Department of Health Research
Ministry of Health and Family Welfare
Government of India

Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health & Family Welfare
Government of India

Workshop on Regulatory Pathway forNewer/Repurposed Drugs for Rare Diseases

A Joint Initiative of ICMR and CDSCO

Agenda

Date: 26th September, 2024
Venue: Conference Hall, 2nd Floor, ICMR Headquarters
https://echo.zoom.us/j/89523836986

Time	Topic	Experts
10:00-10:05 AM	Welcome and Introduction to workshop	**Dr. Ruchi Singh, Scientist F and Head, Discovery Research Division, ICMR**
10:05-10:15AM	Address	**Dr. Rajiv Bahl, Secretary, DHR and Director General, ICMR**
10:15-10:25AM	KeynoteAddress	**Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India,CDSCO**
	Tea Break	
10:30-11:15 AM	Overview in orphan drug regulation	**CDSCO**
11:15-12:00 PM	Innovative Approaches in Drug Development for Rare Diseases	**Dr. Jonaki Sen, Professor, Biological Sciences and Engineering, IIT Kanpur**
12:00-12:45 PM	Regulatory Submission Process for Orphan Drugs	**CDSCO**
12:45-1:30 PM	Challenges in Newer Technologies for rare diseases	**Dr. Arkashubhra Ghosh, GROW labs**
1:30 – 2:15 PM	LUNCH	
2:15-3:00 PM	Ethical Considerations in Orphan Drug Research	**Dr. Roli Mathur, Scientist-G & Head, ICMR Bioethics Unit, DHR**
3:00-3:15 PM	Role of ICMR in advancing drug research and therapeutics for Rare Diseases	**Dr. Monika Pahuja, Scientist E, Discovery Research Division, ICMR**
03:15-03:55 PM	Q&A (Open Session)	**Chaired by Prof. Y K Gupta**
03:55-04:00 PM	Vote of Thanks	**Dr. Naveen Sharma, Scientist C, Discovery Research Division, ICMR**