

LAB to TAB™

ACCESS TO INTERESTING BIOSCIENCES STORIES FROM YOUR TAB

HiMediaLaboratories™ Newsletter Volume - 9 | June 2019

Message from CEO



Dear Patrons,

Subsequent to the splendid response of humongous success of our last “Lab to Tab™” issue, we are glad to present to you new issue of June-2019 which is carrying enchanting articles and news. One of our major achievements this year is that, the HiMedia has been honored with ‘**PRIDE OF**

MAHARASHTRA AWARD’ under the category of “**Best Company of the Year Award**” for 2018 and Dr. G. M.

Warke, Founder and CMD, HiMedia Laboratories Pvt. Ltd. bestowed with “**Brand Ambassador of Maharashtra**” for 2018 (Category : Research and Innovation) by Maharashtra Industrial and Economic Development Association (MIEDA). We share this honor with you, my dear patrons, as you are the one what make this company great. I thank you once again for all your continuous support and trust. We promise to give the best services in the future also.

In ‘**The Science Galaxy**’ segment, this time we have an article on ‘**Human Microbiome : A Revolution in the Health Management**’ from **Dr. Yogesh S. Shouche**, a distinguished Scientist of NCCS, Pune, India. We are grateful to Dr. Souche for writing such a superb article exclusively for us that gives meticulous insights into the human microbiome.

Another great news to share with our patrons is establishment and donation of State-of-the-Art **Regenerative Medicine Research Centre (RMRC)** to Sir J J Hospital by HiMedia Laboratories Pvt. Ltd., for carrying out research in stem cell for eye care, giving new hope to the eye patients. Apart from this few more interesting articles in the “Lab to Tab™” store for our curious minds.

We hope you enjoy reading this updated version of “Lab to Tab™” e-Newsletter and we look forward to your feedback so we can continuously improve it along the way. Please write to us at info@himedialabs.com or techhelp@himedialabs.com with your recommendations and requirements so that we could design and put into action newer plans that’ll help us to serve you better.

BIOSIMILARS : Current Market Scenario, BioProduction Capabilities - Ms. Gauri Page

Antibodies are amongst one of the most expensive therapeutics as they have widespread applications in chronic diseases such as cancer in high doses (more than 100mg). Large scale processes are required to produce them to satisfy market demands. One of the major factors contributing to the high cost of therapeutic antibodies is the medium used for cultivation.

Regulatory Affairs in BioSciences

- Mr. Akshay Chougale

In today’s competitive state, the proper conduct of regulatory affairs activities are vital to save the time of the product lifecycle and influence the economics of the company. HiMedia stands as the regulatory backbone for many Biopharmaceuticals and health care segments. It has uniquely positioned a system in place to help in decision making at critical milestones of the product lifecycle.

Detection of Antimicrobial Resistance : Molecular Methods - Dr. Arunagiri S.

Antibiotics have been important cornerstones of modern medicine to treat life-threatening bacterial infections. Due to the indiscriminate use of Antibiotics, Antimicrobial Resistance (AMR) has emerged as a major global and multifaceted problem. Hence, early diagnosis is vital to avoid clinical failure and treat multi-drug resistant bacteria.

Gut Microbiome : A Boon for Health

- Ms. Trupti Raut

The microbiome is important for maintaining human health, and if things go wrong it can contribute to disease. Human gut microbes are key contributors to metabolic functions and also protect against pathogens, educate the immune system. Hence, the microbiome is attracting the attention for research.

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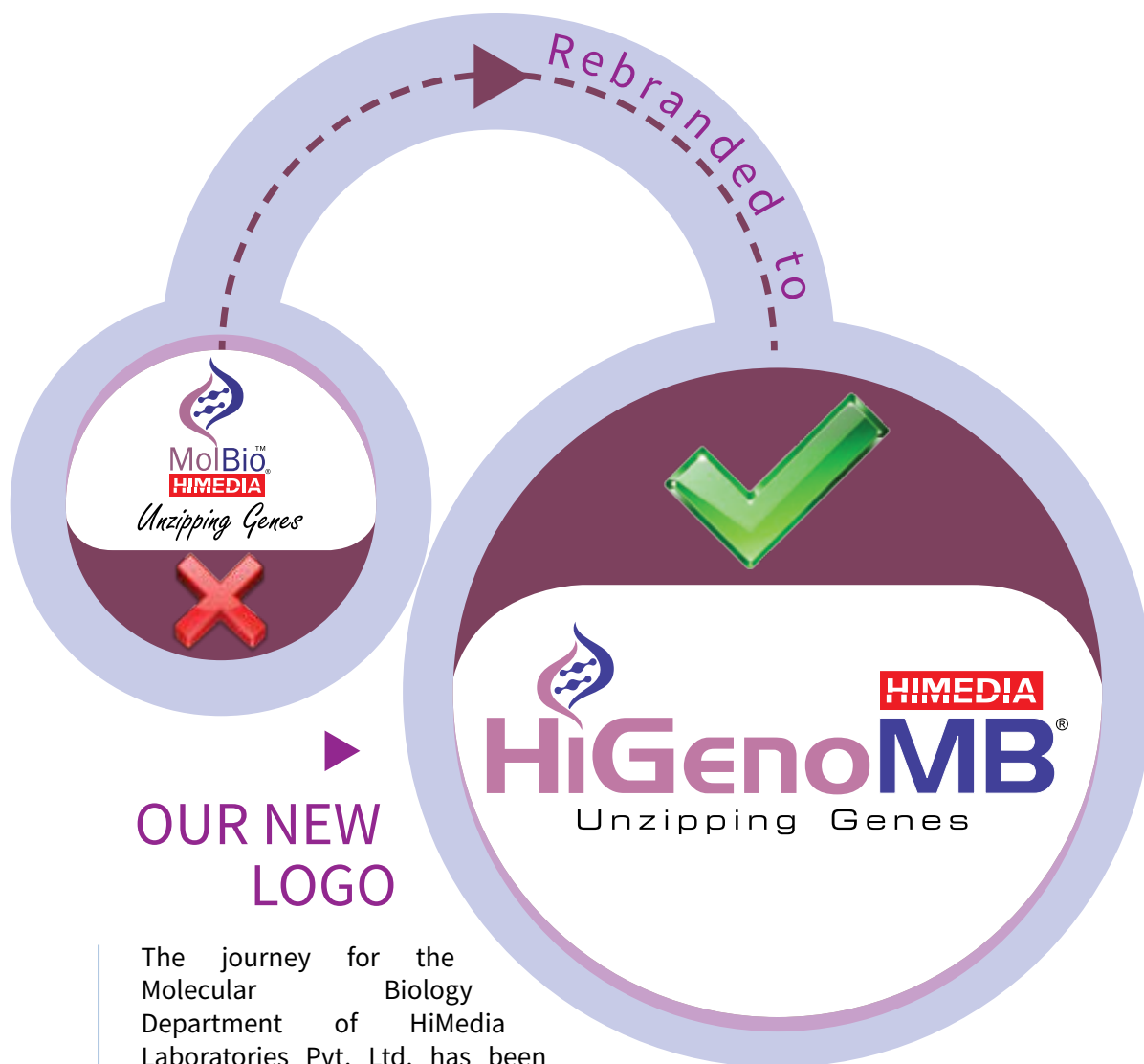
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OUR NEW LOGO

The journey for the Molecular Biology Department of HiMedia Laboratories Pvt. Ltd. has been a remarkably engaging and enriching experience for all who have been involved. This year onwards, we at Molecular Biology have transformed ourselves into more enthusiastic, more passionate and more determined team workers in bringing across a positive change in our research endeavours and overall operations. We have kick started this process by changing our name, from 'Mol Bio' to 'HiGenoMB'.

Henceforth HiMedia's Molecular Biology division will be referred to as HiGenoMB®. The new brand name brings with itself a new approach, a new outlook towards developing the most diverse, innovative and cost-effective product portfolio for Molecular Biology based applications. As a Make in India initiative, HiMedia has always pioneered in bringing about a revolution in various segments of the Life Sciences Industry. HiGenoMB® looks to propel this undertaking towards a brighter and more successful future in providing molecular solutions with user friendly techniques and concepts. HiGenoMB® has taken up the mantle of being the truly reliable Indian Molecular Biology brand for our scientists and research in the country and the world over.

“Every Success story is a tale of constant Adaption, Revision and CHANGE...”

- Richard Branson





Dr. Arunagiri Subramanian

(Asst. Manager, R&D, Molecular Biology Dept.)

Dr. Arunagiri Subramanian has completed his Ph.D. in Medical Microbiology from Haffkine Institute, Mumbai and had worked on MRSA a global Antimicrobial Resistance (AMR) pathogen for his doctoral study. With a special interest in AMR, he currently focuses on Molecular Medical Microbiology and other projects in the Molecular Biology Department.

Knowing tiny molecules can make a huge change in the world!

Deaths attributable to antimicrobial resistance every year by 2050



Simplification of a complex process!



Insta NX®
(LA1056)



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(LA1073)

Let's know more about Molecular Methods to detect antimicrobial resistance. A boon for modern science. Antibiotics have been important cornerstones of modern medicine and have played a valuable role in the treatment of life-threatening bacterial infections. Due to the indiscriminate use of Antibiotics, **Antimicrobial Resistance (AMR)** has emerged as a major global and multifaceted problem. Hence, early diagnosis is important to avoid clinical failure and treat multidrug-resistant bacteria.

Molecular methods, mainly Real-Time PCR remain unrivalled by any other technology as early diagnostic tools due to the greater speed and accuracy for detection of the AMR markers over phenotypic results that are too time-consuming, not conclusive, or unavailable. This ensures direct support to initiate an optimal treatment or control strategy in a timely manner. As rightly quoted by the American physicist Martin H. Fischer **“Knowledge is a process of piling up facts; wisdom lies in their simplification”**. Keeping in mind, the **Need of the**

HOURLY diagnosis, HiMedia Laboratories Pvt. Ltd., has developed **Rapid, Novel, Sensitive, Specific** and **Affordable** Real-Time PCR kits for detection of below mentioned clinically significant AMR markers that are categorized as either **“Serious”**, **“Urgent”** or **“Concerning”** threat by the **Centers for Disease Control and Prevention (CDC)**.

Extended-spectrum β -lactamase producing Enterobacteriaceae (ESBLs)

Extended-spectrum β -lactamases (ESBLs) represents the most important contributing factor to resistance against β -lactam antibiotics. Nearly 26,000 (or 19%) healthcare-associated Enterobacteriaceae infections are caused by ESBL-producing Enterobacteriaceae. Patients with bloodstream infections caused by ESBL-producing Enterobacteriaceae are more likely to die than those with bloodstream infections caused by a non ESBL-producing strain. ESBLs producing Enterobacteriaceae have been marked as **“Serious”** threat by CDC thus requiring early diagnosis, more

monitoring and prevention activities (1, 2).

Carbapenem-Resistant Enterobacteriaceae (CRE)

Carbapenem-resistant Enterobacteriaceae (CRE) is defined as being resistant to at least one of four carbapenem antibiotics and/or produce a carbapenemase (the enzyme that inactivates carbapenems and can be spread to other bacteria). CRE infections account for an estimated 1,40,000 cases of healthcare-associated infections annually and produce high attributable mortality rates of 26% to 44%. CREs has been marked as **“Urgent”** threat by CDC thus requiring early diagnosis, more monitoring and prevention activities (1, 2).

Methicillin-Resistant Staphylococcus aureus (MRSA)

Methicillin-Resistant Staphylococcus aureus (MRSA) is one of the most common causes of nosocomial or community-based infections associated with higher hospital costs and mortality. MRSA strains generally are now resistant to other antimicrobial classes including aminoglycosides, β -lactams, carbapenems, cephalosporins, fluoroquinolones and macrolides. These MRSA strains harbour the *mecA* gene or the *mecA* homolog *mecC* gene which encodes resistance to methicillin and all β -lactam antibiotics. MRSA has been marked as a **“Serious”** threat by CDC thus requiring early diagnosis, more

monitoring and prevention activities (1, 2).


Vancomycin-Resistant Enterococcus (VRE)

About 20,000 of the estimated 66,000 healthcare-associated Enterococcus infections are caused by Vancomycin-Resistant Enterococcus (VRE) strains which cause 77% of drug-resistant infections with approximately 1,300 deaths attributed to these infections. Vancomycin-Resistant Enterococci (VRE) is therefore recognized as major global pathogens causing healthcare-associated infections. Common resistance mechanism to vancomycin is encoded by *vanA* and *vanB* clusters. VRE has been marked as a **“Serious”** threat by CDC thus requiring early diagnosis, more monitoring and prevention activities (1, 2).

Being in the clinical diagnostic industry for over 43 years, HiMedia Laboratories Pvt. Ltd., are actively engaged in combating AMR by developing Innovative and Affordable diagnosis as our prime objective pioneering from **“Microbiology”** to **“One-Stop Molecular Diagnostic Solution”**.

References :

1. Centres for Disease Control and Prevention (US). Antibiotic resistance threats in the United States, 2013. Centres for Disease Control and Prevention, US Department of Health and Human Services; 2013.
2. Anjum MF, Zankari E, Hasman H. Molecular Methods for Detection of Antimicrobial Resistance. Microbiology spectrum. 2017;5(6).



ESBL

Extended Spectrum β -Lactamases (ESBLs) Gene Detection Kit (MBPCR131)

*bla*_{CTX-M}, *bla*_{TEM}, *bla*_{SHV} and *bla*_{OXA-10/11}

MRSA

Methicillin Resistant Staphylococcus aureus (MRSA) Detection Kit (MBPCR133)

mecA and *mecC* and species specific

CRE


Carbapenemase Gene Detection Kit (MBPCR132)

*bla*_{KPC}, *bla*_{NDM}, *bla*_{VIM}, *bla*_{IMP}, *bla*_{OXA-23}, *bla*_{OXA-48}, *bla*_{OXA-51} and *bla*_{OXA-58}

VRE

Vancomycin Resistant Enterococci (VRE) Detection Kit (MBPCR134)

vanA and *vanB* and species specific



Real-Time PCR Kits to combat AMR



Pride of Maharashtra article for Newsletter

HiMedia's credentials are well appreciated by various organizations at national and international level. HiMedia has been the recipient of several prestigious awards in the past four decades. The list is endless from receiving 'Rajiv Gandhi National Quality Awards' twice and 'Niryat Rattan Award' to officially enumerating HiMedia as amongst the top 3 global microbiology media manufacturers by the very prestigious 'American Society of Microbiology', in their

'Handbook of Microbiological Media' which is a veritable treatise on all the microbiological media.



We proudly announce that we have now one more glittering feather in our cap. Recently, on February 21, 2019, HiMedia has been bestowed with most prestigious '**PRIDE OF MAHARASHTRA AWARD**' under the category of "**BEST COMPANY OF THE YEAR AWARD**" for 2018 and **Dr. G. M. Warke** - Founder & CMD, HiMedia Laboratories Pvt. Ltd.

honored with "**BRAND AMBASSADOR OF MAHARASHTRA**" for 2018 (Category: Research & Innovation) by Maharashtra Industrial and Economic Development Association (MIEDA). The award was conferred by Padma Vibhushan Dr. Raghunath Mashelkar - President, Global Research Alliance & Former Director General of Council

of Scientific & Industrial Research (CSIR) in the presence of eminent persona like Murtaza Khorakiwala (Managing Director, Wockhardt Limited), Shri. Chandrakant Salunkhe (Founder & President, Maharashtra Industrial & Economic Development Association and SME Chamber of India), Shri. Satish Wagh (CMD, Supriya Lifescience Ltd.) and Dr. Lalit Kanodia (CMD, Datamatics Group of Companies).



During this award conferring ceremony, **Dr. G. M. Warke** was quoted as '**The Father of Indian Microbiology Business**' for his historic contribution to the world of microbiology.

The Science Galaxy

Human Microbiome: A revolution in the health management



Dr. Yogesh S. Shouche

Principal Investigator, National Centre for Cell Science (NCCS),
National Centre for Microbial Resource (NCMR), Pune, India.



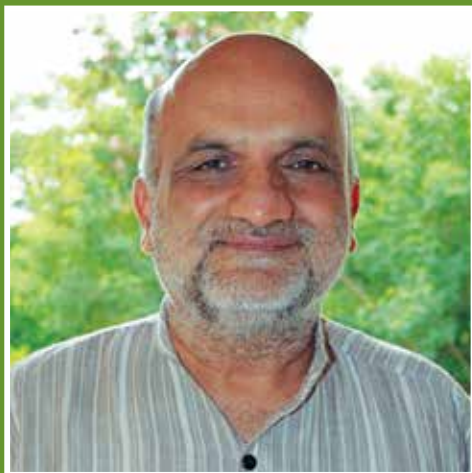
A revolution in the diagnosis and treatment of metabolic disorders is at our doorstep now. It is going to change the way we look at these diseases and their treatment methods and this revolution has come from the understanding of the microbes that are associated with our body, collectively called the microbiome.

The fact that the human body harbors diverse microbial communities is not new but our understanding about them was very rudimentary till the end of the last century. Like any other ecosystem, majority of microbes associated with human body could not be grown in the laboratory and studied but the beginning of this century saw the application of genomics techniques for their understanding which was followed by others like proteomics, metabolomics, etc.

Today, we understand a great deal about our body associated microbes their role in health and disease. In most lifestyle associated metabolic disorders such as diabetes, obesity and even in psychological disorders, the association of altered microbiome is noticed. In some cases, there are some insights into the molecular mechanism of this association and the disorder. In a recent example, a diagnostic test for Non-Alcoholic Fatty Liver Disease has been developed that is based on the analysis of fecal microbiome.

It is believed that restoration of dysbiosis may help in the disease management and there has been a success in chronic gastroenterological disorders like antibiotic-resistant *C.difficile* diarrhea, Inflammatory Bowel Disease, Irritable Bowel Syndrome and Crohn's disease.

The others may follow soon. However, considering the fact that microbiome varies with geography and diet; there may not be a universal solution but region-specific microbiome therapies need to be developed. This necessitates an understanding of the region-specific healthy microbiome. All major countries including China, Australia, Japan, USA, Canada, and Europe have microbiome initiatives and India too is planning to join the group soon with the initiation of Department of Biotechnology, Government of India funded initiative on mapping the microbiome of major endogamous groups across the country. This exercise will help India to develop specific solutions to major metabolic disorders that are affordable and personalized.



Dr. Yogesh S. Shouche

Dr. Yogesh S. Shouche is a distinguished Scientist in Microbiology, currently, working as Principal Investigator in National Centre for Microbial Resource (NCMR) (previously recognized as the Microbial Culture Collection) at the National Centre for Cell Science (NCCS), Pune, India.

With strong teaching and research experience of more than 28 years in the field of Microbial Ecology, Microbial Molecular Diversity & Taxonomy, Human health & Microbiome, he has several national and international collaborations and more than 25 successful grant applications from various funding agencies. Under his proficient guide-ship and research acumen, more than 20 students have already been awarded Ph. D. degree from the University of Pune and 8 are currently registered.

Dr. Yogesh has more than 330 publications in reputed international and national journals in his credit. He has been the editor and reviewer for the International journals such as Federation of European Microbiological Societies (FEMS) Ecology, International Journal of Systematic and Evolutionary Microbiology, Microbial Ecology, etc. He has contributed a chapter in renowned Bergey's Manual of Determinative Bacteriology.

His research team has now taken 'Indian Human Microbiome Initiative', aimed at studying the distinct features of the Indian Microbiome and its evolution with respect to host specificity, eco-physiology of the gut microbiome, role of gut microbiomes in healthy individuals, diet diversity, geography, gastrointestinal and respiratory diseases and metabolic disorders.



- **Did you know that your Gut feeling depends on a lot of factors?**
- **Microbiome is the most important one of them!**



Ms. Trupti Raut
(Assistant R&D Manager)

Ms. Trupti completed Masters in Microbiology from Mumbai University. She has 9 years of experience in HiMedia's R & D wing. She's a seasoned professional who has received an extensive training from the Bhabha Atomic Research Center. She has an expertise in Antimicrobial Susceptibility Testing and acquaintance as a technical writer.



Let's begin by getting to know the human microbiome better! It composes of bacteria, archaea, viruses and eukaryotic microbes that reside in and on our bodies. It typically comprises of the genetic material within a microbiota. The microbiome is important for maintaining human health, and when things go wrong, it can contribute to a disease. These microbes have tremendous potential to impact our physiology, both in health and during sickness. Microbes that reside in the human gut are key contributors of metabolic functions and they protect the immune system. Through these basic functions, also they affect our physiologic functions directly or indirectly.

<Watch this tab>

<https://www.youtube.com/watch?v=A-lqdPch9t0>
<https://www.healthline.com/nutrition/gut-microbiome-and-health#section5>

The gut microbiome acts as a barrier against harmful microbes by competing for nutrients, ecological binding site occupancies and production of antimicrobial substances. Numerous antimicrobial compounds, such as defensins, cathelicidins and C-type lectins, are produced by microbes in the GI tract. The presence of commensal bacteria or their structural components have the capacity to protect the gut from invading pathogens and preventing the overgrowth of the commensals themselves. Induction can be mediated through various signalling pathways.

What's the equation between the Gut Microbiome and Antibiotic like?

We show an antibiotic and a gut microbiome hanging out together.

In healthy individuals, the microbiome and host have a mutual relationship in which both partners benefit. However, pathogens may invade and cause diseases under certain conditions. Although, antibiotics fight bacterial pathogens and can cure life-threatening infectious diseases, improper use can easily create an imbalance in microbiota in the gut. Thus, antibiotic is considered as bilateral tool since they have side effects on human health. An unbalanced microbiota in the gut is also a contributing factor in autoimmunity. The destruction of healthy gut flora can make the mucosal lining more susceptible to leakage, which some researchers believe is a precondition for developing autoimmunity.

Healthy Guts all the way.



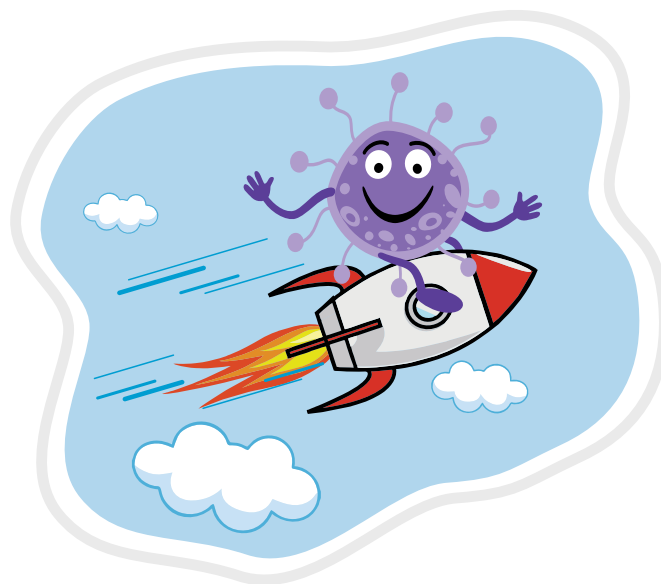
The importance of a healthy gut microbiome extends beyond the gut. Microbes may also play a role in many activities taking place outside the gut, such as brain-gut interactions, for example, influencing the host's response to stress. Additionally, microbial products such as acetate, can travel across the intestinal and blood-brain barrier to interact with areas of the brain that help control appetite.

<https://www.youtube.com/watch?v=QE9QWFg-XNs>

Humans and microbes depend on one another: our bodies provide microbes with resources, and the microbes provide functions necessary for our health. Hence, the microbiome has received increasing attention over the last 15 years. Although gut microbes have been explored for several decades, investigations of the role of microorganisms that reside in the human gut have attracted much attention beyond classical infectious diseases. In

fact, environmental factors such as dietary habits, drug treatments, intestinal motility and stool frequency and consistency are all factors that influence the composition of the microbiota and should be considered while further research.

Way forward with Microbiomes!



Any such in-depth research in microbiome needs well authenticated reference standards to validate the procedures we use in Microbiome studies and to direct us. Towards this ATCC has designed and developed Microbiome standards after 2 decades of extensive research. ATCC Microbiome Standards are fully sequenced, characterized, and authenticated mock microbial communities that mimic mixed metagenomics samples. Each community is prepared from authenticated strains that have been selected for relevant phenotypic and genomic attributes. The robust applicability of these controls, combine with ATCC's commitment to authentication and characterization, make ATCC Microbiome Standards the ideal tool for standardizing data from a wide range of sources and generating consensus among microbiome applications and analyses. (<https://www.atcc.org/microbiome>).

HiMedia, being official distributor of all ATCC products, would be happy to make these standards available for microbiome research.

(https://www.atcc.org/support/find_atcc_distributors)



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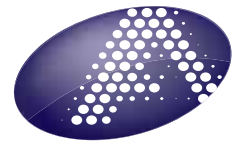
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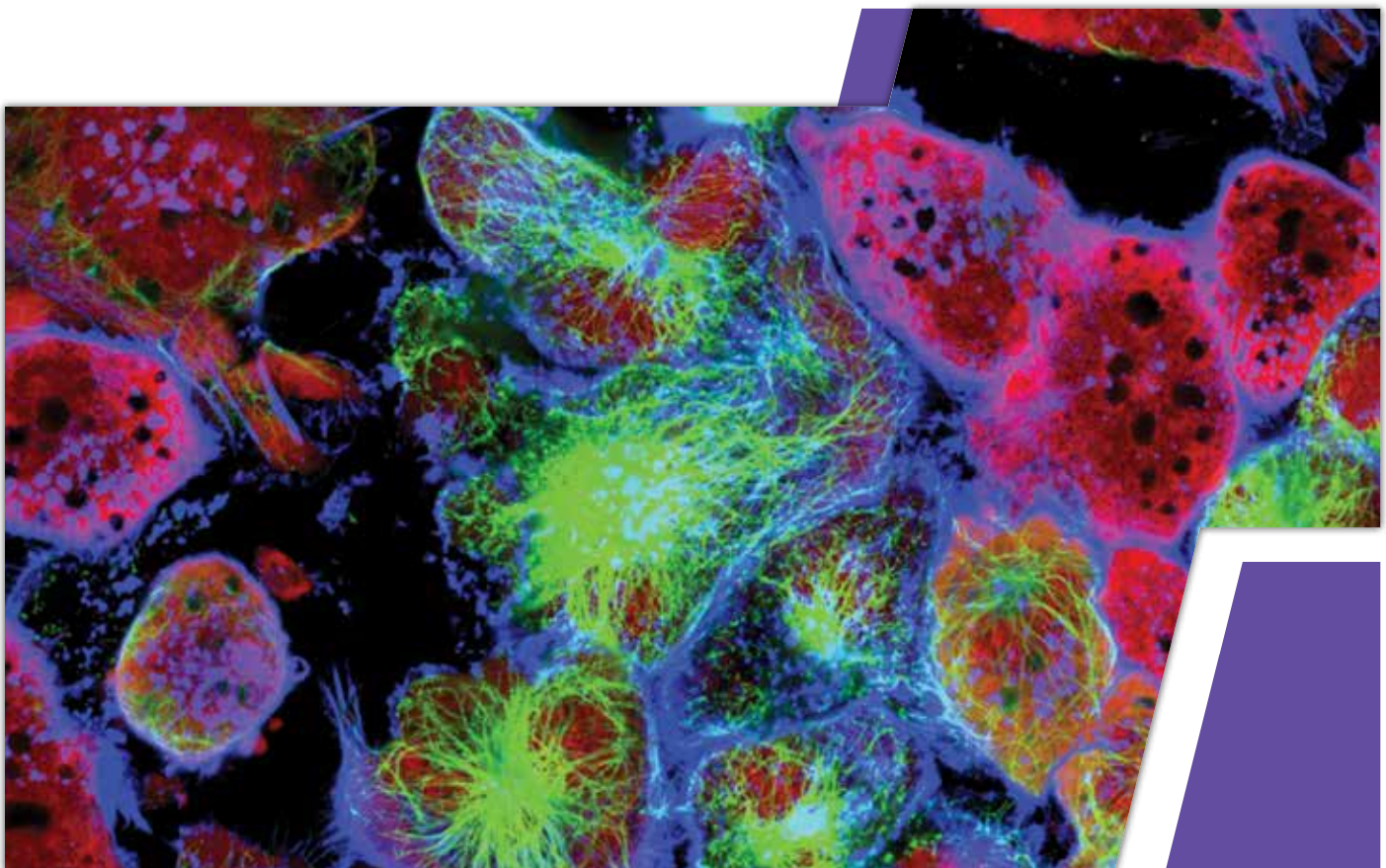
Dear Patrons,

HiMedia is pleased to announce that we have been appointed as an authorized distributor in India for ATCC products and services.

We are delighted to serve you with this new product range, and we are thankful for your continued trust in our service.

For additional product information, contact us at atcc.sales@himedialabs.com

For detailed information about the ATCC portfolio, visit the ATCC website online at www.atcc.org



• The amazing world of BIOSIMILARS and their effect on market scenarios and bio production capabilities



Ms. Gauri W. Page
Animal Cell Culture Department

Know the expert!

Ms. Gauri W. Page is a talented Research Scientist working in Animal Cell Culture wing of HiMedia. She completed her post-graduation from University of Mumbai. She has been actively involved in development of new products and services. With an expertise in development of high throughput screening assays, she has developed a comprehensive portfolio of cell proliferation and cytotoxicity assay kits. She is also engaged in media optimization for Biosimilar manufacturing using recombinant CHO clones.

Get to know antibodies!



Antibodies are amongst one of the most expensive therapeutics being used. This is mainly due to their widespread applications in chronic diseases such as cancer in high doses (more than 100mg) due to their low potency. Large scale processes are required to produce 10-100kg per year to cope up with market demands.



Market Dynamics

Sizing

By 2024, the Global biosimilar market is expected to generate \$24 bn in revenue from its current number of \$6 bn. That's a CAGR of 32% from 2019-2024. EMEA region with 44% share is the largest market followed by Asia Pacific and America. Indian companies have almost 56 biosimilar in global pipeline.

Major Challenges

Although the potential opportunities in biosimilar segment is huge; there are several roadblocks in its wide stream use

1. Regulatory uncertainty of biosimilar on interchangeability with innovator
2. Intense competition with respect to pricing pressure reducing the profit margins
3. Increased production complexity due to variable nature of different clones and the lack of ability to completely duplicate the manufacturing process and quality of innovator

Countering challenges with serum free media.

One of the major factors contributing to the high cost of therapeutic antibodies is the medium used for cultivation. With more than a decade of experience in Animal Cell Culture, HiMedia is now geared up to step into the field of BioProduction. We have established fully equipped BioProduction



R & D facility that contains more than 17 bioreactors of various scales, a battery of automated instrument for cell counting, high throughput liquid handling systems and advanced analytical

instruments. We have developed a comprehensive

range clone-specific serum-free, protein-free media and feed supplements and BioProduction services to assist at each step of Biosimilar manufacturing. Understanding the growing need for anti-cancer antibodies, we predict that our affordable lower cost SFM will eventually make our Pharma companies more competitive in the highly competitive global Biosimilar market with a fairly priced final product and will enable them to provide these medicines at affordable cost in developing as well as developed nations.





Tata Mumbai Marathon 2019

*“One Run Can Change Your Days.....
Many Runs Can Change Your Life”*



Marathon is an event where people from different profession participate including Bollywood celebrities, sports personalities, business tycoons, and amateur athletes.

that ‘the running could be a panacea for society can help to bring together people, from across the world, of different



The Tata Mumbai Marathon (TMM) amongst the top ten marathons in the world, was held on Sunday, January 20, 2019 and as usual, it has truly put India on the global map of distance running. The Tata Mumbai Marathon previously known as Standard Chartered Mumbai



We too being a strong follower of the TMM thought process



caste, creed, and social strata, onto a common platform, and this platform can be a great leveller’. That





is the reason employees as well as higher authorities of HiMedia actively participate every year in this Marathon to witness this thought process.

This event is not only the major participative sport event in the country but also the biggest fund-raising platform for Civil Society Organisations. And We HiMedians keenly contribute and enthusiastically run for the cause.

This year also total 74 HiMedians participated. Amongst which 9 expert marathoners which included Manoj Rane, Dr. Ashish

Phadnis, Datta Parab, Hemant Dukhande, Mahadev A, Deepak Rajguru, Rahul Parab, Bhisaji Rawool, Sanjay Salvi finished half marathon challenge successfully, while Dr. Priti V. Warke, Rashmi Kotian, and Nilesh Singh achieved success in 10 K category and rest of them participated in Dream Run actively. And we promise to continue participating and keep inspiring



people for achieving better health by all possible means.





CSR Activity

Setting up Regenerative Medicine Research Centre A joint venture of HiMedia Laboratories Pvt. Ltd. and Sir J J Hospital, Mumbai



“HiMedia BioSciences Serving Humankind” is our mission and we work persistently towards it by providing quality products to



make life precious. While achieving this at the scientific level, we are also sensitive about what we owe to the betterment of society and work tirelessly for enriching the quality of lives of the communities using our CSR platform. For this we have been making generous contributions for the philanthropic causes to improve the healthcare system and to empower people on social as well as economic levels.

On February 12, 2019, an MOU was exchanged between HiMedia Laboratories Pvt. Ltd., Mumbai and Department of Ophthalmology of Sir J J Hospital, Mumbai, in the presence of Shri Girish Mahajan (Hon. Minister, Medical Education,

Maharashtra), Shri Jaykumar Rawal (Hon. Minister, Employment Guarantee Scheme and Tourism, Maharashtra) and Padma Shri Dr. Tatyrao P. Lahane in Mumbai. Dr. Lahane was Dean of Ophthalmology department at Grant Government Medical College and Sir J. J. Hospital, Mumbai.

Having World record of more than 1,00,000 cataract surgeries to his credit, he is also been endorsed for modernizing OPD of J. J. Hospital along with computerizing the system. Dr. Lahane along with other eminent scientists such as Dr. Ragini H. Parekh (Head of the Ophthalmology Department of the J. J. Hospital and Grant Medical

College), Dr. Aabhay Chowdhary (Professor & Head of Microbiology Department, School of Medicine at D. Y. Patil University, Navi Mumbai), Dr. Vishal G. Warke (Director R&D, Cell Culture and Immunology, HiMedia) and Dr. Priti V. Warke (Director, Cell Culture & Head Regulatory Affairs, HiMedia) will work together for this noble cause. This crucial project is all about stem cell research for eye care, giving new hope to the eye patients.



Establishment and donation of state-

of-the-art Regenerative Medicine Research Centre (RMRC) to Sir J J Hospital is being done through CSR funds of HiMedia Laboratories Pvt. Ltd. It mainly comprises the provision of infrastructure facilities and necessary consumables for research and several another form of expertise at RMRC. While Sir J J Hospital will look into providing samples to RMRC, carry out Primary and Stem cell research besides conducting joint innovative Regenerative research.



“Social Activities by HiMedia Employees”

“Chala Gaavi” Initiative - Maha Shramadaan- Activity by Paani Foundation

Enthusiastic participation by HiMedia Team on May 1, 2019 for this noble cause.



Paani Foundation, founded by actor and director Aamir Khan and his wife Kiran Rao, is a non-profit, non-governmental organization that is active in Maharashtra, India. The main aim of this entity is drought prevention and watershed management in Maharashtra state. It is the commitment towards making the state drought-free through this movement.



on 1st May. HiMedia team reached Vadzire village, Sinnar, Nashik at around 6.10 in the morning. They were overwhelmed by welcome gesture of villagers. Entire day they worked on site enthusiastically. The pure feeling that **‘we owe something to our society’** gave this infectious energy to work

whole day in this hot, challenging climatic conditions. At the end of the day of Maha Shramadaan, great sense of satisfaction clearly reflected on participant’s faces. CEO of Paani Foundation Mr. Satyajeet Bhatkal personally visited the site to interact with the entire team.

HiMedia’s entire team salutes the Paani foundation team for initiating such a great movement throughout Maharashtra for drought prevention and watershed management. We also express our deep gratitude for giving HiMedia team an opportunity to participate and work on Maharashtra day - Maha Shramadaan activity. The HiMedia team assured them to participate every year and also strongly believes that **together we can make entire Maharashtra state drought-free** very soon through this movement.



‘Chala Gaavi’ (‘Back to the Villages’) is one of the key initiatives taken by Paani Foundation, in which people are invited to offer Shramdaan (voluntary labor) in certain villages on 1st

May. The day is also recognized as Maharashtra Day as well as Labour Day. This year, over 1.3 lakh citizens actively participated and went to various villages in Maharashtra on 1st May to do ‘Maha Shramdaan’ (voluntary work) for a day for this social cause.

When it comes to Corporate Social activities HiMedia team is always on toes for such noble causes. Not to miss this important opportunity, a team of 21 members from HiMedia Laboratories Pvt. Ltd. Palkhed, Dindori, Nashik enthusiastically participated in this grand Maha Shramdaan initiative



National Events



YC College Instrument Workshop 2019 @ Satara



BARC Scientists Meet 2018 @ Mumbai



Road Show 2019 @ IRSHA, Pune

Workshops at Biotechnology Colleges for Students, 2018-19 @ Tamil Nadu

**KSR College
of Technology**

@ Thiruchengode

RT PCR Demo and Teaching Kit
Workshop



Sankara College

@ Kanchipuram

Teaching Kit Workshop



Nehru College

@ Coimbatore

CAU

(Central Agricultural University)

2019 @ Ajmer, Rajasthan



International Events



Arab Lab

2019 @ Dubai



CPI India

2018 @ Mumbai





AQUINO

REHYDROL - B

"A Perfect isotonic solution to keep your bacteria viable, healthy and active for 3 weeks."



REHYDRATION FLUID FOR GPT

Product Code : LQ254IX

Rehydration fluid for GPT is recommended as a diluting fluid for performing Growth Promotion Test with enhanced stability

FREEDOM FROM TEDIUM

- Growth Promotion Tests (GPT), described in various pharmacopoeias (USP, BP, EP, JP, IP) is carried out to determine suitability of test medium for growth of specified microorganisms
- Dilution methods for GPT are tedious while commercial cfu preparations are expensive

- Culture preparations in this fluid can be stored upto 20 days
- Reduces overall time taken for inoculum preparation
- Overcomes tedious dilutions preparations
- Cost effective

The basic requirements for the GPT are as follows :

1. The new batch of medium must be inoculated with a small number of micro-organisms i.e. 10-100 cfu/0.1ml.
2. The laboratory should test the medium with the microorganisms required by the pharmacopoeias.
3. The microorganisms must not be more than five passages removed from reference culture.



Day 0



Day 5



Day 10



Day 15



Day 20

* For E.coli ATCC 8739, stability has been observed for upto 20 days

Patent Applied



- **Regulation of BioSciences.**
- **Rewards for the future.**

Mr. Akshay Chougule

(Executive Quality Assurance - Regulatory Affairs)

Akshay Chougule is a post graduate from Mumbai University with more than 3 years of experience in Pharmaceutical, Chemical and Capsule industries. An expert in regulatory affairs and compliance system, he is currently interested in facilitating the development and implementation of management systems through regulatory intelligence.



Importance of Regulatory Affairs

In today's competitive environment the reduction of the time taken for the product to reach the market is extremely crucial. The regulatory affairs are of economic significance for the company since it affects the time taken to ship a product from the lab to the customer.

A new drug costs a lot to develop, hence even a slightest of delay in bringing it to the market has considerable financial repercussions. Even worse, failures to fully report all the available data or the release of product bearing incorrect labelling, may easily result in the need for a product scrutiny.

How should a regulatory professional be?

A good regulatory affairs professional should have a 'right first time' approach, means involves making sure that all activities are carried out in the right manner the first time and every time. Regulatory affairs professional plays a very important part in coordinating scientific endeavor with regulatory



demands throughout the life of the product, helping to maximize the cost-effective use of the company's resources. The Regulatory Affairs department is very often the first point of contact between the government authorities and the company.

A conceptual understanding of Regulation and Regulatory Affairs

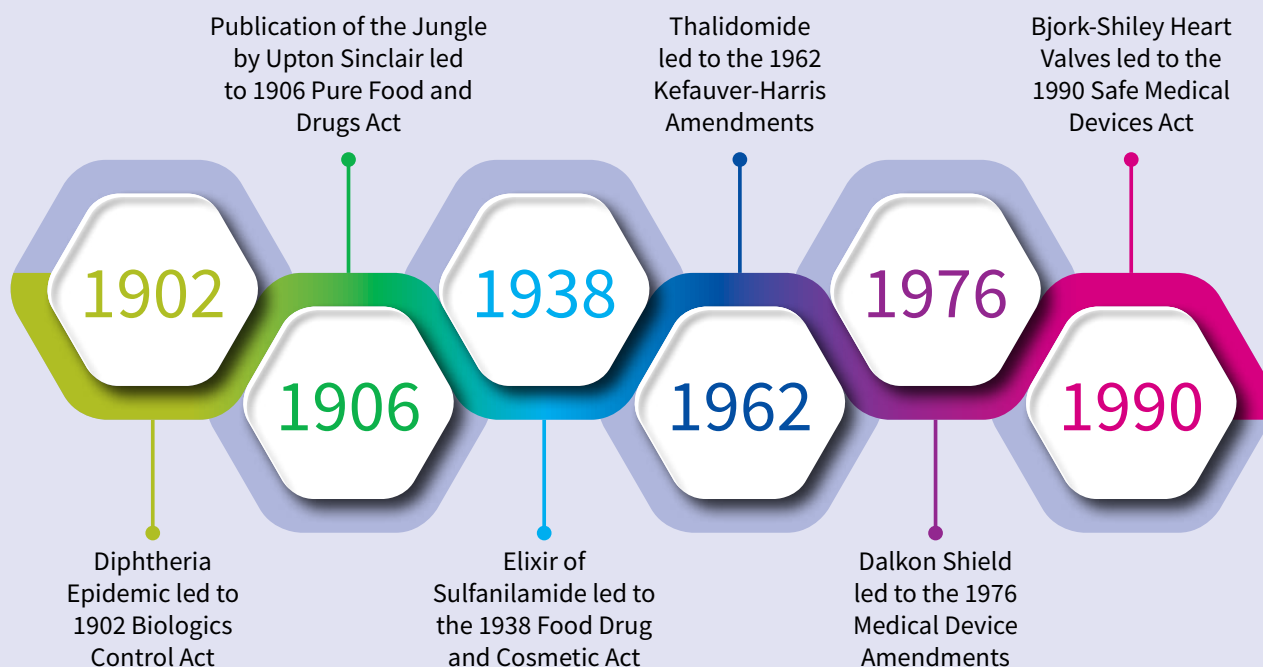


Regulation involves extensive evaluation of a particular product to ensure protection of public health, promotion of the product, drug registration, marketing authorization, import, distribution and pharmacovigilance.

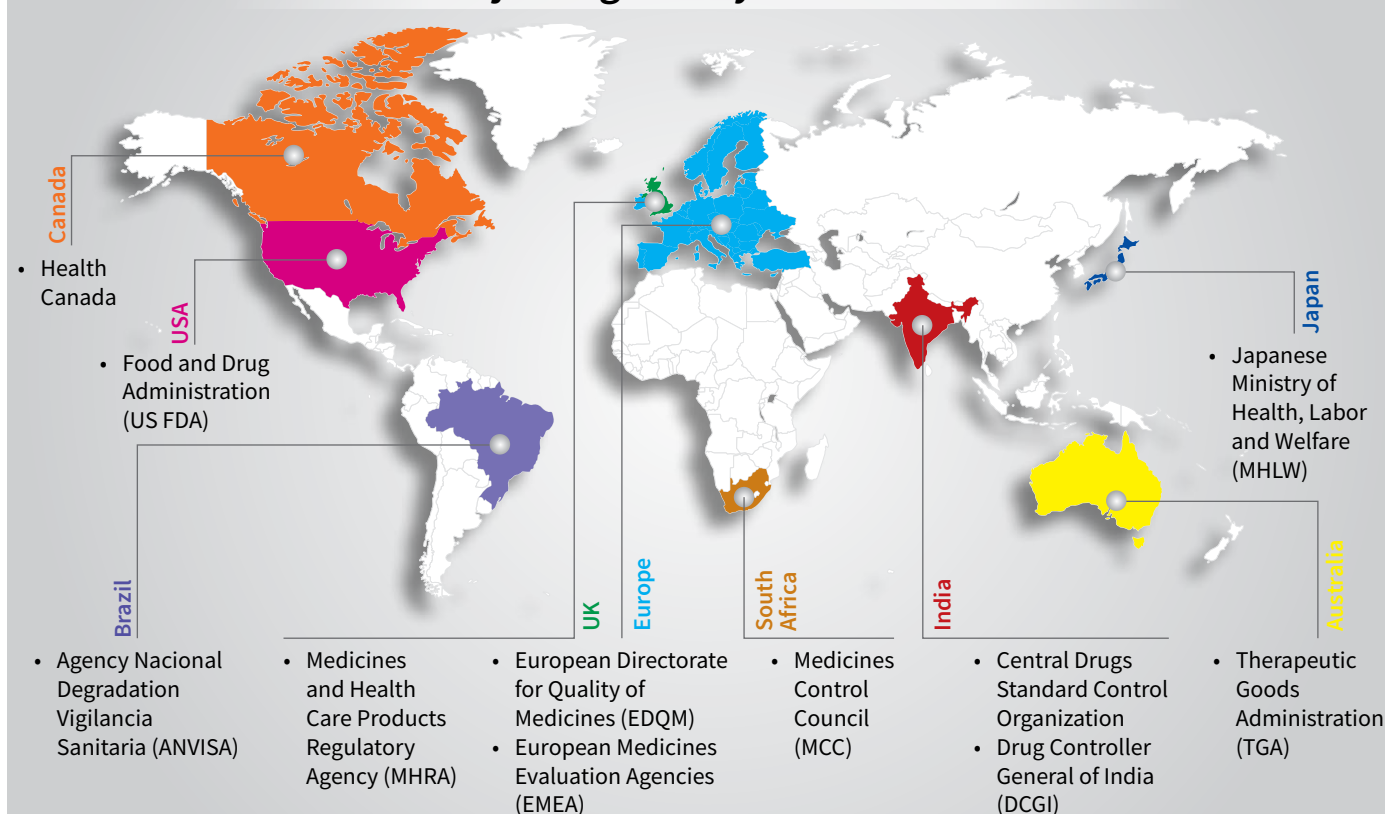
Regulatory affairs is a comparatively new profession which has developed from the desire of governments to protect public health, by controlling the safety and efficacy of products in areas including pharmaceuticals, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines.

Major incidences made us understand that rules and regulations are required to prove safety along with the efficacy of drug.

Such incidences are as follows:



Major Regulatory Authorities



HiMedia's Role

At HiMedia we enable product movement at the global regulatory from the laboratory to households. We've stood as the regulatory backbone for many Biopharmaceuticals and other health care sectors. We have a unique direction and system in place which guides in decision making at critical milestones of the product lifecycle.

HiMedia has the experience and knowledge to provide the required oversight to successfully meet the regulatory demands for several products and services.

This is because our S.M.A.R.T. quality management system reaffirms commitment to quality products, customer service and continued improvement.

Exhibitions and Conferences

UPCOMING EVENTS

Jun 18



18 Jun 2019 -
20 Jun 2019

CPHI - China 2019, Shanghai

Venue : Shanghai New International Expo
Centre (SNIEC), Shanghai, China
Stand No.: E1M37

Jul 03



03 Jul 2019 -
05 Jul 2019

Bio Pharma Expo 2019, Japan

Venue : Tokyo Big Sight, Japan
Stand No.: A8-32

Sep 24



24 Sep 2019 -
27 Sep 2019

Analitica Latin America, 2019

Venue : Sao Paulo Expo, Sao Paulo/SP, Brazil
Stand No.: D083

Nov 26



26 Nov 2019 -
28 Nov 2019

CPHI India 2019, Mumbai

Venue : Bombay Exhibition Centre, Mumbai,
India

Jun 20



AMERICAN
SOCIETY FOR
MICROBIOLOGY

20 Jun 2019 -
24 Jun 2019

American Society for Microbiology (ASM) Microbe 2019

Venue : San Francisco, California

Jul 09



analytica Lab Africa

09 Jul 2019 -
11 Jul 2019

Analytica LAB Africa 2019, Midrand

Venue : Gallagher Convention Centre,
Johannesburg, South Africa

Nov 18



MEDICA®

18 Nov 2019 -
21 Nov 2019

MEDICA 2019, Dusseldorf

Venue : Dusseldorf Exhibition Centre,
Düsseldorf, Germany
Stand No. : 3D36

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