



**Regulatory Council**  
**is pleased to invite you to virtual Workshop on**  
**Recent Regulatory Updates**  
**on**  
**15th October 2022 (Saturday)**  
**1.30 PM-6.00 PM**  
**AGENDA**

S. No	Topic	Timings	Speakers
1.	ISCR Address	1.30 PM – 1.45 PM	Ms. Yasmin Shenoy, Sanofi India  Moderator : Mr Abhinav Shrivastava, Pfizer India
2.	Recent Regulatory updates	1.45 PM – 2.15 PM	Ms. Deepti Nair, GSK India
3.	Manage Sugam Challenges <ul style="list-style-type: none"><li>• Initial Clinical Trial Applications</li><li>• Post - approval submissions</li><li>• SAE submissions</li></ul>	2.15 PM-3.15 PM	Mr. Nitin Wani, Pfizer India  Ms. Harshada Bendre, Novartis Healthcare Pvt Ltd  Mr Jamal Baig (Sanofi India), Ms Nishi Kumari (Merck India)
4.	Subject Expert Committee Preparation - Tips/Tricks	3.15 PM – 3.45 PM	Ms. Amita Bhave, Novartis Healthcare Pvt Ltd  Ms. Sneha Gupta, IQVIA India
	Break	3.45 PM – 4.00PM	
5.	Manage Regulatory Authority CT inspections (US FDA)  BA/BE Centres (DCGI)	4.00 PM- 5.00 PM	Ms Ami Shah, SperaMed Consulting  Mrs. Ameer Kanuga, Veeda Clinical Research
6.	Career options in Clinical Research	5.00PM – 5.20PM	Dr. Kiran Marthak, Veeda Clinical Research
7.	Regulatory aspects Clinical Research with Medical Device	5.20 PM-5.50 PM	Mr. Parveen Jain, Fresenius Medical Care  Dr. Poornima Trivedi, Fresenius Medical Care
8.	Vote of Thanks	5.50 PM-6.00 PM	Ms. Yasmin Shenoy, Sanofi India

**TARGET AUDIENCE:** We invite ISCR Members, fellow Regulatory colleagues within the Regulatory Council, Regulatory professionals, Investigators, Ethics Committees members, aspiring clinical research professionals to join us for this session.

**Registration fees of INR 500/- per person**

**Online Registration:** [https://www.iscr.org/Upcoming\\_Events.aspx](https://www.iscr.org/Upcoming_Events.aspx)