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Session #6

Dr. M. K. Bhan Memorial Session on

Medical Products: From Target to Market

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Session White Paper

CHAIR, COMMUNICATIONS

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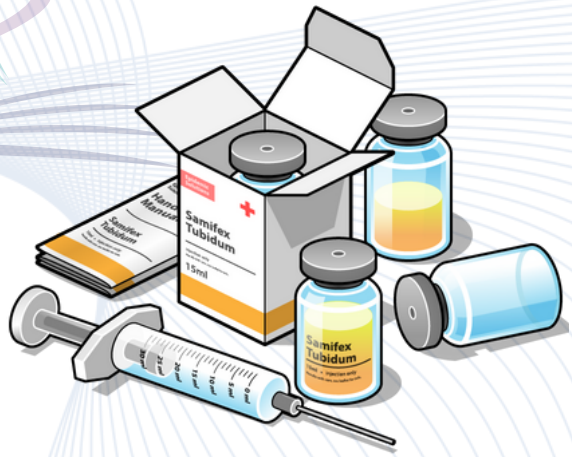
Introduction

The development of drugs, vaccines, diagnostic tests, medical devices, and biological therapeutics—collectively known as "Medical Products"—begins with basic research at the bench level. Promising medical products from proof-of-concept studies advance through rigorous research and development at academic and industrial levels, adhering to guidelines from regulatory agencies.

The entry to market depends on three main factors. First, safety and effectiveness of the medical product. Second, the price point advantage versus the product in market. Third, the competetive medical products that are already in the market and have established their presence with the physician and patient community.

In India, the Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services, Ministry of Health & Family Welfare, serves as the National Regulatory Authority (NRA). For products marketed in the USA, compliance with guidelines from the US Food and Drug Administration is mandatory.

The World Health Organization also pre-approves medical products for resource-limited countries through global donor agencies like the Global Fund or GAVI, the Vaccine Alliance.



The initial step in the product development life cycle involves small-scale manufacturing of the candidate medical product (R&D lots). These lots undergo quality, stability, and effectiveness testing in laboratory or small animal models. The subsequent stage is commercial-scale manufacturing, where efficiency considerations impact the product's market price. These lots are utili zed in various phases of clinical trials, and by the end of Phase 3, the manufacturing protocols are finalized.

Regulatory guidelines specify requirements for developing drugs, vaccines, devices, diagnostic products, and biologic therapeutics, with particular considerations for oral versus injectable forms. The development pathways for medical devices and diagnostic kits differ, with national regulatory authorities providing detailed information.

This session on **"Medical Products: From Target to Market"** offered insights into medical product development. It introduced the general audience to foundational knowledge and informed students and young professionals about industry and regulatory career opportunities.

Kashmir Global Connect, an initiative of Kashmir Care Foundation, proudly presented **Dr. Riyaz Bashir**, **Dr. Hira Nakhasi**, **Dr. Aasim Amin**, **Dr. Arshid Khuroo**, **Dr. Mudasir Andrabi**, and **Dr. Mahrukh Banday**—esteemed Kashmiri researchers in medical product development. They contributed to highly productive R&D programs in drugs, biosimilars, vaccines, and devices and were recognized as world-renowned scientists. Collectively, they published over 500 scientific papers and mentored many students and young professionals in advancing their careers.

These experts engaged in a free-flowing conversation about their academic and professional journeys to becoming leaders in medical product development. This dialogue aimed to motivate students and professionals from medical and non-medical disciplines to consider careers in this field. The experts discussed the roles of chemical engineers, mechanical engineers, and those with mixed degrees in science and management. They also highlighted the significance of Project Managers, who managed project timelines and directions.

Through sharing their experiences, these experts aspired to inspire and guide medical students and young professionals to join the field of medical product development. By fostering a culture of inquiry and collaboration, they envisioned a future where Kashmiri students and physicians would become researchers and future leaders in this domain.

Know the panelists:


Dr Arshad H Khuroo

Dr. Riyaz Bashir did his schooling at Tyndale Biscoe and DAV schools. After completing his premedical education at Amar Singh College in Srinagar, he completed his MBBS at Govt Medical College in Srinagar. He then moved to the United States and completed his post-graduate training in Internal medicine and cardiology. He did his interventional cardiology training at the Mayo Clinic in Rochester, MN. He is currently a professor of Medicine at Temple University Hospital in Philadelphia.

He has dedicated his career to finding effective therapies to improve survival and reduce the suffering of patients with blood clots. He has a robust clinical practice in which he sees patients with complex arterial and venous disorders referred to him nationally and internationally for endovascular treatment.

During these endovascular procedures using the available devices for acute blood clots (acute PE and DVT), he noted that the thrombus removal with these devices was suboptimal and bleeding risks were relatively high. The persistence of these blood clots leads to a highly debilitating condition like chronic thromboembolic pulmonary hypertension and post-thrombotic syndrome, which inspired him to develop a device that is dedicated to effective thrombus removal from blood vessels. Mr. Marvin Woodall, the former President of Johnson and Johnson's Interventional Systems, guided and mentored him in developing the Bashir Endovascular Catheter and forming a company called Thrombolex Inc.

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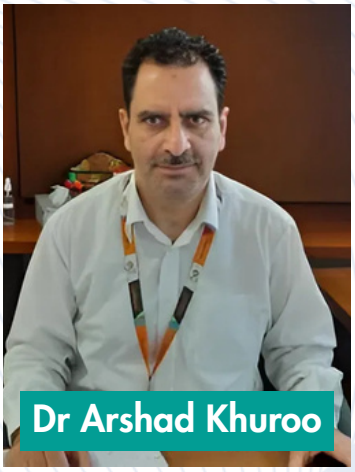
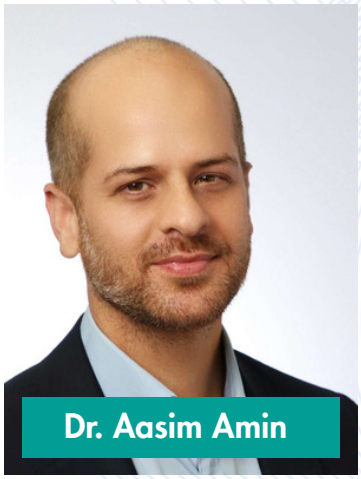
Dr. Arshad H Khuroo is currently heading Bioequivalence and Bioavailability function in R&D unit of SUN Pharma, India. He was born in a village in district Baramulla, did his basic education from the same village school. After completing his graduation in Pharmacy from Jamia Hamdard, Dr. Arshad joined Ranbaxy Research Labs as trainee chemist. He was the first graduate hired by the pharma giant, owing to the fact that this pharma company was never hiring any student below PG level in its R&D division.


Dr Arshad Khuroo

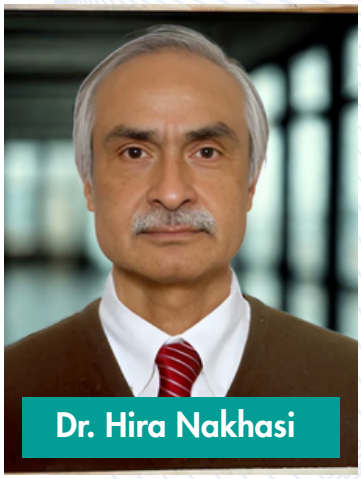
Dr. Arshad set the trend and did not just stop here. He completed his post-graduation from BITS Pilani, followed by his Ph.D. from BIT Ranchi. His hard work, sincerity, and zeal for learning, helped him to climb to the ladder of success career.

He is currently managing more than 250 scientists across India and Eastern Europe. Dr Arshad is author/co-author of more than 100 scientific publications, has successfully faced more than 100 regulatory inspections and has 30 years of experience in conduct of pharmacokinetic studies for all regulated markets across globe. Dr Arshad is passionate about conducting management development programs. Till date he has conducted more than 60 workshops on self-motivation, effective communication skills, collaboration, challenging status quo, in India as well as at overseas locations. Dr. Arshad has also authored a book, entitled, ***"Echoes of Experience: 30 Insights from Life's Journey."***


Dr. Aasim Amin

Dr. Aasim Amin is a Clinical Pharmacologist with a background in Pharmaceutical Sciences and Biomedical Sciences from the University of Kashmir, India, and KU Leuven, Belgium, respectively. Currently, he is serving as an Associate Director in Clinical Development at MorphoSys, Germany, where he leads the development of Tafasitamab, a monoclonal antibody for Non-Hodgkin Lymphoma, approved for use in R/R DLBCL.

Dr. Amin has over 8 years of industry experience, specializing in the clinical development of pharmaceuticals and biologics. In his role at MorphoSys, Aasim's leadership extends to driving advanced clinical programs to regulatory approvals. Prior to his current position, he contributed to the development of new chemical entities, including the small molecule Remimazolam, indicated for Anesthesia. Aasim's expertise and experience positions him as a key player in advancing therapeutic innovations and improving patient outcomes in the field of Oncology. Aasim did his schooling at Tyndale Biscoe, Srinagar and subsequently graduated in Pharmaceutical Sciences from the University of Kashmir. He then moved to the Belgium and completed his post-graduate training in Biomedical Sciences. He did his training in Clinical Pharmacology at the Center for Human Drug Research, Netherlands

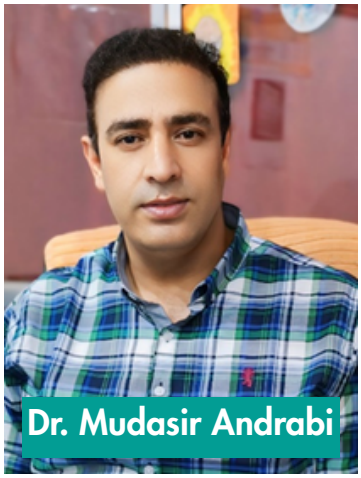

Dr. Hira Nakhasi

Dr. Hira Nakhasi is currently the Director of the Division of Emerging and Transfusion Transmitted Diseases (DETTD) at the Center for Biologics Evaluation and Research (CBER) of the US Food and Drug Administration. As the Director of the DETTD, he is responsible for approving assays to screen blood donors for blood borne pathogens and retroviral diagnostic to ensure USA blood safety. He received his master's and Ph.D. degrees in Biochemistry from the M.S. University of Baroda, India.

Dr. Nakhasi did his postdoctoral training at the National Institutes of Health, Bethesda, Maryland and Columbia University, New York, USA. His scientific expertise lies in molecular virology, parasitology, cell biology, immunology and vaccinology.

His main research is focused on Leishmania pathogenesis and develop methods to evaluate safety and efficacy genetically modified Leishmania vaccines and diagnostic tools. He has published over 150 publications including reviews and book chapters, being a member of the review committees of several high impact journals, reviewer of grants, and being invited to speak at national and international forums. He is also a member of the several scientific organizations.

Over the years he has received numerous awards including US Department of Human and Health Services Distinguished Service Award. He is elected Fellow of American Society of Tropical Medicine and Hygiene. He also has been recipient of several grants from International agencies such as Global Health Initiative and Technologies, Japan; Wellcome Trust UK and National Institutes of Health, USA worth over 10 million dollars for his studies on Leishmania vaccine development.


Dr. Mudasir Andrabi

Dr. Mudasir Andrabi is a distinguished scholar and researcher with 16 years of expertise in animal and health sciences. He currently serves as the Head of the Division of Animal Biotechnology at SKUAST-Kashmir. His research areas like Biotechnology, Bioengineering, Microbiology, Recombinant Biotechnology, and Stem Cell Research. He holds a Ph.D. in Biotechnology from Jamia Millia Islamia and IIIM Jammu, as well as a postdoctoral fellowship from the University of California, Berkeley.

His research has significant implications for public health and veterinary science, offering innovative solutions for disease prevention, diagnostics, and treatment. The potential for commercialization and widespread adoption of his technologies highlights their real-world impact, benefiting industries, healthcare providers, and consumers alike.

Prof. Andrabi's research excellence is exemplified by his recent groundbreaking development of a Lactobacillus-based recombinant vaccine for salmonellosis in poultry. This vaccine demonstrates strong protection against multiple serovars and ensures Salmonella-free egg production. It stands out for its remarkable efficacy rate exceeding 95% and its unique ability to prevent vertical transmission, addressing a critical need in the poultry industry. In another notable discovery, Prof. Andrabi developed a bioengineered Burn Recovery Bandage. These electrospun bandage strips, loaded with stem cell exosomes, have proven 100% effective compared to existing ointments like Burnol and Soframycin, with no scar formation observed.

Additionally, Prof. Andrabi has created a novel wound healing cream (Heal-Exo-Fast Cream) for wound healing and tissue regeneration. This formulation, validated for pre-clinical trials, has shown positive results in both small animals (rats) and larger animals. Loaded with exosomes that facilitate cell communication, proliferation, migration, and tissue regeneration, the cream is natural, easy to use, and promotes healing, prevents infection, and maintains a moist wound environment. Prof. Andrabi has also developed an efficient and economically viable real-time multiplex PCR kit for the rapid diagnosis of re-emerging tick-borne zoonotic infections, Rickettsia, and scrub typhus, which cause Acute Undifferentiated Febrile Illnesses in humans. This diagnostic kit is currently undergoing clinical trials and has been validated for use with 200 patients.


Dr. Mahrukh Banday

Dr. Mahrukh (Mahi) Banday has over a decade of commercial experience, successfully guiding both startups and large corporations towards significant growth. Known for building and nurturing high-performing teams, she cultivates a collaborative and loyal workforce that consistently exceeds performance targets. Mahi's expertise spans sales, customer experience, marketing, product management, strategic planning, budgeting, finance, operations, and R&D.

Her academic background is distinguished, with a Baccalaureate Degree in Veterinary Medicine (DVM), a Master's in Pathology, Immunology, and Microbiology, and a Doctorate in Molecular Genetics. This combination of deep academic knowledge and keen business acumen allows her to deliver exceptional results across healthcare and biotechnology fields.

Her career highlights include managing multimillion-dollar product portfolios, overseeing IPOs, and winning global awards for marketing excellence. Currently, Mahi serves as the VP, Commercialization, Therma Inc. San Fransisco, USA. She has held significant roles such as Vice President of Marketing, Product & Operations, and Sr. Director of Product Management and Marketing.

Mahi completed her early schooling at Woodland School and Mallinson School in Kashmir before moving to South India, Punjab, and finally the USA.

A summary of the session authored by Dr Mahrukh and Dr. Mudasir has been published in **Daily Greater Kashmir** and can be accessed here

GK Medical Products: From Target to Market Click Here

The full recording of the session is also available to watch on the Kashmir Care Foundation's **YouTube channel** via link given below

Session Recording Click Here

For suggestions and feedback, please contact:

CHAIR, COMMUNICATIONS
info@kashmircarefoundation.org