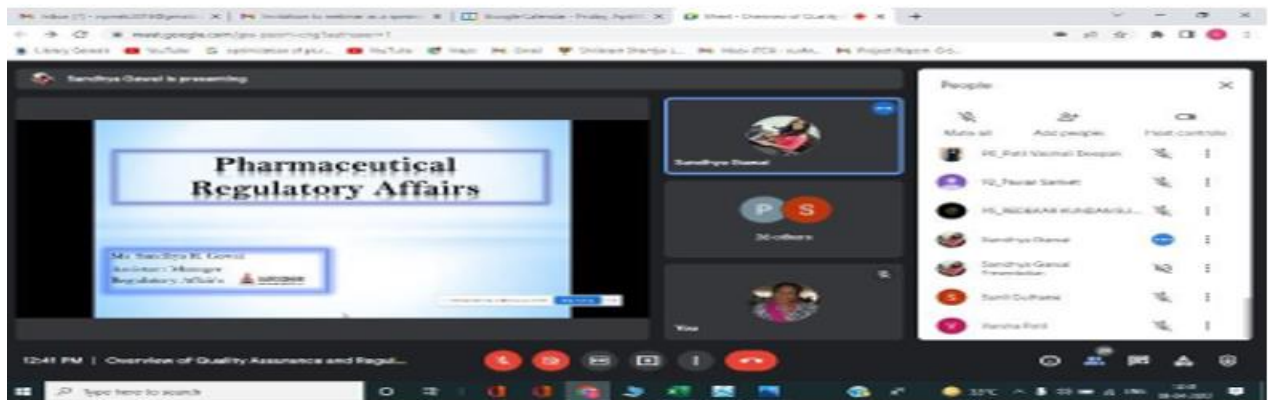
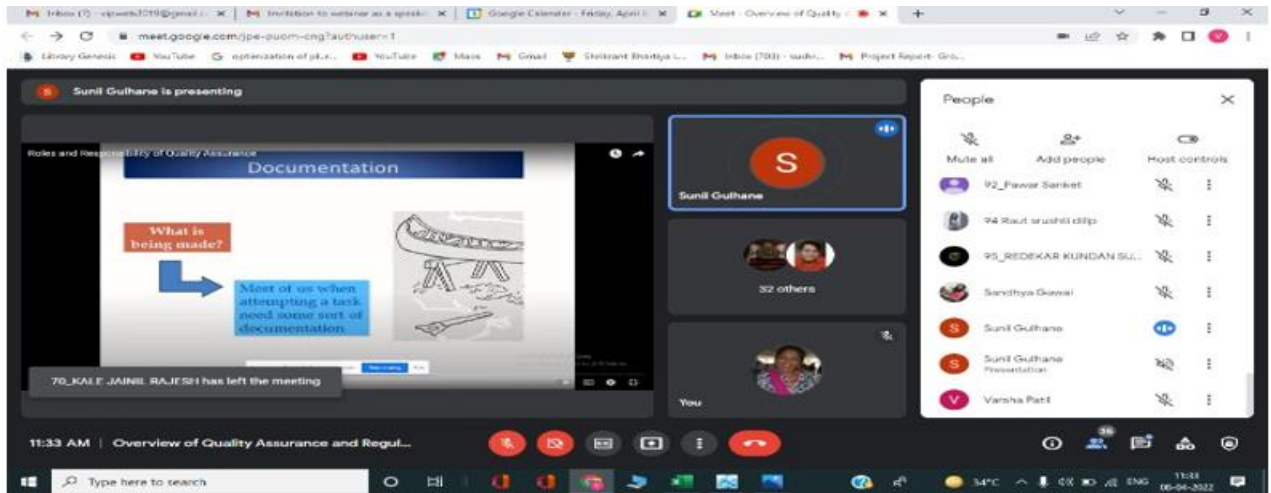
The second speaker i.e. Ms. Sandhya Gawai was introduced by Nitisha Patil and she explained various things related to regulatory affairs. She explained everyone regarding role and interactions of regulatory affairs, dossier, submission of dossier, registration process, CTD triangle, stability zone, scope. She also told regarding job description of RA executive. Last but not least Prof. Sushruta Mulay stated gratitude to everyone including speakers and day finished by getting great knowledge by both the speakers.





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Invitation to webinar as a speaker

Sushruta Mulay <sushrutamulay@gmail.com>  
to spgullhanes, g.sandhya118

**Respected sir and Madam**

You have been invited as speakers for national webinar on 8 April 2022 on following topics,

1. Quality Assurance in Pharmaceutical industry.
2. Pharmaceutical Regulatory affairs

Kindly accept our invitation.

Thanking You  
Sushruta Mulay  
Assistant Professor, VIVA Institute of Pharmacy, Virar(East).

Sent from [Mail](#) for Windows





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