



Office of the Principal Scientific Adviser
to the Government of India



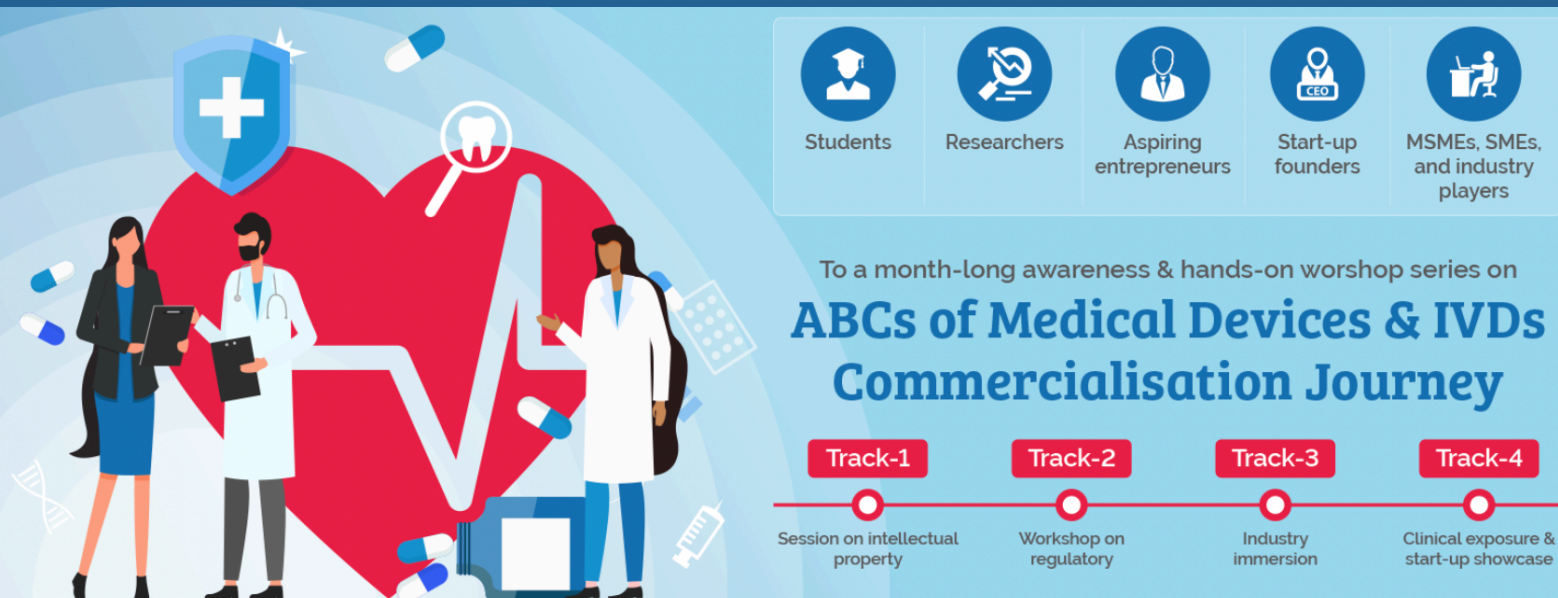
ABCs of Medical Devices & IVDs Commercialisation Journey

REPORT



RICH
Research and Innovation
Circle of Hyderabad

ABCs of Medical Devices & IVDs Commercialisation Journey



A Brief

Research and Innovation Circle of Hyderabad (RICH), the nodal agency for the Hyderabad Science and Technology Cluster, an initiative spearheaded by the Office of Principal Scientific Adviser to the Government of India. Established in 2017 by the Government of Telangana, the organisation focuses its work across three primary verticals: Food and Agriculture, Life Sciences, and Sustainability. Through its various initiatives, RICH aims to solve complex local and national challenges by fostering collaborative networks among diverse stakeholders in the research and innovation space and empower innovators to transform scientific research into impactful solutions that generate wealth and employment and create social good.

In July 2023, RICH conducted the month-long awareness and hands-on workshop series for students, aspiring entrepreneurs, researchers, startups, MSMEs, SMES/Industry professionals on commercialisation of Medical Devices and In-vitro Diagnostics (IVDs) of category A, B, C, and D. With this initiative, RICH reaffirms its commitment to driving the growth and transformation of the Life Sciences sector in Telangana.

Programme Partners

Intellectual Property Partner



Regulatory Partner



Industry Partners



Programme Partners

Clinical Partners



Clinical Research Organisation Partner



Start-up Showcase Representatives



And Many More....

Programme Overview



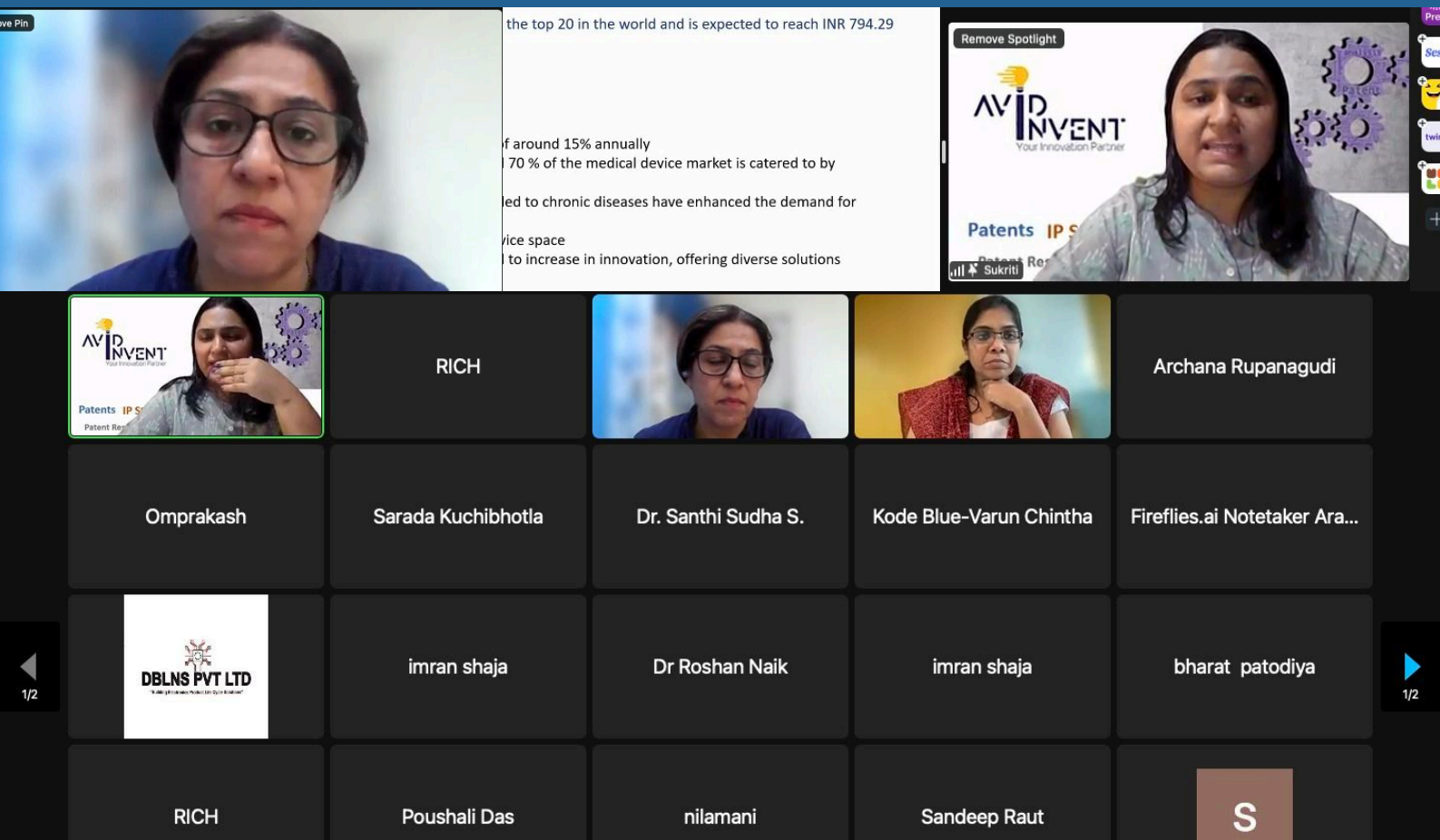
The month-long series focussed on creating awareness along with in-depth support to understand the various stages involved in scaling a proof-of-concept validated idea to a marketable product. The series was divided into 4 tracks related to intellectual property, regulatory, industry immersion and Clinical Exposure, followed by a highlight event of Medical Devices and IVDs startup showcase. The series was launched with over 40 participants present in hybrid format on 3rd July 2023.



Programme - Track-1

Intellectual Property

Track-1 of the series on intellectual property (IP) was aimed to bring awareness on intellectual property (IP) to students, aspiring entrepreneurs, researchers, startups, MSMES, SMES/Industry professionals on commercialisation of Medical Devices and In-vitro Diagnostics (IVDs) of category A, B, C, and D. The session provided insights into the types of IP provisions applicable to medical devices or IVDs, the process of prior art search and market research, steps for filing a patent in India and abroad, and its applicable provisions. Thus, broadly on ideation research, patent due diligence, and patent navigation in the pre-patent stage and beyond. The session was conducted by experts from HealthTech and MedTech intellect patent space, Dr. Puneeta Arora and Ms. Sukriti Goyal, co-founders of AvidInvent. The two hours online session on 7th July 2023 was attended by around 30 participants.



the top 20 in the world and is expected to reach INR 794.29

around 15% annually

70 % of the medical device market is catered to by

to chronic diseases have enhanced the demand for

ice space

to increase in innovation, offering diverse solutions

AVID INVENT
Your Innovation Partner

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Patent Res

Sukriti

RICH

Archana Rupanagudi

Omprakash

Sarada Kuchibhotla

Dr. Santhi Sudha S.

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Dr Roshan Naik

imran shaja

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Poushali Das

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Sandeep Raut

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Programme - Track-2

Regulatory

Track-2 of the series on Regulatory was purposed to bring process clarity on regulatory compliances in Indian market as adhering to right regulatory compliance is imperative for commercialising medical device or an IVD product. The track was led by Dr. Priyankana Mukherjee, Chief Manager and Head BioNEST at IKP Knowledge Park, Bangalore, representing IKP Global Regulatory Forum (IGRF). The track was designed only for medical devices and IVDs start-ups and was delivered in two parts. The first part was on 3rd July 2023 where overview of regulatory requirements was briefed and start-ups were encouraged to fill the evaluation questionnaire to be part of second part. The second part was a full day hands-on workshop on 21st July 2023 attended by around 20 shortlisted start-ups.



Programme - Track-2

Regulatory

In the second part of the track, Deputy Drugs Controller of India, Dr. A. Ramkishan from Central Drugs Standard Control Organisation (CDSCO), South Zonal Office - Hyderabad, under Directorate General of Health Services, Ministry of Health & Family Welfare, and Ms. Sarala Devi, Assistant Drugs Controller of India, CDSCO Hyderabad along with Dr. P.V. Appaji, Director General Emeritus Pharmaceuticals Export Promotion Council of India (Pharmexcil) briefed about the support available for medical devices start-ups and on MDR 2017 requirements for medical devices and IVDs. The CDSCO team along with Mr. Kamal Prasad - Founder & Director of PathnSitu Biotechnologies interacted with start-ups to address their specific queries. Additionally, as part of the workshop, Mr. Kamal Prasad along with Dr. Priyankana Mukherjee highlighted the details of one of the key document Device Master File (DMF) required for submission of regulatory application.



Programme - Track-3

Industry Immersion

Track-3 of the series was aimed to foster direct interaction between the participants and industry expert to bridge the gap between theoretical and the real-world challenges faced in the manufacturing of medical devices and IVDs . The immersion session provided a platform for knowledge sharing, networking, and collaboration between industry experts and students, aspiring entrepreneurs, researchers, startups, MSMES, SMES/Industry professionals to gain a deeper understanding of the industry and its commercialisation journey. The session was on 14th July 2023 and around 30 participants joined. Dr Rajiv Chhibber, Vice President of Sahajanand Medical Technologies, Dr. Kuldeep Raizada, Founder & Chairman of Akriti Ophthalmic, Dr. Rachana Tripathi and Dr. Shesheer Kumar, Co-founders of Huwel Life Sciences and Mr. Kamal Prasad, Director of PathnSitu Biotechnologies and their team were instrumental in bringing the impactful industry experience and expertise. This great opportunity led to the learning of latest trends in the MedTech sector and get an industry perspective on commercialising medical device or IVD innovation, thus, enabling immense understanding of manufacturing processes and the necessary compliances.

The participants got an opportunity to visit some of the leading industries in Telangana's Medical Devices Park in Sultanpur. The participants visited and understood the process of stent and other allied products manufacturing in Asia's biggest state-of-the-art stent manufacturing facility, Sahajanand Medical Technologies (SMT). They also witnessed the manufacturing of eye wears for the famed Telangana's Kanti Velugu initiative at Akriti Ophthalmic Pvt. Ltd. The participants were able to understand the end-to-end manufacturing of PCR testing kits from the cutting-edge made in India COVID-19 RT-PCR testing kit manufacturer, Huwel Life Sciences. Additionally, the participants got a virtual tour of cancer diagnostics products manufacturer, PathnSitu biotechnologies.

Programme - Track-3

Industry Immersion



Programme - Track-4

Clinical Exposure

Track-4 of the series was all about clinicians, who are one of the key stakeholders of medical devices and IVDs commercialisation journey. The session was on 26th July 2023 and around 30 start-ups joined for the full day event. The first half of the day provided expert insights to the start-ups on clinical ideation and necessity of clinical validation by Dr Venkat Ramana Sudigali FRCR MBA, CEO, Excell Hospital, Hyderabad and on clinical validation studies processes by Venkat Pola, co-founder, Medclinica. The start-ups also understood the process of hospital procurement from Dr. Nagasuri Balaji Pavan Sai Ram from AIG Hospital and Mr. Kamal Prasad from PathnSitu Biotechnologies.



Programme - Track-4

Start-up Showcase

The second half of the day was the highlight session, the start-up showcase. Around 20 start-ups were part of the showcase which was graced by several clinicians and industry experts opening several collaboration opportunities for the startups.



Media Coverage

S.No.	Date	Publication	Link/ Pg no.
1	July 04, 2023	https://www.medtechspectrum.com/	https://medtechspectrum.com/news/25/158/rich-launches-month-long-session-on-medical-device-and-ivd-commercialization-journey.html
2	July 04, 2023	www.pharmabiz.com	http://www.pharmabiz.com/NewsDetails.aspx?aid=160091&sid=2
3	July 11, 2023	Pragati Express	Print/ Page No. 03
4	July 27, 2023	www.expresshealthcare.in	RICH concludes workshop series on medical devices and IVDs - Express Healthcare
5	July 27, 2023	www.medtechspectrum.com	Hyderabad's RICH Concludes Medical Device & IVD Commercialisation Workshop Series (medtechspectrum.com)
6	July 27, 2023	https://in.linkedin.com/company/medtechspectrum	Hyderabad's RICH Concludes Medical Device & IVD Commercialisation Workshop Series (medtechspectrum.com)
7	July 28, 2023	www.pharmabiz.com	RICH concludes workshop series on ABCs of medical devices and IVDs commercialisation (pharmabiz.com)
8	July 28, 2023	Pragati Express	Print, Page No. 02
9	July 29, 2023	Southern Mail	Print, Page No. 02
10	July 29, 2023	Business Diary	Print, Page No. 02

Media Coverage

ABCS OF MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS (IVDs) COMMERCIALIZATION JOURNEY – A MONTH-LONG AWARENESS AND HANDS-ON SESSION ANNOUNCED!

Hyderabad : July 2023
Research and Innovation Circle of Hyderabad (RICH) launched the month-long awareness and hands-on session for students, aspiring entrepreneurs, researchers, start-ups, MSMEs, and SMEs/industry players on the commercialization of Category A, B, C, and D medical devices and in-vitro diagnostics (IVDs). RICH at the launch event of 'ABCs of Medical Devices and In-vitro Diagnostics Commercialization Journey' Image credits: RICH. The month-long series focuses on creating awareness and providing in-depth support to the participants, so they understand the various



stages of scaling up a proof-of-concept validated idea to a marketable product. The series is divided into four tracks: intellectual property, regulatory requirements, industry immersion, and clinical exposure. These are followed by a highlight event, a medical device and IVD start-up showcase. "The journey of bringing a novel medical device to market is a long, complex, and daunting one. Risks and uncertainties are part of the commercialisation journey, and this magnifies for MedTech innovations. Clarity of process and collaboration with key stakeholders paves the way to success. This series wishes to cultivate and nurture an impactful MedTech innovation culture and ecosystem," says Rashmi Pimpale, CEO of RICH. The series is structured to bring in experts from the HealthTech and MedTech intellectual property space and the start-up AvidInvent, who can throw light on ideation and research, patent due diligence.

Research and Innovation Circle of Hyderabad (RICH) Concludes the Workshop Series ABCs



Hyderabad: a month-long awareness and hands-on workshop series called "ABCs of Medical Devices and In-vitro Diagnostics (IVDs) Commercialisation Journey" came to a successful end. It was attended by aspiring entrepreneurs, researchers, start-ups, MSMEs, SMEs, and industry players. This was the first edition of this workshop series by Research and Innovation Circle of Hyderabad (RICH). "The journey of bringing a novel medical device to market is a long, complex, and daunting one," said Rashmi Pimpale, CEO of RICH. "Within the realm of MedTech innovation, risks and uncertainties loom even larger. However, with a clear process and collaborative efforts involving key stakeholders, success becomes attainable. The participants unanimously agreed that the series not only enriched their understanding but also facilitated the creation of beneficial connections." "The journey of bringing a novel medical device to market is a long, complex, and daunting one," said Rashmi Pimpale, CEO of RICH. "Within the realm of MedTech innovation, risks and uncertainties loom even larger. The intellectual property track focused on ideation research, patent due diligence, and patent navigation under the guidance of experts from AvidInvent, who are in the HealthTech and MedTech intellectual patent spaces.

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Research and Innovation Circle of Hyderabad (RICH) Concludes the Workshop Series "ABCs of Medical Devices and In-Vitro Diagnostics (IVDs) Commercialisation Journey"

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The series was divided into four tracks: intellectual property, regulatory, industry immersion, and clinical exposure. Each track was led by experts in the field, providing participants with in-depth knowledge and practical insights into the various stages

involved in scaling a proof-of-concept validated idea to a marketable product.

"The journey of bringing a novel medical device to market is a long, complex, and daunting one," said Rashmi Pimpale, CEO of RICH. "Within the realm of MedTech innovation, risks and uncertainties loom even larger. However, with a clear process and collaborative efforts involving key stakeholders, success becomes attainable. The participants unanimously agreed that the series not only enriched their understanding but also facilitated the creation of beneficial connections."

The intellectual property track focused on ideation research, patent due diligence, and patent navigation under



the guidance of experts from AvidInvent, who are in the HealthTech and MedTech intellectual patent spaces. The regulatory track covered the key stages in bringing a medical device or IVD to market, including regulatory compliance, market authorisation, and post-market surveillance. Officials from Central Drugs Standard Control Organisation (CDSCO) under the Directorate General of Health Services, Ministry of Health &

Family Welfare, Government of India, along with ICICI Knowledge Park's (IKP) Global Regulatory Forum (IGRF) provided participants with a detailed understanding of the regulatory process for entering the Indian market.

The industry immersion track gave participants the opportunity to visit leading medical device and IVD companies in Telangana, such as Sahajanand Medical Technologies (SMT), Akriti Ophthalmic, Hu-

wel Life Sciences, and Pathn-Situ Biotechnologies, and learn about their manufacturing processes and compliance requirements. Finally, the clinical exposure track provided participants with the opportunity to observe clinical trials and gain insights into the clinical validation process.

The series concluded with a start-up showcase, which also provided networking opportunities for hospitals and start-ups to come together and forge new collaborations.

"The ABCs of Medical Devices and IVDs Commercialisation Journey" reflects RICH's continued commitment to driving the growth and transformation of the life sciences sector in Telangana.

RICH is the nodal agency for the Hyderabad Science and Technology Cluster, an initiative spearheaded by the Office of Principal Scientific Adviser to the Government of India. Established in 2017 by the Government of Telangana, the organisation focuses its work across three primary verticals: Food and Agriculture, Life Sciences, and Sustainability. Through its various initiatives, RICH aims to solve complex local and national challenges by fostering collaborative networks among diverse stakeholders in the research and innovation space, and empowering innovators to transform scientific research into impactful solutions that generate wealth and create social good.

Testimonials

Mohamed Jameer Basha J
Caldor Health Technologies

Great work. Helped in clarifying lots of doubts. Paved the way for many potentially collaborative links. Would love to be a part of upcoming events. Thanks for providing the platform.

Arshad M Koya
Coexin Technologies Healthcare

Appreciate the organisers for conducting such useful sessions.

Dr. Roshan Naik
Diagopreutic

The sessions were very helpful.

Ravi Chivukula
HeARTHealth Technologies

Thanks to RICH, Dr. Sushmitha Sundar, and Mr. Aravind Kumar for organizing the "ABCs of Medical Devices and IVDs Commercialisation Journey" and getting the stakeholders at one location for the startup showcase. Having been around for a while as a serial entrepreneur, I am confident to say that this is the first of it's kind I attended.

Contact Us

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