**IIHMR UNIVERSITY, JAIPUR**

**EVENT OUTCOME REPORT**

**"Master Class Episode 136"**

| **"Master Class Episode 136"** |
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| **TOPIC: "Drug Approval Process and Regulatory Challenges"** |
| **DATE: 01st May 2025 – from 10:00 AM to 3:30 PM (IST)** |
| **VENUE:** IIHMR University, Jaipur |
| **SPEAKER:** Dr. Varsha Pradhan, Partner – Regulatory Affairs, Roche Products (India) Pvt. Ltd., New Delhi, India |
| **NUMBER OF PARTICIPANTS:** 126 students from 1st year MBA (Pharmaceutical Management) |
| **INTRODUCTION:** The 136th episode of Master class Session titled -"Drug Approval Process and Regulatory Challenges held on: 01st May, 2025 at IIHMR University. This session featured the guest speaker Dr. Varsha Pradhan (Partner – Regulatory Affairs, Roche Products (India) Pvt. Ltd., New Delhi, India). The event was moderated by Dr. Ashok Kumar Peepliwal, Professor, School of Pharmaceutical Management, IIHMR University, Jaipur, Rajasthan, India and Student Co-ordinator Ms. Kasturi Sawarkar, Batch: MBAPM-16 |
| **OBJECTIVE:** This session aims to introduce detailed overviews of Regulatory frameworks and authorities, navigating regulatory challenges, understanding drug approval types and filings, Global drug licensing and export procedures, Regulatory application beyond initial approvals, Developing practical regulatory knowledge. |
| **Salient Novel Points Covered:**<br><br>**ROLE:** Dr. Varsha Pradhan provided an insightful overview of pharmaceutical regulatory affairs integrated with foundational business laws, making it particularly suitable for advanced learners. It begins with the application of Indian business statutes—such as the Contract Act and Consumer Protection Act—to pharmaceutical operations, establishing a unique legal-business interface. A distinctive feature is the in-depth exploration of India's drug regulatory evolution, including lesser-covered laws like the Excise Duties and Narcotic Drugs Acts. It further delves into national pharmaceutical policy, highlighting aspects of industrial licensing and R&D funding under the DPCO, which are often overlooked in similar programs. It provides a global perspective through detailed study of WHO and ICH guidelines, international drug approval processes, and licensing challenges across various regions including the EU, Africa, Asia, and Australia-New Zealand. Advanced regulatory topics such as SUPAC (Scale-Up and Post-Approval Changes), CMC documentation for APIs, and computerized system validations add a technical edge. Additionally, the inclusion of biosimilars and biologics regulations, electronic submission protocols like ICH M2-eCTD, and global pharmacovigilance practices underscores the program's relevance to current industry standards and international compliance.<br><br>**KEY TAKEAWAY POINTS FROM THE SESSION:**<br><br>**1. Understanding of Core Business Laws in Pharma**<br><br>Participants gain insights into how general business laws such as the Indian Contract Act, Sale of Goods Act, Consumer Protection Act (1986), and Information Technology Act impact the pharmaceutical industry. These laws form the legal backbone of business transactions and operations, helping professionals navigate commercial and contractual obligations within the pharma sector.<br><br>**2. Indian Drug Regulatory Framework**<br><br>The session offers an in-depth look into the evolution of drug regulation in India, including the Pharmacy Act (1948), Drugs and Cosmetics Act (1940), and Excise Duties Act (1955). This historical and regulatory perspective helps |

professionals understand the rationale behind current practices and anticipate regulatory expectations in compliance and audit situations.

**3. National Pharmaceutical Policy and DPCO**

A critical takeaway is the focus on Drug Price Control Order (DPCO) and its relationship with industrial licensing, R&D, and public healthcare access. Learners understand how government controls on drug pricing affect pharmaceutical marketing strategies and innovation incentives. WHO and ICH Guidelines for Global Compliance

It emphasizes international harmonization through WHO certification and ICH guidelines (S, E, M). This equips learners to work in cross-border regulatory roles, preparing dossiers that meet the standards of various global regulatory agencies.

**5. Drug Approval Processes and Global Licensing**

Participants are introduced to drug approval pathways including INDA (Investigational New Drug Application), NDA (New Drug Application), ANDA (Abbreviated New Drug Application), and DMF (Drug Master File) in the USFDA system. It also highlights the regulatory challenges of international licensing in the EU, Asia, Africa, and Australia-New Zealand, essential for companies aiming to expand globally.

**6. Active Pharmaceutical Ingredient (API) Regulatory Requirements**

This part covers the CMC (Chemistry, Manufacturing, and Control) requirements, documentation of API sections, registration samples, and post-approval change management. Understanding these technical and regulatory details is vital for ensuring quality and consistency in manufacturing.

**7. Regulation of Biologicals and Biosimilars**

Participants explore the US and EU guidelines on biosimilars, which are a growing segment in global therapeutics. It also addresses growth drivers for biosimilars in India and the regulatory pathways for their approval, helping professionals align with emerging trends.

**8. Electronic Pharmaceutical Documentation & Submission**

It delves into electronic documentation systems, including ICH M2-eCTD standards for submitting regulatory documents electronically. Participants also learn about SOPs, batch records, and documentation practices required for global audits and compliance.

**9. Post-Marketing Surveillance (PMS) and Pharmacovigilance**

A key learning area is the concept of medicine safety, ADR (Adverse Drug Reaction) reporting, and pharmacovigilance regulations across countries like the US, EU, and Turkey. Professionals learn to monitor and manage risks even after drug approval, a critical responsibility in regulatory and quality roles.

**10. Pharmaceutical Qualification and Validation**

Finally, the session explains Qualification and Validation (Q&V) principles, scope, and types of documentation required to validate computerized systems in the industry. This is crucial for ensuring regulatory compliance in manufacturing and data handling systems, especially under USFDA and EU inspections.

**Future Scope:** The Master Class on "Drug Approval Process and Regulatory Challenges" offers significant future scope for professionals and students in the pharmaceutical and healthcare industries. As global regulatory frameworks become more complex and essential to the success of drug development, this master class equips participants with the knowledge needed to navigate international systems such as those of the USFDA, EMA, and WHO. It opens career opportunities in regulatory affairs, pharmacovigilance, compliance, and quality assurance across multinational companies. Additionally, with the pharmaceutical industry increasingly focused on biologics, biosimilars, and personalized medicine, professionals trained in these regulatory pathways are in high demand. The session also benefits aspiring entrepreneurs and startup founders by providing a solid foundation in the regulatory lifecycle of drugs, helping them bring products to market efficiently and compliantly.

IIHMR UNIVERSITY

Master Class
Episode 136

# Drug approval process and regulatory challenges

Thursday, 01st May 2025 | 10:00 AM to 03:30 PM (IST) | IIHMR University, Jaipur

MODERATOR

**Dr. Ashok Kumar Peepliwal**
Professor
School of Pharmaceutical Management
IIHMR University, Jaipur, Rajasthan, India

SPEAKER

**Dr. Varsha Pradhan**
Partner - Regulatory Affairs
Roche Products (India) Pvt. Ltd.
New Delhi, India

STUDENT CO-ORDINATOR

**Ms. Kasturi Sawarkar**
Batch: MBAPM-16
IIHMR University, Jaipur
Rajasthan, India


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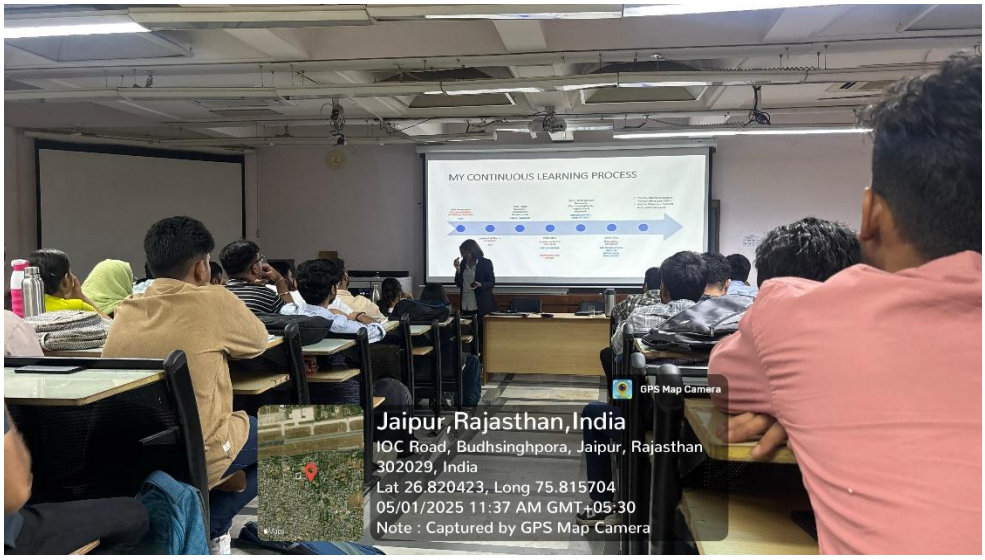
MY CONTINUOUS LEARNING PROCESS
GPS Map Camera
Jaipur,Rajasthan,India
IOC Road, Budhsinghpora, Jaipur, Rajasthan 302029, India
Lat 26.820423, Long 75.815704
05/01/2025 11:37 AM GMT+05:30
Note : Captured by GPS Map Camera


GPS Map Camera
Jaipur,Rajasthan,India
IOC Road, Budhsinghpora, Jaipur, Rajasthan 302029, India
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GPS Map Camera
Jaipur,Rajasthan,India
IOC Road, Budhsinghpora, Jaipur, Rajasthan
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Drug approval process and regulatory challenges
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IOC Road, Budhsinghpora, Jaipur, Rajasthan
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Drug approval process and regulatory challenges
GPS Map Camera
Jaipur,Rajasthan,India
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302029, India
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Note : Captured by GPS Map Camera

# Master Class Session Episode 136

**Date: 01/05/2025 (10:00 AM to 03:30PM)**

## Attendance Sheet

| Sr. No. | Students Name | Stream with Batch | Sign |
|---|---|---|---|
| 1 | Paras Gupta | PM-16 | |
| 2 | Avichal Gupta. | PM-16 | |
| 3 | Bhavneet Singh | PM-16 | |
| 4 | Aditi Mishra | PM-16 | |
| 5 | Priyanka Singh | PM-16 | |
| 6 | Avinash Pandey | PM-16 | |
| 7 | Anand Ray | PM-16 | |
| 8 | Dimpal chaudhari | PM-16 | |
| 9 | vaidya Disha Tushar. | PM-16 | |
| 10 | Mansi Gaikwad | PM-16 | |
| 11 | Mansi Gupta | PM-16 | |
| 12 | Shashank Chauhan | PM-16 | |
| 13 | Aayush Chauhan | PM-16 | |
| 14 | Muskan Lariya | PM-16 | |
| 15 | Paras Kirti | PM-16 | |
| 16 | Jayesh Shetty | PM-16 | |
| 17 | Druvi Baid | PM-16 | |
| 18 | Meet Rupareł. | PM-16 | |
| 19 | Manjish A. Gupta | PM-16 | |
| 20 | prashant. Borkar | PM-16 | |
| 21 | Unmesh Anil Patil | PM-16 | |
| 22 | Shashikant Mahajan | PM-16 | |
| 23 | Khemvardhan | PM-16 | |
| 24 | Kripa sarun shrivastava | PM-16 | |
| 25 | Devangan Bharat Jeevan | PM-16 | |
| 26 | Kshitij Shevkar. | PM-16. | |
| 27 | Shubham Sharma | PM-16 | |

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## Attendance Sheet

| Sr. No. | Students Name | Stream with Batch | Sign |
|---|---|---|---|
| 28 | Abhinav Chaudhary | PM16 | |
| 29 | Abhinav Patidar | PM16 | |
| 30 | Naman Pathak | PM16 | |
| 31 | AKASH Dashine | PM-16 | |
| 32 | Yashodeep deore | PM-16 | |
| 33 | prashant Berle | PM-16 | |
| 34 | Roshan Lathi | PM-16 | |
| 35 | Mangi Mahalkar | PM-16 | |
| 36 | Rohan Sharma | PM-16 | |
| 37 | Shefali Gupta | PM-16 | |
| 38 | Laxmi Punse | PM-16 | |
| 39 | Sanjana patil | PM-16 | |
| 40 | Amarsha Mahadule | PM-16 | |
| 41 | Anuja Yerkuntwar | PM-16 | |
| 42 | Kunal Sapkal | PM-16 | |
| 43 | Rishikesh Patil | PM-16 | |
| 44 | Devanshu Thoshi | PM-16 | |
| 45 | Utkarsh Ks. Singh | PM-16 | |
| 46 | Vansh Bhatt | PM-16 | |
| 47 | Sapna | PM-16 | |
| 48 | Swarnim Raj | PM-16 | |
| 49 | Reetik Raj | PM-16 | |
| 50 | Namit Kumar | PM-16 | |
| 51 | PANKAJ YOGI | PM-16 | |
| 52 | Gautam Chitkara | PM-16 | |
| 53 | Sandeep patel | PM-16 | |
| 54 | Khemvardhan Tanwar | PM-16 | |

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| Sr. No. | Students Name | Stream with Batch | Sign |
|---|---|---|---|
| 55 | Sagar Bhalerve | PM16 | |
| 56 | Steffi anthony | PM16 | |
| 57 | Saarthak Kumbhkarni | PM16 | |
| 58 | Anshula Chaple | PM16 | |
| 59 | Bhumika Patidar | PM16 | |
| 60 | Aishwarya Agrawal | PM16 | |
| 61 | Priyanshi Mandloi | PM16 | |
| 62 | Tanay Maji | PM16 | |
| 63 | Divyaroop Das | PM16 | |
| 64 | Deepanshu Parewa | PM-16 | |
| 65 | Jahnavi Patidar | PM-16 | |
| 66 | Ranveet Kaushik | PM-16 | |
| 67 | Krishna Rathod | PM-16 | |
| 68 | Harshal Bari | PM-16 | |
| 69 | Janak Padole | PM-16 | |
| 70 | Sonali Tomar | PM-16 | |
| 71 | Jahnavi Ramteke | PM-16 | |
| 72 | Diksha Gupta | PM-16 | |
| 73 | Avantika Kalaskar | PM-16 | |
| 74 | Jagrati Goyal | PM-16 | |
| 75 | Ankush Kumar | PM-16 | |
| 76 | Akshita Jaiswal | PM-16 | |
| 77 | Shruti Bhadwaik | PM-16 | |
| 78 | Akshat Shrimal | PM-16 | |
| 79 | Deepanjali Kumari | PM-16 | |
| 80 | Shweta Kumari | PM-16 | |
| 81 | Tuhi Jain | PM-16 | |
| 82 | Ritika Madhaiya | PM-16 | |

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**Date: 01/05/2025 (10:00 AM to 03:30PM**

## Attendance Sheet

| Sr. No. | Students Name | Stream with Batch | Sign |
|---|---|---|---|
| 83 | Nikita Panchore | PM-16 | |
| 84 | Ankita Vyas | PM-16 | |
| 85 | Sudhanshu Solanki | PM-16 | |
| 86 | Yogansh Khare | PM-16 | |
| 87 | Ballekari Saikrishna | PM-16 | |
| 88 | Yash Sawant | PM-16 | |
| 89 | Neeraj Kumar Sahu | PM-16 | |
| 90 | Talleen Dighe | PM-16 | |
| 91 | Santosh Soumyadarshi | PM-16 | |
| 92 | Devendra Singh Chouhan | PM-16 | |
| 93 | Dreishti Mohaniya | PM-16 | |
| 94 | Yash Daga | PM-16 | |
| 95 | Singh Sweta Sanjaykumar | PM-16 | |
| 96 | Sachin Verma | PM-16 | |
| 97 | Rahul | PM-16 | |
| 98 | Kasturi Samarkar | PM-16 | |
| 99 | Anshi Y. Bulsara | PM-16 | |
| 100 | Twisha G. Bhatt | PM-16 | |
| 101 | Aastha Misra | PM-16 | |
| 102 | Adhokshaja Haritas | PM-16 | |
| 103 | Narayan S Nayak | PM-16 | |
| 104 | Singh Nilesh Pankaj | PM-16 | |
| 105 | Hemaeangan. J | PM-16 | |
| 106 | Divesh Pravin Bavishkar | PM-16 | |
| 107 | FATHIMA SHAHALA | PM-16 | |
| 108 | Gangawal Ruturaj Rajesh | PM-16 | |
| 109 | Shrittari. RK | PM-16 | |
| 110 | Madhusudan SD | PM-16 | |
| 111 | Baswa Nandini | PM-16 | |
| 112 | Archit Shukla | PM-16 | |
| 113 | Devam Raval | PM-16 | |
| 114 | Anuradha Dangi | PM-16 | |
| 115 | Amit kumar | PM-16 | |
| 116 | Ayush Payal | PM-16 | |
| 117 | Bhavesh Parihar | PM-16 | |
| 118 | Anilat Indrali | PM-16 | |

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| Sr. No. | Students Name | Stream with Batch | Sign |
|---|---|---|---|
| 119 | Jatin Saini | PM - 16 | Jatin |
| 120 | Sakshi Saini | PM - 16 | Sakshi |
| 121 | Jyot Kanchiya | PM - 16 | JK |
| 122 | Ishank Yadav | PM - 16 | Ishank |
| 123 | Shivansh Mehrotra | PM - 16 | Shivansh |
| 124 | Manashvi gayvad. | PM - 16 | Manashvi |
| 125 | Pushparaj Patil | PM - 16 | Pushparaj |
| 126 | Avinash Yadav | PM - 16 | Avinash |
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