

**IIHMR UNIVERSITY, JAIPUR**  
**EVENT OUTCOME REPORT**  
**“Master Class Episode 137”**

“Master Class Episode 137”	
<b>TOPIC: “Foundation &amp; Framework of Regulatory Affairs : An Overview, function &amp; global significance Overview of US Submission &amp; Europe post approval.</b>	
<b>DATE: 2<sup>nd</sup> May 2025 – from 10:00 AM to 01:30 PM IST.</b>	
<b>VENUE: IIHMR University, Jaipur (ONLINE MODE)</b>	
<b>SPEAKER: Dr. Ankit Trivedi (Senior Team lead at Syenos Health)</b>	
<b>NUMBER OF PARTICIPANTS: 60 students from 1<sup>st</sup> year MBA (Pharmaceutical Management)</b>	
<b>INTRODUCTION:</b> The 136 <sup>th</sup> episode of Master class Session titled -“ <b>Foundation &amp; Framework of Regulatory Affairs : An Overview, function &amp; global significance Overview of US Submission &amp; Europe post approval.</b> ” held on: 02 <sup>nd</sup> May 2025 at IIHMR University. This session featured the guest speaker Dr. Ankit Trivedi (Senior Team lead at Syenos Health) . The event was moderated by Dr. Ashok Peepliwal, Professor, School of Pharmaceutical Management, IIHMR University, Jaipur, Rajasthan, India and Student Co-ordinator Mr. Bhadoriya Mohit Netrapal, Batch: MBAPM-16.	
<b>OBJECTIVE:</b> This session aims to introduce detailed overview of Regulatory Affairs, Guidelines, Regulatory understanding, and Evolving trends within the Pharmaceutical Industry. By the end, attendees understood the role of Regulatory Environment in Pharma Buisness.	
<b>Salient Novel Points Covered:</b>  The session began with a warm introduction, followed by a deep yet simple explanation of what Regulatory Affairs truly means in the pharmaceutical industry. Here are the key takeaways from the masterclass:  1. Role of Regulatory Affairs in Pharma: The speaker explained how Regulatory Affairs acts as a bridge between pharmaceutical companies and global health authorities. It ensures that all products meet safety, efficacy, and quality standards before reaching the market.  2. Drug Approval Process (USA, EU, etc.): He walked us through the entire drug approval lifecycle — right from pre-clinical data, Investigational New Drug (IND) submission, clinical trial phases, to the final New Drug Application (NDA) or Marketing Authorization Application (MAA).  3. Country-Specific Regulations: We learned how different countries like the USA (FDA), Europe (EMA), Australia (TGA), Canada (Health Canada), Brazil (ANVISA), and Russia (Minzdrav) have unique regulatory frameworks. The speaker emphasized the importance of customizing submissions as per local guidelines.  4. Types of Regulatory Submissions: He explained the difference between ANDA, NDA, MAA, and CTD formats. We also understood what variations, renewals, and supplemental filings.  5. Labeling & Product Lifecycle Management: A special focus was given to how product labels must comply with region-specific laws, and how Regulatory teams continue to manage the product even after it is launched — through updates, renewals, and post-market surveillance	

#### 6. Challenges in Regulatory Affairs:

From managing country-specific requirements to dealing with ever-evolving guidelines, the speaker shared real-world challenges faced by Regulatory professionals — especially while working with multiple global markets.

#### 7. Role of Technology & Tools:

We also got a brief overview of modern tools used in Regulatory Affairs such as document management systems, eCTD submission tools, and global databases like IDMP.

**Q&A and Interactive Session :** The session encouraged active participation from students, who not only clarified their conceptual doubts about the Pharma sector, but also asked relevant questions about how to co-relate their previous experiences with Regulatory Norms.

**Future Scope:** The future of Regulatory Affairs in the pharmaceutical industry is both dynamic and full of opportunity. As more pharmaceutical companies aim to expand globally, the need for professionals who understand diverse international regulatory requirements is steadily increasing. Regulatory Affairs is no longer limited to just compliance and documentation—it is now a strategic function that plays a vital role in product development, global launches, and lifecycle management. With the rise of digital technologies, the field is moving towards electronic submissions (eCTD), AI-assisted regulatory tracking, and advanced data management tools. Moreover, the emergence of personalized medicine, biosimilars, and advanced biologics presents new regulatory challenges, making the role of regulatory professionals even more critical. Growing markets in Latin America, Southeast Asia, and Africa are also creating fresh opportunities. In addition, the post-COVID era has shown a shift towards remote working and global collaboration, making cross-border regulatory roles more accessible. Overall, Regulatory Affairs offers a stable, evolving, and impactful career path for those who are detail-oriented, adaptable, and willing to keep pace with global healthcare advancements.

# Foundation and framework of Regulatory affairs: An Overview, function, and Global significance *along with* Overview of US submission and Europe post approval

📅 Friday, 2nd May 2025 ⌚ 10:00 AM to 01:30 PM (IST) 🇮🇳



**MODERATOR**

**Dr. Ashok Kumar Peepliwal**

Professor  
School of Pharmaceutical Management  
IIHMR University, Jaipur, Rajasthan, India



**SPEAKER**

**Mr. Ankit Trivedi**

Senior Team Lead  
Syneos Health Care  
Ahmedabad, India

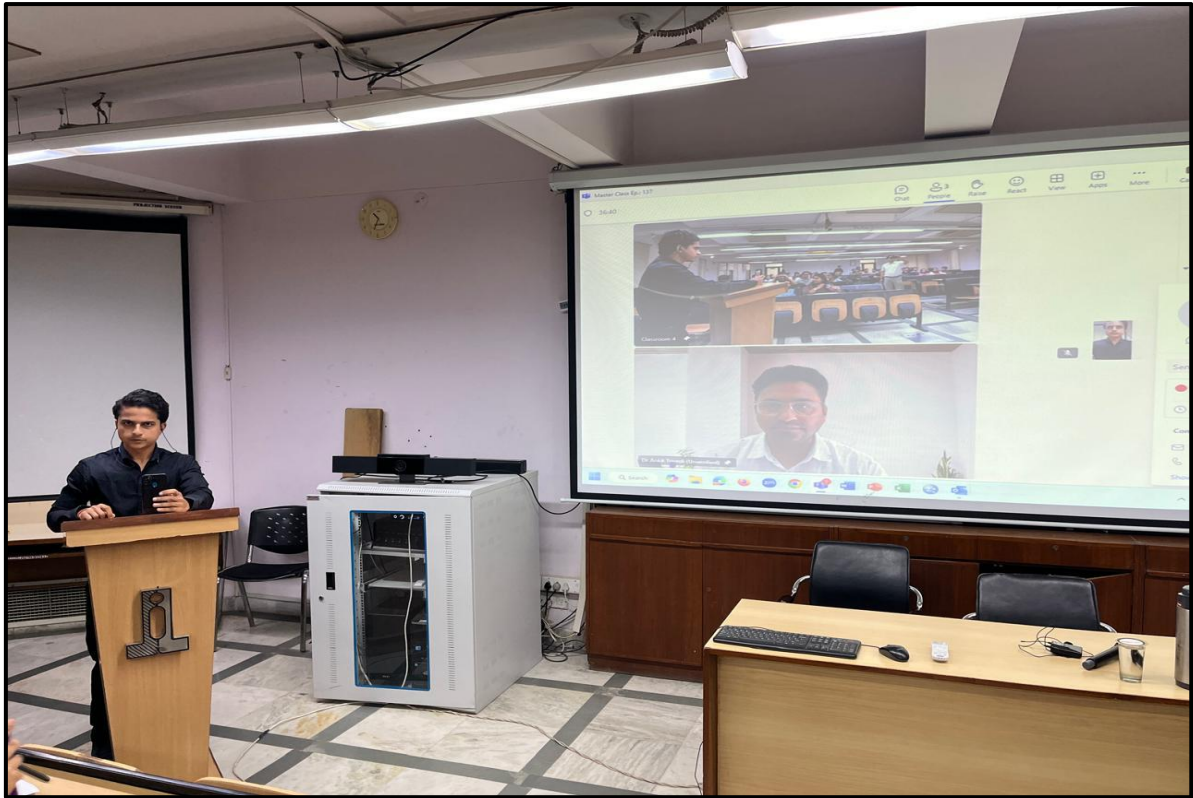


**STUDENT CO-ORDINATOR**

**Mr. Bhadoriya Mohit**

Batch: MBAPM-16  
IIHMR University, Jaipur  
Rajasthan, India







# Master Class Session Episode 137

Date: 02/05/2025 (10:00 AM to 01:30PM)

## Attendance Sheet

Sr. No.	Students Name	Stream with Batch	Sign
1	Astha Mishra	MBA-PM-16	Astha
2	Pooja Gupta	MBA-PM-16	Pooja
3	Mani Gupta	MBA-PM-16	Mani
4	Kunal Sapkal	MBA-PM-16	Kunal
5	Gautam Chitkara	MBA-PM-16	Gautam
6	Neeraj Sabu	MBA-PM-16	Neeraj
7	Benke Prashant	MBA-PM-16	Benke
8	Chaudhary Dimpal	MBA-PM-16	Dimpal
9	Yash Daga	MBA-PM-16	Yash
10	Deeksha Gupta	MBA PM 16	Deeksha
11	Deepanjali	MBA PM 16	Deepanjali
12	Yashodeep Deore	MBA PM 16	Yashodeep
13	Bhurat devangan	MBA PM 16	Bhurat
14	Devendra Singh	MBA PM 16	d. Singh
15	fatima shaleh	MBA PM 16	fatima
16	Gupta Manjish	MBA PM 16	G. Manjish
17	Harshat Bari	MBA PM 16	harshat
18	Hemangan J	MBA PM 16	Hem
19	Aniket Indrale	MBA PM 16	Aniket
20	Ishank Yadav	MBA PM 16	Ishank
21	Jagriti Goyal	MBA PM 16	Jagriti
22	Janvi Patidar	MBA PM 16	Janvi P
23	Pooja Tanak	MBA PM 16	Pooja
24	Rathod Krishna	MBA PM 16	Rk
25	Khemvudhan	MBA PM 16	Khem
26	Lakshmi	MBA PM 16	Lakshmi
27	Madhusudan	MBA PM 16	Madhu
28	Mani	MBA PM 16	Mani



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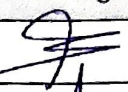



Sr. No.	Students Name	Stream with Batch	Sign
29	Naman pathak	MBA PM 16	naman
30	Kumar Namit	MBA PM 16	Kumar
31	Nikita Panchore	MBA PM 16	NP
32	Shashank Chaudhan	MBA PM 16	Shashank
33	Kalturi	MBA PM 16	Kasoo
34	Yash Sawant	MBA PM 16	Yash
35	Sapna	MBA PM 16	Sapna
36	Santosh	MBA PM 16	Santosh
37	Sanjana	MBA PM 16	Sanjana
38	Sachin verma	MBA PM 16	Verma
39	Rahul	MBA PM 16	Rahul
40	Ravneet	MBA PM 16	Ravneet
41	Priyanka Singh	MBA PM 16	Priyanka S
42	Pooja Kiri	MBA PM 16	Kiri P
43	Unmesh Patil	MBA PM 16	Unmesh Patil
44	Rishabh Patil	MBA PM 16	Rishabh
45	Ruhparaj Patil	MBA PM 16	Patil
46	Bhavesh	MBA PM 16	Bhavesh
47	Nalhin akash	MBA PM 16	Ak.
48	Narayan Nayak	MBA PM 16	Nayak
49	Shashikant mahajan	MBA PM 16	Shashikoo
50	Shifali Gupta	MBA PM 16	S. Gupta
51	Shivansh	MBA PM 16	Shivansh
52	Shrithani	MBA PM 16	Shrithani
53	Shubham	MBA PM 16	Shubham
54	Shuleta	MBA PM 16	Sh
55	Nilish	MBA PM 16	Nilish
56	Sonali Tomar	MBA PM 16	Sonali



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Sr. No.	Students Name	Stream with Batch	Sign
57	Bhadoriya Mohit	MBA PM 16	
58	Archi Shukla	MBA PM 16	
59	Nandani	MBA PM 16	
60	Khemvaradhan	MBA PM 16	
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