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A HiMedia Newsletter Volume -13, May 2022

Digital Transformation

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- **The Science Galaxy -**
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic : A critical view
- **Digital Transformation – HiMedia's Perspective**



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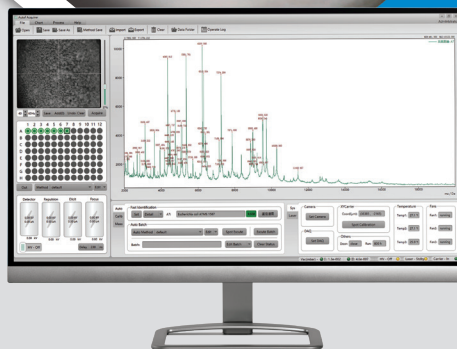
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microbial ID
system.



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- Biggest database in the world with free lifelong cloud based updates
1003 genus, 4943 species, 15993 strains
- 300 tests/hr
- Finer LASER – Higher resolution!
- Less than 1 minute of vacuum up time
- Customizable pre-treatment reagents
- Maintenance free system

MESSAGE FROM THE CMD



Dr. G. M. Warke, Ph.D.
Founder & CMD - HiMedia Laboratories Pvt. Ltd.

Dear All,

Welcoming the new financial year, I wish each, and everyone be blessed with good health, prosperity, growth, and happiness.

As we move forward, I would like to thank every member along with our customers and clients for your support. While we add more services and products to our offerings with enhanced support, it is the trust that our customers have held upon us which acted as catalyst to our overall growth over 5 decades.

Our goal is to keep adapting to newer requirements and be cost-effective, yet relevant to the required technical advances such as genomics sequencing and bioinformatic services, automation in DNA/RNA Extraction, PCR amplification technologies, media for monoclonal antibodies (Biosimilars), organoid development, tissue & organ regeneration, 3D Bioprinting, COVID-19 vaccine, and cultured meat. We are in the process of acquiring ISO 22000, a Food Safety Management System (FSMS) which is the food certification standard, needed for production & supply of safe cultured meat.

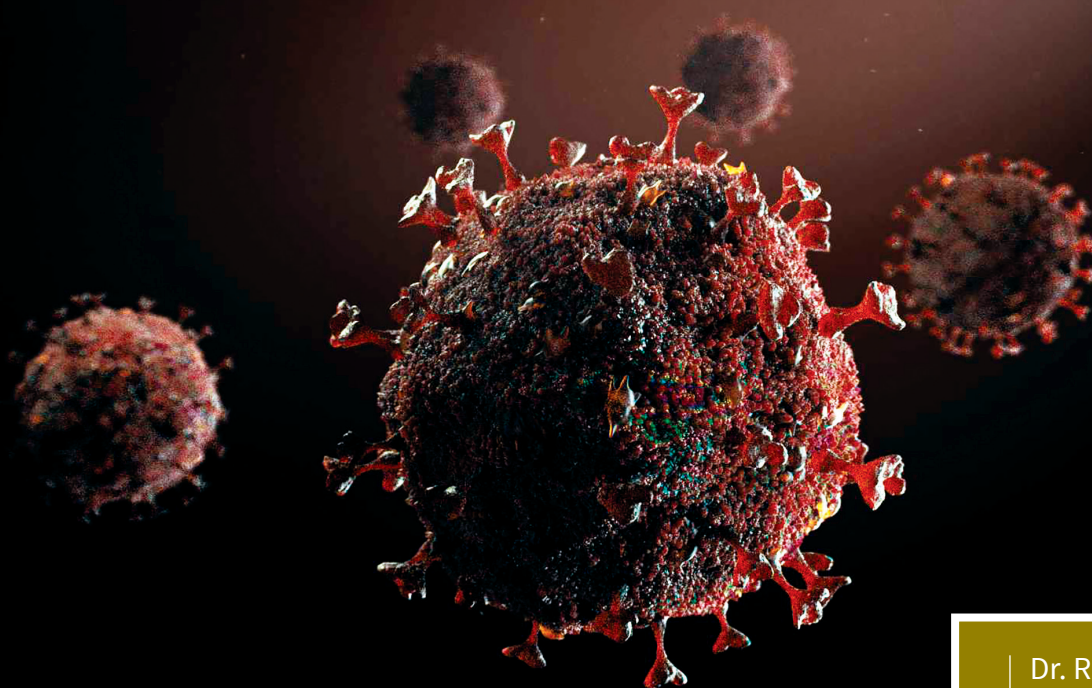
We have implemented stringent NABL quality norms in Microbiology lab, per international quality management and regulatory standards and are in the process of acquiring NABL for the molecular sequencing facility.

We have introduced HiPetriSlim™, the thinnest version of a petriplate, HiMIC™ Plate Kit is an easy way of evaluation of MIC using CLSI and EUCAST guideline, Autof MS1000 MALDI TOF MS for microbial identification through proteomics way with world's biggest microbial database, and field-testing kits for water.

Our venture into intuitive medicine by means of PCR based detection of anti-microbial markers is helping clinicians to decide their drug of choice. We are also enhancing the biostatistics space for sequencing and post sequencing gene mapping analysis.

Additionally, we have introduced a semi-defined serum replacement solution, NuSera™, designed to replace fetal bovine serum in cell culture.

In this special edition of our newsletter, we have quite interesting subjects covered by HiMedia team on developments within the biotechnology industry. In the science galaxy section, we are honored to have a guest column on a critical review on SARS-COV-2 pandemic by Dr. Robin Mukhopadhyaya, former Professor and Principal Investigator -Virology, Advanced Centre for Treatment, Research and Education in Cancer (ACTREC). The article is his personal take on the entire global situation during the COVID-19 pandemic.



Dr. Robin Mukhopadhyaya,
Ph.D.
Formerly, Professor & Principal
Investigator Virology, Advanced
Centre for Treatment, Research &
Education in Cancer (ACTREC)



Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic: A critical view

All human developments in science and technology aim to assure establishment of increasing degree of certainty. Whenever there are events with uncertain profiles it leads to chaos in social organisation and takes some refractory period to have some control on the overall management of the situation.

In the intervening period qualitative and quantitative losses beyond control ensues, very often imparting extreme economic and psychological strains on us, more on the generations of less resourceful, marginal populations. For nearly two years the human life movements are going through periodic chaos followed by semi-ordered social behaviour as the raging air-borne viral pandemic by SARS-CoV-2 is sweeping through the whole world. This effect we are witnessing is somewhat like events such as massive earthquakes or tsunamis.



Origin of SARS-CoV-2

After the initial hiccups, most developed countries raised the query on where did SARS-CoV-2 come from? Taking cue from earlier well managed similar influenza like viral infections with novel isolates, the suspicions were that either it was transmitted in the wild from an animal to a person before exploding in Wuhan, China where earliest infections were detected, or it was an engineered virus that escaped from the well-known high security virus research laboratory in Wuhan! However, despite some initial efforts with WHO support did not establish much to be sure enough regarding this issue and the lab engineered virus-leak theory remained by and large speculative, at the best. Most subject experts, epidemiologists in particular, consider initiation of the pandemic events from a yet uncertain natural source(s). Subsequent exponential increase in disease burden, resulting chaos and maddening efforts to manage the same, often disrupting health care systems, led to less focus on the origin issue. However, generation of new SARS-CoV-2 variants, massive economic contractions in last two years, and continuing, will not let the world forget the origin issue to come up again in future, though it is of no use spending time on that really.

The pandemic magnitude

Till first weekend of January 2021, WHO reports close to three billion infections spanning more than 200 countries and about five and half million deaths related to SARS-CoV-2 induced inflammation and other characteristic complications of novel types, the underlying mechanisms of some of which are yet to be firmly established. The viral pandemic, as found in an earlier event of similar magnitude, the Spanish flu pandemic a century back with around 50 million deaths, is going through waves of infections. Each wave is dominated by constantly evolving (mutating) strains with different infection and resultant host clinical profiles.

Response patterns in different geological territories

The events started in China and in contrast to the century old pandemic, with the advanced rapid travel logistics/ mass transit modes available in the contemporary world, the infections started spreading faster in those countries with more frequent flight schedules and business ties. Initially reports on the badly needed clinical characterizations of the new disease started percolating slowly in the expected global dissemination of bio-medical information. However, the increasing noise on the virus origin from China, particularly raising concern of lab-leak theory, resulted in Chinese state machinery closing down exotic animal markets in major cities but simultaneously almost stopped sharing the pandemic related data including infection statistics. It also restricted journalists from visiting hospitals in Covid hot spots and health care workers from interviews and making the Wuhan lab almost inaccessible to the outside world. While the state machineries in countries facing advent of the new viral infections tried to grapple with the situation by reducing probability of human interactions through human movement restrictions in shops, malls, eateries and entertainment outlets, the clinicians were struggling to understand the meaning and underlying physiology and biochemistry of the

uncharted clinical manifestations and its management.

The well proven virus control strategies for such mega scale infections are therapeutic intervention with antivirals and inducing herd immunity through vaccination. China, Russia, and the western world, notably USA, Germany, UK made fast progress in culturing the virus, characterizing the genome and its proteins, and initiating vaccine development in state or privately funded biotech firms. Largely the freewheeling western societies with more frequent travel habits, ease of travel and lenient socio-political environments, started showing rapid spread of infection and in comparison, the infection at that stage was rather nominal in India. Though several experts globally were echoing that all countries are going to get in the pandemic net, somehow the authorities here were not convinced to believe in the prospect of infection spread and assimilate the gravity of the situation. There were delay in setting up a central monitoring body, task force for making policy decision and a complacency in absence of appropriate and defined guidelines barred the sensing of incoming health care fiasco.

By late 2019 and early 2020, some smaller countries like Vietnam could manage to curb citizen movement and international travel strictly and could withstand the early infection bouts using minimally existing health care facilities. However, most South Asian countries with large tourist-based revenue generation were rather slow to take such strict stance and thus the spread got firmly established. Same was the scenario largely with mid and south American countries, east European countries, rest of Asia and the two countries of Australia and New Zealand also showed entry of the virus. Africa, where health care system is most fragile and already under severe stress from multiple infectious diseases including AIDS, the situation started to become alarming. WHO stepped in big way by making systemic update of global infection data, advisory dissipation and requesting developed countries to speed up drug and vaccine development with a compassionate consideration for the underdeveloped countries, especially the African nations. Already Europe, USA, Brazil, and Russia were loaded with cases and trying to cope up with the situation in a messy, often direction less way as a coherent grip on the situation by state machinery was yet to be consolidated.

In about four months since the initiation of the pandemic, Indian infection record started becoming glaringly stark and exponential, as it happens in any pandemic. It is then that the utter chaos started with thousands of infected



subjects showing rapid lung function deterioration, oxygen insufficiency and needed urgent hospitalization. In retrospect the scenario and pace of state stance were similar for AIDS in the late eighties! Though experts warned by mid-eighties that AIDS will eventually spread in all countries, the then Indian medical regulatory authority was very late to wake up; often, an undiscussed/ undebated view then was dominating in some quarters that since Indians are conservative in their social behaviour and monogamous, AIDS will not be a health care issue in India! However, history got documented in the normal pattern as was in other countries and Maharashtra had at one stage >1% rural population infected with HIV, the AIDS pathogen!

Though there were some early confusions about route of infections, in absence of peer reviewed documented data about the nature of virus spread, it was a certainty of aerosol/ airborne infection spread like other influenza viruses. This allowed a general consensus of using masks and safe distance maintenance as basic behavioural steps to minimise spread of the virus in any resident population and WHO stressed this point repeatedly along with frequent hand washing/ sanitizations practise. However, it was found that implementation was rather a difficult task, irrespective of the literacy status of the populations! China, with its state machinery having absolute power to control all human activities as and when it wants, made mask and isolation mandatory and strictly implemented almost total lockdown in hot spots throughout the country with severe travel restrictions, flight suspensions. It was then becoming evident that these two Covid specific practices are the minimally expensive but effective personal protection from infection. However, most advanced western countries with their rather well laid personal freedom and liberty perspectives watched helplessly flouting of these suggestions! Public place, eateries, pubs went on getting usual crowding parallel to the increasing number of cases needing hospitalizations with an ever-increasing demand for oxygen supply.

By the time the Indian government initiated centralised concerted efforts towards the mid 2020 to handle the slowly crumbling health care scenario, more evident in resource poor rural sectors with high death rates, an extreme shortage of oxygen and availability of ICU beds with ventilator in city hospitals became limiting factors to sustain treatment of older patients and those with major co-morbidities like diabetes and cardiac ailments. Around this time flight restrictions were imposed slowly around the globe thus throwing the shipment logistics in disarray momentarily with a supply chain break for essentials. The situation also highlighted the long-term effect of rather severely sub-optimal spending in health care systems in a country of 1.4 billion people. Similar realizations also occurred in many other countries with identical crisis. As the mega cities started to experience the onslaught of exponentially increasing unmanageable patient loads, finally drastic lock down measures got implemented with closure of educational institutes, and business places that normally gather crowds (e.g., hospitality industry), domestic and international flights, all mass transit systems. The lockdown had to be implemented gradually to smaller cities and towns as the infection spread to all places with rail and road connectivity. This was the first wave of infection that started waning by end 2020. In 2021 the second wave started by March with the more virulent delta strain dominating and

started tapering by September.

Clinical management of Covid19 infection in early days

While planning and initiation of vaccine development were underway, the hospitals with its clinicians and the nodal health authorities were trying desperately to look for medications to control virus replication pace in the host body. There was no antiviral targeted for the new scantily characterized virus and thus existing antivirals for use in other infections or repurposing of known drugs for treating other unrelated diseases were the only avenues to look for. However, the US FDA approved the first intravenous antiviral injection remdesivir for hospitalised patients though WHO issued conditional recommendation against its use, meaning that there is not enough evidence to support its use! Some other antiviral drugs like favipiravir and ritonavir were also tried. India being a malaria infested country was familiar with the drugs Hydroxychloroquine and chloroquine, which started getting rampantly used, even exported to USA with US FDA approving emergency use but withdrew that authorization when data analysis showed that the drugs are not effective for treating COVID-19 and can also cause serious heart problems. Similarly, Ivermectin, a broad spectrum anti-parasitic agent for treatment of intestinal strongyloidiasis and onchocerciasis, got used in several countries though there were no positive effects. The anti-inflammatory corticosteroid dexamethasone was used to treat or prevent organ dysfunction and lung injury from inflammation as it showed some reductions in the risk for deaths for people on ventilators and for people who needed supplemental oxygen. Thus, whatever was showing indications of even insignificantly marginal apparent improvements, were tried in the initial chaos, more so in countries with little drug regulatory expertise, shortage of able clinicians and suitably trained health care staff. Apart from these, convalescent plasma from blood donated by people who have recovered from COVID-19 with high antibodies were used to treat some hospitalized people with early illness or compromised immune systems, though with not much appreciable benefit at large. Additionally, different monoclonal antibodies, some directed to inflammatory cytokines, were also used though use of such costly antibodies again did not assure any significant and consistent outcome and thus none could become part of standard clinical management dossier for Covid-19 infected patients. Towards the end of the first wave, with installation of oxygen plants and ventilator import/ local fabrication in war footing and availability of more clarity on the underlying damages happening due to the virus, the clinicians, though now under extreme fatigue, at least got a semblance of the situation and were able to have a control on the clinical management if appropriate infrastructures were not limiting. It was the most damaging clinical war fought in the modern world after AIDS.

Social cost of the Covid war

The extreme measure of stopping all outdoor activities and man movement to block virus spread meant stoppage of all outdoor developmental work and thus unthinkable loss of jobs for marginal workers and contract labourers with negligible savings and lack of alternative source of income. Parental



loss of income interrupted children's education, appropriate food intake and proper housing/ shelter opportunities. City centric construction activities came to standstill and the labourers, mostly migrants from poorer states and distal rural set ups, faced an uncertain future though tried to stay put initially hoping for the betterment of situation. However, they finally gave up with dwindling meagre savings and an unprecedented human migration happened in India, often on foot for hundreds of miles as vehicular traffic movement was restricted and limited trains were permitted, resulting in many tragic deaths on way. A large number either are demoralised to return or tried to find job near hometown, mostly without success. On one hand this human cavalcade was a tragic scenario and on the other hand with renewed infection waves after a lull, disposal of dead bodies in hundreds, often being dumped underground on riverbanks or floated in the rivers became horror scenes of second wave that will linger as bad dreams for all the current generations. The other tragic loss to all nations, including our country, was the loss of the frontline workers with Covid infections. There were large number of casualties among of the doctors, health care workers, sanitation staff and the police personnel trying to control law and order, implementing movement restrictions and keep general security unfailing when disaster is all around. They died to save others, just like the military personnel, very tragic indeed. The loss of means of living not only dealt blow, often irrevocable, to the referred casual workers but also to small business owners, small vendors, sellers of small items and local transporters. Additionally, many kids got orphaned as bread earners died in different strata of society, this will impact the dreams and life course of many in yet unknown directions. Full extent of loss of life sustenance will become clear only when the pandemic is over, and life returns to near normalcy.

The Covid vaccine saga

Each global crisis in human life has led to generation of innovative and novel ideas and new technologies emerged, which are often disruptive in nature and makes immense



impact on human living. There are plenty of examples about the innovations brought out during the two world wars. The Covid crisis implied that such a pandemic must be confronted with vaccine development at war footing now that the world has experience in complete (smallpox) or near complete (polio) elimination of deadly viral diseases. Also scores of other debilitating viral diseases are kept at bay lifelong with timely vaccinations in childhood (measles, mumps, rubella, varicella etc). There are now vaccines for other pathogenic viruses like HBV, HPV and Ebola. Vaccine science has matured over the years and seasonal influenza vaccines are also routinely churned out. However, normally vaccine development is a long process from exploratory research to pre-clinical toxicology to three phases of clinical trials followed by regulatory clearance, manufacturing, and quality control; the flow of events usually spans over several years involving a large number of trial participants. This time it was a game changer; extreme urgency of vaccine development for Covid-19 witnessed immediate financial supports from many governmental as well as non-governmental global coalition like CEPI (Coalition for Epidemic Preparedness Innovations). Making inactivated virus as candidate vaccine was an established technology and China made first such vaccine using this route. Russia, UK, USA all ventured in viral-vector vaccines, also an established technology (used for Ebola vaccine) with Covid-19 spike region as antigen since this part of the surface antigen or epitope makes contact with host cell for invasion. Thus, blocking the interaction with an antibody (neutralising antibody) will inhibit viral entry to the target host cell in the nasopharynx- oropharynx. An unprecedented fast track clinic trial strategy was followed with minimally acceptable sample size for all the candidates and given emergency use authorization by respective regulatory authorities to get vaccines in market within a year, unthinkable in normal course so far. However, while these were fast forwarding the vaccine efficacy validation process for the first time, an innovative vaccine candidate emerged, the mRNA vaccines, developed independently by Moderna in US and German BioNtech firm in collaboration with US pharma giant Pfizer, this invention was a game changer giving idea for a new platform technology. USA primarily used these two candidates for its population and later the Janssen viral vector type vaccine was also used (this is the only single dose vaccine while most are two dose course). Europe, Japan, Australia, and New-Zealand authorised m-RNA as well as vector-based vaccines.

India is very uniquely positioned for long as a major global supplier of large number of vaccines, thus with huge available infrastructure. The Oxford-AstraZeneca developed viral-vector vaccine Covishield was quickly licensed to the largest global vaccine supplier, Serum Institute of India and after

due clinical trial data review it got emergency use authorization. Later Bharat Biotech, an Indian biotech pharma, developed inactivated virus based

Covaxin, which also followed similar route and received approval soon. Whether vector based or whole virus based, the candidates provide almost similar level of protection (from disease severity, not necessarily reinfection). Some people opine that whole virus derived vaccine will provide better protection, however, there is no scientific basis or peer reviewed data to support that. Ultimately viral spike protein-host cell surface interaction blocking will be carried out by vaccine induced antibodies to spike protein only, whether the protein is on inactivated whole Covid-19 virus or on a heterologous viral backbone. Yes, whole virus will produce many more antibodies but for any of those to neutralise will imply other viral proteins involved in cell invasion! Shorter production time and higher yield make vector-based vaccine development a much faster and cheaper process, the reason that nearly 85% adult vaccines delivered in India was Covishield, which is also cheaper than Covaxin. In recent time Covaxin has been authorized for children in 15-18 age group. Another existing idea translated successfully was DNA vaccine (circular strands of DNA), first in the world, developed by Zydus Cadilla and the three-dose candidate ZyCoVd has been recently authorised. The biotech firm Gennova at Pune is now conducting clinical trial for India's first mRNA vaccine for Covid-19.

With 1.4 billion people, it was a massive task to immunize the adult population with two doses of shots. But it was a commendable feat to administer >1.5 billion doses overall in one year period with >61% adults fully vaccinated and senior citizens and front-line workers already eligible for third (booster) dose. By and large there was voluntary participation in vaccinations, sometimes in some pockets people needed counselling. Surprisingly in several European countries and a large population in USA refused and protested, still doing so, against vaccination and all those places are seeing huge surge and casualties in each wave of infection, they also protested against lockdown and movement restrictions. Overall, multiple vaccine development and significant level of disease severity control in new or reinfections so fast in a new global pandemic is a major scientific landmark and shows ever expanding limit of human efforts.

Economic implications of pandemic

Each government of the world, rich or poor, had unprecedented financial strains over the past two years with most sectors incurring losses, except largely the agricultural productions and the online delivery services, the latter actually reaping huge profits. Efforts to ramp up normalcy back was hampered in labour intensive sectors as subsequent waves disrupted such efforts. MSME suffered badly and overall consumer demand reductions led to accumulation of bad loans, or rather a

significant increase in bad loans. The total bank loans written-off in 2020-21 stood at Rs 2.08 lakh crores! A large chunk of revenue from all taxes were used to pay for free vaccinations provided to citizens and it will continue further. This will in turn lead to reduction in some developmental work in near future though a return of near normalcy is expected to boost productivity with renewed vigour, the financial market so far is reflecting that sentiment.

Living with Covid

The sequential waves of infections with appearance of different mutants with altered features are not allowing development of a firm SOP for treatment. This is so because clinical symptoms are varying, viral localization and viral replication are showing often different profiles and thus implying each time changed host response. Latest strain Omicron is a highly infectious strain, spreading fast but Delta is still around too. With majority being vaccinated with at least one dose, infection is not usually leading to severity as in earlier two waves, but it should be kept in mind that those with co-morbidities or underlying long covid damages if infected are carrying high risk. No responsible clinician or peer reviewed data has said now you can take it easy Full territory is unknown, clinicians and researchers are trying to gauge the scenario for best strategy to assist recovery with minimal damage; it is the seriousness of citizens that is often slackening, probably due to fatigue but many a times with misleading notions when guards are let down. We are also not sure even after third booster how long the required protection will persist! This way possibly we must learn to live with endemic Covid infection for some time to come with changed/ adapted lifestyle, hoping that sustained resilience and appropriate behaviour will lead mankind in commanding seat soon.

Biosketch of Dr. Robin Mukhopadhyay

Formerly, Professor & Principal Investigator Virology, Advanced Centre for Treatment, Research & Education in Cancer (ACTREC). Tata Memorial Centre, Kharghar, Navi Mumbai-410210.

Academic background: Ph.D. (Immunology)-Cancer Research Institute, Tata Memorial Centre/University of Mumbai.
Post-doc (Virology)- NCI, NIH, USA; Mentor: Robert C Gallo.

Expertise: Virus characterization, bioassay development, viral vector development, improved production of therapeutically important recombinant protein (mammalian system), VLP technology, start-up biotech program audit.

Major achievements: i] First commercially successful DBT sponsored biotech project: HIV-1 & 2 Sero-diagnostic Western Blot (licensee-J Mitra & Co, New Delhi); ii] First complete sequence of HIV-2 from India/Asia.

Awards/Recognitions: i] Science in Society' inaugural year award of the Indian National Science Congress, 2004; ii] All India Biotech Association award, 2000-2001; iii] VASVIK award in Biological Sciences & Technology, 1998; iv] Fellow, National Academy of Sciences (FNASc).





Mr. Shankarram Srinivasan
Head- Systems,
Information Technology



Digital Transformation – HiMedia's Perspective

HiMedia Laboratories is ranked amongst the top life science manufacturers, developing many path breaking products in microbiology, cell biology, molecular biology, and other allied life sciences.

"Digitise or Die!" by Dr. Ram Charan. The corporate guru and global advisor to CEOs can't emphasize more on the fact that digital is the future of every business. IT team at HiMedia has been working relentlessly towards creating an effective digital transformation strategy.

To have an edge in a hypercompetitive market, it has become imperative for organizations within the manufacturing industry to be at the fore of digital capabilities, transforming manufacturing methods with the help of technologically driven disruptions.



IT team at HiMedia has been innovating by adopting latest information technology tools and has implemented many innovative projects viz.

- Implemented SAP ERP in 2006.
- Implemented Suite on HANA in 2013, 1st life science company in Asia
- Implemented S/4 HANA in 2019.
- Managing around 20 plants and 30,000 SKUs

Currently implementing key digital transformation tools

- Robotic Process Automation,
- RFID for Smart Warehouse
- Artificial Intelligence (AI) and Machine Learning
- Internet of Things - Smart Laboratory, Smart factory
- Analytics and Predictions using AI /ML

Our highly motivated, multi-skilled IT team led by our IT Director, Mrs. Saroj Warke:

- Manoj Rane
- Shankarram S
- Sheetal Warke
- Rahul Parab
- Jagdish Bharambe
- Suresh Gurram

COVID-19 – Challenges met with a robust and scalable IT set- up

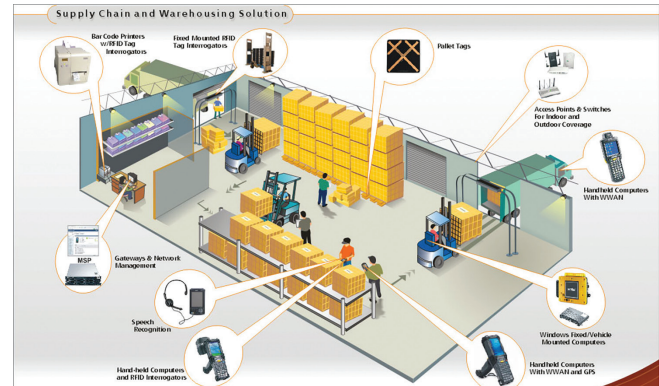
COVID-19 came like a slow trickle and engulfed the entire world in no time, forcing global entities to face the hard reality of functioning in a world that was not yet prepared to face the challenge of functioning remotely full- time and HiMedia was no different. New government rules kicked in, temporarily disabling some of our manufacturing sites. As the demands for Viral Transport Medium, the COVID-19 sample collection kit and RT-PCR test kits grew exponentially, we had to scale our manufacturing at new sites exponentially.

The demand of the kits that were manufactured in few lakh units per year, soared to 10 lakhs units per day. This made us sit up and look to ramping up our scale manifold. The exponential and unprecedented demand of VTM kits led us to quickly set up multiple new manufacturing units at various sites and meet the supply demand at breakneck speed.

The IT team at HiMedia proudly takes the onus of being at the helm of making necessary provisions during the pandemic to make manufacturing workflows easier which included IT systems, printers, and barcoding hardware along with applications for new manufacturing plants overnight. What helped us the most is our core Virtual Desktop Infrastructure by which we could make provisions of thin clients and laptops to all employees enabling them to work remotely, without compromising security policies. SAP on S4/HANA really proved its capability wherein we could manage all our orders and inventory in rapidly setup manufacturing scenarios.

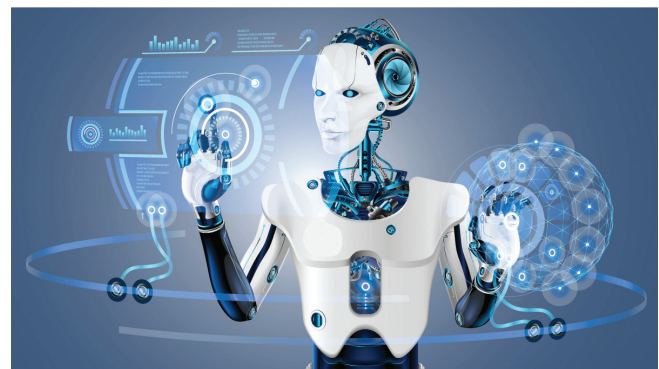
Key digital transformation initiatives at HiMedia

• RFID (Radio Frequency Identification Devices) enabled smart warehouses



Our huge state-of-the-art warehouses in India, US and Europe are RFID and Barcode enabled, enabling us to manage the warehouse operations, production, and dispatch accurately and quickly.

• Robotic Process Automation (RPA)



Robotic Process Automation is reengineering the repetitive human processes to Software Defined Robots mimicking human action and decisions. They are also called Digital workers or Software Robots.

Robotic workers can work 24/7 and do repetitive tasks and free key human resources to carry out discretionary processes

Today our BOTs are working and running 24/7 in following areas

- Bank reconciliation
- Follow up functions for Purchasing, Accounts receivable etc
- Automations in Paperless Office.
- Smart Document Management System
- Smart Invoicing - Use of Artificial Intelligence based Invoice readers to read and process vendor Invoices in less than 10 seconds

Success of these processes has caused our departments to ask for more Robots to help them carry out their processes.

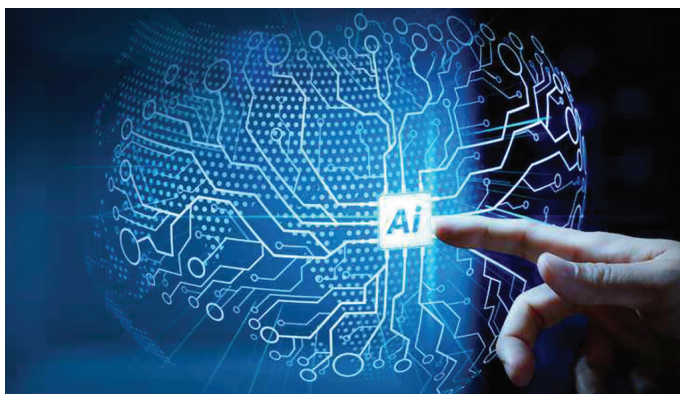
Smart Laboratory and Smart Factory using Internet of Things (IoT)



Use of Sensors and Machine Integration connected to a network, to provide real time access to shop floor information and process information. Working on implementing Industry 4.0, which will yield tremendous benefits in terms of process automation and process mining.

- a. Smart Laboratory :** IoT enabled quality assurance laboratory, tightly integrated with barcode processes.
- b. Smart Factory :** Machines are made IoT compatible, enabling real time visibility to production and processes.

Artificial Intelligence and Machine Learning

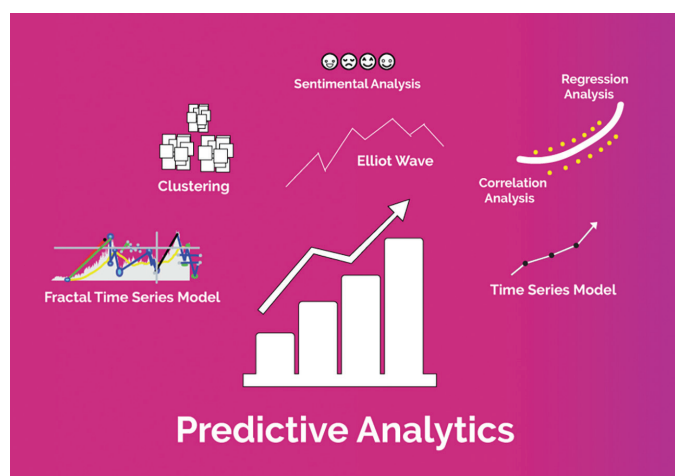


Artificial intelligence (AI) is the ability of a computer, or a robot controlled by a computer to do tasks that are usually done by humans because they require human intelligence and discernment.

It is trained by using latest Machine Learning (ML) to define models, train them and helps in defining newer processes using Artificial Intelligence to mimic human decisions. We are undertaking the task of supporting Biotechnology processes with the help of AI Enabled processes.

- a. Use of AI for Diagnostic Applications :** Use of AI and ML to create path breaking diagnostic applications in Microbiology and allied fields.
- b. Smart Invoicing :** Implemented AI and ML assisted processes which now scan, and process vendors invoice copies which are having different structures in under 10 seconds with a 99% accuracy.

Analytics



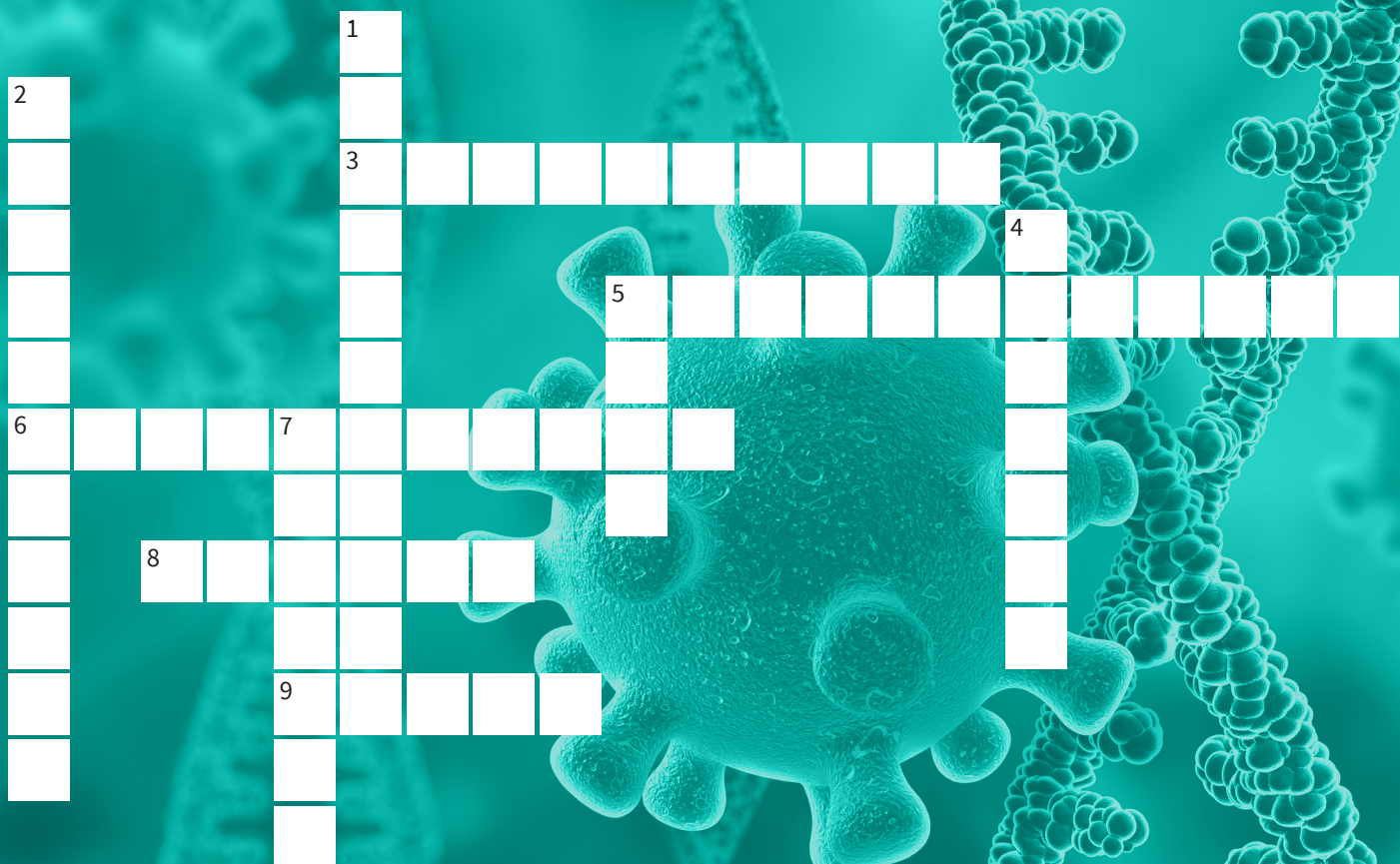
- a. Exploring predictive analytics in business to analyse trends within finance, marketing, life sciences.**
- b. Use of analytics and algorithms in gene sequencing and in life sciences.**

Summary

An effective digital strategy plays a vital role for data-driven companies to steer through ever changing industry trends, capitalize on opportunities and gain a competitive edge. Digital transformation is a continuous process and an essential one to drive growth and profitability of organizations and HiMedia would be leading from the front towards innovating and investing in core infrastructure, people, and technology.



CROSSIT



Across

3. Origin of B-cell
5. Enzyme co-factor for photosynthesis
6. Ability of single cells to divide and produce all the differentiated cell in the organism
8. Pyrimidine base which is found in RNA but not in DNA
9. Organism on which first cell line was observed

Down:

1. A model plant used in tissue culturing
2. Bacteria which obtain energy from chemical compounds
4. A restriction endonuclease
5. An organization which collects, stores and distributes standard reference microorganisms, cell lines and other materials for RND
7. Circular DNA used for cloning



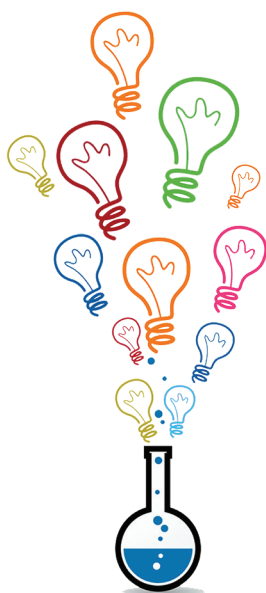
Dr. Kamlesh Jangid, Ph.D.
Manager R&D & Hi-Gx360®
Services, Molecular Biology



Diving Deeper to Rise Higher

As I write this article, there is another variant of the SARS-CoV-2 virus that is wreaking havoc on our planet. B.1.1.529 or the Omicron variant as we all know it has a much higher infectivity compared to its earlier predecessors. Another concern is the inability of several of the existing diagnostic kits to detect this variant by RT-PCR. As we know it now, one of the gene targets used in the RT-PCR based detection of this virus does not show any amplification.

This S-gene target failure (SGTF) is an indication of the presence of the omicron variant in the sample. More rarely, the N-gene target failure (NGTF) is also known to suggest the presence of omicron variant. The failure merely reflects that the specific primers for the S- or N-gene are unable to bind at the target site due to a mutation within this primer binding region.



This does not indicate the absence of this gene in its entirety from the viral genome, which is a general misconception among laymen and the non-scientific. How do we know this? Well, thanks to DNA sequencing and bioinformatic analyses which have empowered us to study the viral genome in greater depths. But let's get to the basics first!

The unprecedented times that we see ourselves in due to the CoViD-19 pandemic have made us all aware of the power of molecular methods in combatting the spread of this deadly virus. Two of the most promising methods that have come to our rescue are undeniably the ability to detect a target gene region from the whole genome of the virus by Real-time reverse transcriptase-polymerase chain reaction, or RT-PCR, and the ability to determine the order of the nucleotides, the building blocks of the genome, using DNA sequencing. While RT-PCR remains the primary diagnostic tool, DNA sequencing has rapidly picked up as the preferred tool for its usefulness in surveillance to understand the epidemiology of virus transmission and to identify the different variants of this virus that are spreading across populations. In fact, genome sequencing of the virus has revealed at least 1575 different Pango lineages/sublineages of the Wuhan Type that are in circulation today (source: www.cov-lineages.org) and all these have different mutations in different regions. For instance, the mutation in the S-gene primer binding region of the Omicron variant leading to SGTF in RT-PCR. Thanks to CoViD, it has at least made each one of us more adept with the words 'RT-PCR' and 'DNA sequencing', and what these methods can achieve for the mankind.

The power of DNA sequencing is in the technological advances that this method has seen over the years. From the original idea of modern sequencing conceived by Maxam and Gilbert (1) and Sanger and colleagues (2) in 1977 to the first high-throughput method developed by 454 Life Sciences (3) and the very recent commercial launch of the most advanced G4 Sequencing Platform (4), the technology has taken deep strides and invaded nearly every field of biology. What started as a hazardous radioactivity-based method that required specialized skills and extended working hours stretching up to two days to generate a mere 100-200 bases of sequence has today matured into a simpler, non-hazardous and a user-friendly technology. In its latest advancement, it is now possible to generate up to 6000 gigabases (Gb) of data per run in about two days with 99.9% accuracy. This unsurmountable throughput has enabled researchers to sequence multiple samples at once and has found users in nearly every field of biology. Whether it is genomic surveillance of disease pathogens, identification of cancer markers, understanding biodiversity, anthropology, pharmacology, forensics or to simply catalog the life on Earth, sequencing has created a niche for itself in every field. The possibilities that DNA sequencing offers are enormous.

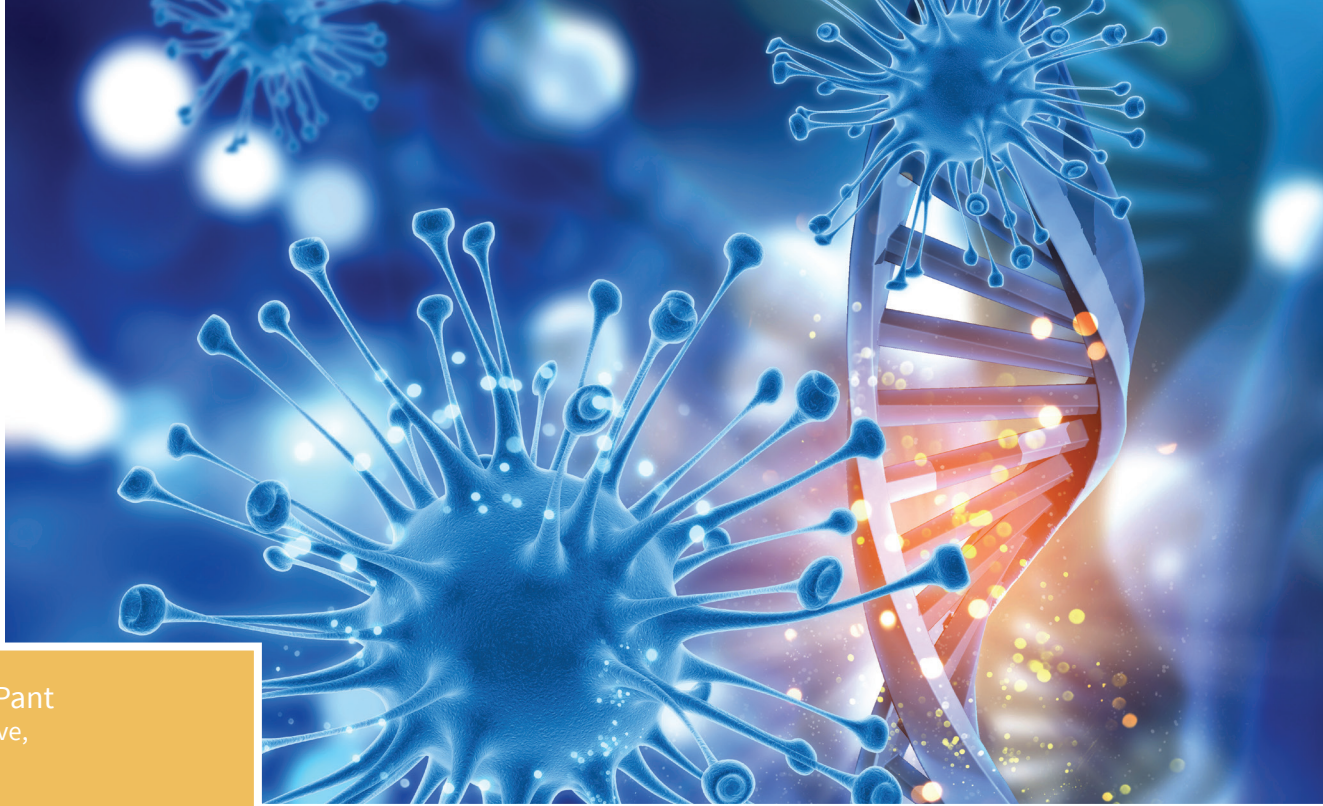
HiMedia® is on track to harvest the potential of this technology with its **Hi-Gx360® services** offering a complete portfolio of sequencing and bioinformatics solutions to serve diverse research areas. At its heart, sequencing in all its available forms was envisioned as a value addition to all branches of biological sciences and public health. It has been at the forefront of verifying and putting to rest many outstanding research questions. However, quality sequencing and bioinformatics has remained inaccessible to many scientific

communities either due to the costs it entails or due to the lack of analytical expertise. Further, with increasing emphasis on the need for robust reproducible scientific analysis, the time is right for a grass roots revolution in sequencing. Hence, after conquering the world with its high-quality microbiology and molecular biology products, HiMedia® is now ready to dive deeper and rise higher to create its impact in the scientific service sector with its Hi-Gx360® offering. Its state-of-the-art facility located at HiMedia® headquarters in Thane is equipped with multiple sequencing platforms covering both Sanger- and next-generation sequencing technologies and has an in-house power horse server capable of doing the most complex bioinformatic analysis within hours. A key feature of **Hi-Gx360®** services is that we are self-sufficient, and user data is not uploaded to the cloud servers for analyses, hence more secure.

In the same vein, **Hi-Gx360®** services will be customizable to the needs of specific projects. By leveraging the knowledge and expertise of our diverse team one can not only optimally use our sequencing services for predesigned projects but also design robust genomics experiments that are scientifically rigorous and designed for the research questions at hand. Our scalable opensource analysis pipelines and data analytics resources are designed to significantly fast track ongoing research and open interesting new avenues for all research professionals in the academic, medical and industrial fraternity likewise. **The Hi-Gx360®** services are customer-oriented and transparent with a special focus towards client empowerment by making knowledge and resources available to them to achieve their project goals, for each client is precious!

References:

1. Maxam AM, Gilbert W. 1977. A new method for sequencing DNA. Proc Natl Acad Sci USA 74, 560-564.
2. Sanger F, Nicklen S, Coulson AR. 1977. DNA sequencing with chain-terminating inhibitors. Proc Natl Acad Sci USA 74, 5463-5467.
3. Margulies M, Egholm M, Altman WE, et. al. 2005. Genome sequencing in microfabricated high-density picolitre reactors. Nature 437, 376-380.
4. <https://www.globenewswire.com/news-release/2021/12/16/2353524/0/en/Singular-Genomics-Launches-the-G4-Sequencing-Platform.html>



Mr. Rahul Pant
R&D Executive,
Cell Biology



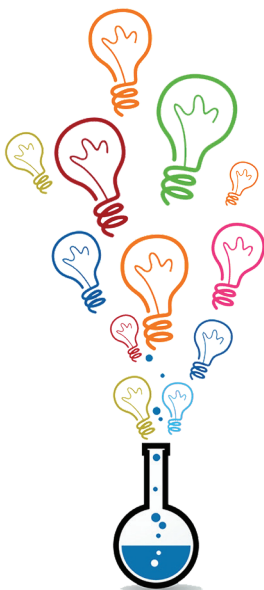
HEK293 cell line:

A effective approach to cell culture media technology in the production of vaccines and biotherapeutics.

Introduction: Human Embryonic Kidney 293 (HEK 293) cells are one of the most commonly used cell lines in biotechnology and research studies. These cells are popular due to their rapid growth and robustness.

Furthermore, because of their efficiency, HEK 293 cells generate exogenous proteins that are used in biomedical and pharmaceutical research. HEK 293 cells are also particularly useful in transfection experiments involving adenoviral-based vectors.

Origin & History: In the 1970s, Alex Van der Eb was the first to cultivate the HEK 293 cell line. Frank Graham, on the other hand, revolutionized the cultivated cell line by creating the calcium phosphate method of cell transfection. The cells came from a healthy fetus that was terminated.



Graham transferred DNA from adenovirus type 5 into human chromosome 19 of HEK cells to create an immortal cell line. Ad5 incorporation into the cells' DNA prevented apoptosis, allowing the cell line to continue producing. Frank Graham had to conduct 293 experiments before finding success, hence the designation HEK 293.

Advantages

Apart from its rapid doubling time and simplicity of culture, there are several reasons why the HEK293 cell line is such a reliable workhorse.

- **Reproducibility of results:** One significant advantage of this cell line is that the results are often reliable and reproducible.
- **Protein Production:** HEK293 cells are extremely efficient at creating huge amounts of recombinant proteins, making them ideal for commercially producing therapeutic medications that have undergone the necessary human post-translational modification.
- **Gene Expression:** HEK cells can be used to express desired genes in both transient and steady ways.
- **Transfection Amenability:** One of the numerous reasons for their popularity is that HEK293 cells are highly receptive to transfection and may be transfected utilising a range of chemical and physical techniques.

Application

- **Receptor Signalling:** HEK293 cells are often employed for heterologous production of cell membrane receptors and ion channels, and numerous researches have used this cell line to examine the signalling pathways of disease-associated G protein-coupled receptors (GPCRs).
- **Protein Production:** HEK293 cells have the ability to create vast amounts of recombinant proteins. They have been utilized extensively for this purpose since their immortalization, with various biotherapeutic proteins and vaccines generated in this cell line.
- **Cancer Research:** The tumorigenicity of HEK293 cells has led to the widespread usage of derivatives of this cell line in cancer research.
- **Viral Vaccine Production:** HEK 293 cell lines have been genetically modified to carry the adenovirus instructions that initiate viral replication. This enables for the manufacturing of a large quantity of the final vaccination product while also removing the adenoviral replication instructions from the vaccine.

HEK293 cell line and serum-free media roles in COVID-19 vaccines

The current Covid-19 pandemic has presented new hurdles for the vaccine business, as well as new vaccine development advances such as DNA/RNA-based vaccinations. The pandemic also boosted demand for well-proven cell-based vaccine manufacturing technology.

In recent years, cell culture media technology has evolved significantly, and commercial providers now offer a variety of serum- and protein-free choices. Because serum tends to bind toxins and impurities, its removal necessitates the use

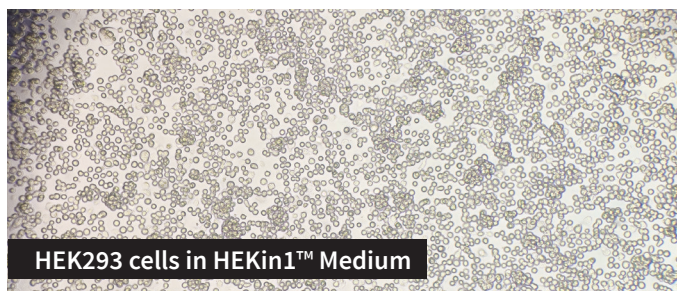
of high-quality media components and close monitoring of culture processes to get the best results.

The most recent example of usage of HEK293 platform for vaccine production is, COVISHIELD™, a COVID-19 vaccine containing recombinant SARS-CoV-2 spike (S) glycoprotein1. This vaccine has been manufactured using genetically modified HEK293 cells. Sputnik V vaccines from CanSino Biologics and Gamaleya Research Institute have also used HEK 293 cells2.

All the HEK-based vaccine manufacturing processes require a highly efficient and productive serum-free and animal component-free medium at each step starting from cell banking to cell expansion and virus production in a bioreactor.

At HiMedia, we have developed HEKin1™, a serum-free and animal component-free medium optimized for the growth and expansion of HEK293 cells under serum-free conditions.

This is a complete media, consisting of Part A and Part B, that will support the growth of HEK293 cells without the need for additional supplements. This media has been tested for its ability to support high-density HEK293 cell cultures under suspension conditions.



Key Features of HEKin1™

- ▶ Scalability for use in shake flasks & bioreactors
- ▶ Completely defined system eliminates variability
- ▶ Consistent performance improves reproducibility
- ▶ Decreased possibility of contamination by adventitious agents
- ▶ Saves time with simplified purification and downstream processing
- ▶ Supports a high cell density, long-term culture, and higher yield
- ▶ Manufactured in GMP & ISO 9001 certified facility

Covid vaccine related Ref:

1. https://www.seruminstitute.com/pdf/covishield_ChAdOx1_nCoV19_corona_virus_vaccine_insert.pdf
2. <https://sputnikvaccine.com/newsroom/pressreleases/the-gamaleya-center-statement/>

Content ref:

- <https://www.sciencedirect.com/science/article/abs/pii/S1056871905000110>
- <https://pubmed.ncbi.nlm.nih.gov/26073013/#:~:text=Mammalian%20cell%20cultures%20are%20increasingly,the%20production%20of%20viral%20vectors.>



Green Chemistry and Bioscience

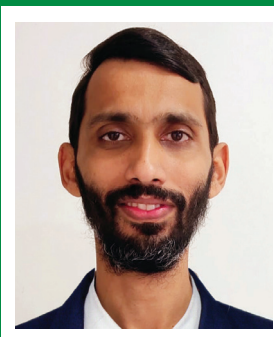
Green chemistry, as the name indicates is a technology imbedded, environmental friendly and cost effective utilization of resources that minimize or even eliminate the production of harmful bi-products in the design and manufacturing of the product. Presence of such unwanted bi-products not only lowers the yield of the desired product but may also interface with the utilization of the product. Green chemistry focuses on how to achieve sustainability through science and technology.

Currently, several green processes are applied for water purification, energy generation and fabrication of electronics, medicines, plastics, pesticides, and many other goods. It is the heart of all synthetic manufacturing processes in majority of the bioscience related products.

Ms. Pooja Y. Parab
Quality Control chemist,
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Mr. Atul R. Palve
Dy. Q. C. Manager,
Chemicals & Biochemicals



Why do we need green chemistry?

Chemistry is undeniably a very prominent part of our daily lives at personal, domestic and industrial levels. Chemical developments bring new environmental problems and harmful unexpected side effects, which result in the need for 'greener' chemical products. Green chemistry works at pollution prevention on the molecular scale. It is an extremely significant area of Bioscience too due to the importance of bioscience products in our day-to-day life and the implications it may show on our environment. The Green Chemistry program supports the invention of more environmentally friendly chemical processes during manufacture of bioscience products which reduce or even eliminate the generation of hazardous substances.

The concept of green chemistry is based on twelve principles that aim at decreasing or removing dangerous materials from the synthesis, production, & application of chemical products, and consequently the use of materials that are dangerous to human health and the environment that should be reduced or eliminated.

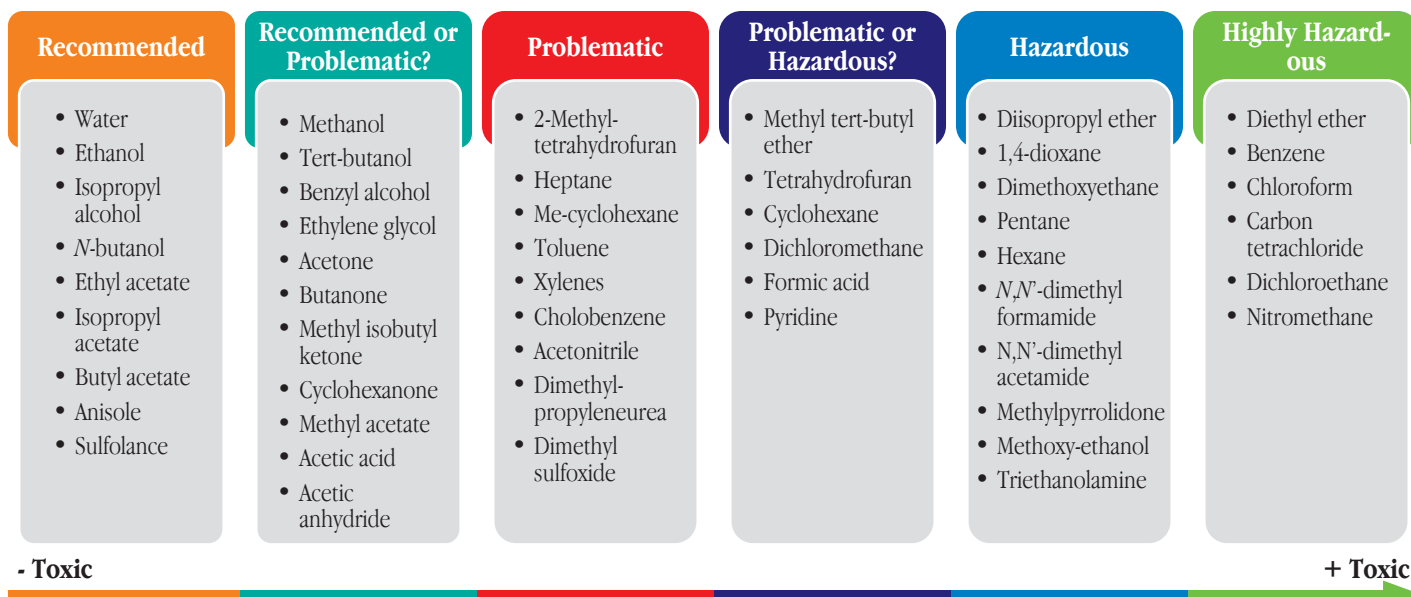
1. Prevent waste than to treat and clean up waste after it is formed.
2. All materials involved in making a product should be incorporated into the final product.
3. Chemical products should be as effective as possible for their designated purpose, but with minimum toxicity.
4. Chemical products should be designed to prevent the efficiency of desired function while reducing toxicity.
5. The use of auxiliary substances should be avoided wherever possible and innocuous when used.
6. The energy requirements of chemical processes should be minimized considering their environmental and economic impacts.

7. The renewable raw materials should be used rather than depleting feed stock.
8. The use of protecting groups in synthesizing chemicals should be avoided in so far as possible.
9. The catalytic reagents which are selective in reaction are preferred over stoichiometric reagents.
10. The product should be designed such that they break down to environment friendly substances after use so that they do not accumulate in the atmosphere & soil.
11. New analytical processes have to be developed to allow on-line monitoring and control prior to formation of hazards substances.
12. The substances and its forms used in chemical process should be chosen in such a way to minimize the potential for the chemical releases.

Thinking out of the box for better tomorrow

- Currently the bioscience & Biotechnology industries and laboratories must contemplate green chemistry through and not only, their analysis. The chosen method reagents, accessories, personnel qualification, time to evaluate the quality of a product are part of the ecologically correct thinking.
- Most of the methods like investigation of impurities and degradation products use high performance liquid chromatography wherein organic solvents such as acetonitrile and/or methanol are used. Many also opt for use of buffer solutions. However most of them never even attempted to use another organic solvent in addition to above or do not use buffer solutions which requires a certain amount of time to prepare due to its low shelf life and an extensive cleaning process of both column and





chromatographic system. Even the accessories used in method can contemplate green thinking. Devices such as HPLC/GLC columns can be reused with some skills but company find it's more convenient to throw away and wait for the new one to arrive.

- It is also important to measure the time for each process or analysis which is part of green chemistry. Rapid and cost-effective methods with personnel adequately qualified for the service, with ecologically correct reagents are currently required.
- Green chemistry addresses challenges by opening a wide and multifaceted research scope thus allowing the invention of novel reactions that can maximize the desired products and minimize the waste and byproducts, as well as the design of new synthetic schemes that are inherently, environmentally, and ecologically benign.
- Some solvents like chloroform, dichloromethane, carbon tetra chloride etc. are used as a solvent in organic synthesis which is not only costly but very harmful for human and some are even environment destructive. In green chemistry an attempt has been made to minimize or eliminate these effects by using water as a solvent.

The Benefits of Green Chemistry

Green chemistry deals with synthesis procedures according to its classic 12 principles, contributing to the sustainability of chemical processes, energy savings, lesser toxicity of reagents and final products, lesser damage to the environment and human health, decreasing the risk of global overheating, and more rational use of natural resources and agricultural wastes.

Research advances have enabled sustainable processes over the years with investments in environmentally correct analytical and policy techniques in line with world conferences since 1968. Despite these efforts, industries need to visualize the economic viability of applying green chemistry to their processes. Investments and dissemination on the importance of green chemistry and how they affect directly from the start of chemical analyses, employees and consumers health until to the environmental sustainability are extremely important for the process of future improvements.



The rule of management is to change the process rather than torment the individuals to do better.

William Edwards Deming

A Tribute



In Loving memory of **Mr. Jay More, Production In-charge**

for Molecular Biology Department at HiMedia Nashik

Factory, who left us with a permanent void in our lives on 3rd December 2020 due to an unfortunate bike accident. We have come through a year without one of the most cherished and capable team members who will be missed by all who interacted with him always. A gentleman who personified perseverance, dedication and being calm under the most stressful times, Jay will always be remembered for the calming and positive effect he had on all of us. We pray Almighty gives abundant strength to his family to cope with the huge loss. Jay is survived by his young daughter & wife. Always in our Hearts and Prayers Om Shanti

HIMEDIA

HiGenoMB
Unzipping Genes



In fond memory of
Mrs. Sujata Wakchoure, Molecular Biologist

Cloning Section - Molecular Biology Dept

We are deeply saddened to inform the passing away of Mrs. Sujata, 29 yo, on the 19th April, 2021 due to COVID related complications.

A young soul with an ever-smiling face, she was extremely caring and a people person.

The entire department misses the presence of an efficient, hardworking and loyal team member like her. She is survived by her husband and a very young son. We pray that the Almighty gives enough strength to her family to overcome this grief.

Always in our Hearts! Om Shanti!

A Loving Tribute from Molecular Biology Department (C- 40, Thane)

HIMEDIA

HiGenoMB
Unzipping Genes



Mrs. Trupti Raut
Assistant R&D Manager,
Microbiology



Changing trends in MIC Evaluation

In recent years, antibiotic resistance has been a major issue worldwide due to the development of resistant genes in a microorganism against multiple antibiotics which leads to treatment failure. Several factors led to this increase, particularly the selection of drug and misuse of drug. Therefore, a greater attention has been paid to antimicrobial activity screening and evaluating methods.

The performance of antimicrobial susceptibility testing is an essential part of clinical laboratories to confirm susceptibility or resistance of selected antimicrobial agents. Several bioassays such as disk-diffusion method and Minimum Inhibitory Concentration by broth or agar dilution are the most commonly used methods for susceptibility testing. Performance of these methods have its own challenges. Disc diffusion (Qualitative) method provides sensitive, intermediate or resistance nature of micro organisms towards selective antibiotics qualitatively.



Determination of Minimum Inhibitory Concentration (MIC) (Quantitative) is more precise method for selection of drug for the treatment of infected patients. Qualitative method has the drawback that it does not provide numerical values. Quantitative method estimates numerical values in the form MIC value which correlates with the pharmacokinetic / pharmacodynamic (PK/PD) parameters to achieve PK/PD Index.

Pharmacokinetics is the study of how an organism affects a drug, whereas pharmacodynamics (PD) is the study of how the drug affects the organism. Both together influence dosing, benefit, and adverse effects considered as a PK/PD models. PK/PD is the critical process for determination of MIC breakpoints (interpretive criteria) of an organism against antimicrobial agents. Breakpoints are used to categorize the MIC of an isolate as “Susceptible,” “Intermediate,” “Susceptible-Dose-Dependent”, “Non-Susceptible,” or “Resistant.” Clinical Laboratory Standards Institute (CLSI) and European Committee on Antimicrobial Susceptibility Testing (EUCAST) have been established standards which guides the clinician to select the appropriate treatment.

MIC plays an important role in patient treatment as well as in drug development. Traditional methods are time consuming but are cost effective and provides flexibility to the experiments. Each method has its advantages and disadvantages towards the success and failure of the experiments. To speed up these processes automated or semi-automated commercial products have been developed in the market.

Traditional Techniques:

Broth dilution and Agar dilution methods are gold standard methods for the determination of Minimum Inhibitory Concentration. Broth dilution MIC can be performed by two technique i.e. Broth Micro dilution Method and Macro Broth dilution Method. Broth Micro dilution method is performed in microliter quantity in 96 well Microtiter Plate whereas macro broth dilution method is carried out in test tube or flask. For broth the processes, series of antibiotic concentration in mcg/ml is achieved in liquid medium. Similarly, series of antibiotic concentration is prepared in agar plate. Visible growth of tested organism is observed after appropriate temperature and condition. Lowest concentration at which organisms get

inhibited is considered as Minimum Inhibitory Concentration.

Modern Techniques:

Tradition technique are cumbersome, it involves many steps like weighing of ingredients, preparation of stock solutions and growth medium, sterilization process, arrangement of glass wares etc. While conducting the experiments and carrying out many steps, simple manual error may lead to the failure of the experiment. To reduce the risk, modern techniques are evolved.

- 1. Gradient strip method
- 2. Broth Microdilution Kit

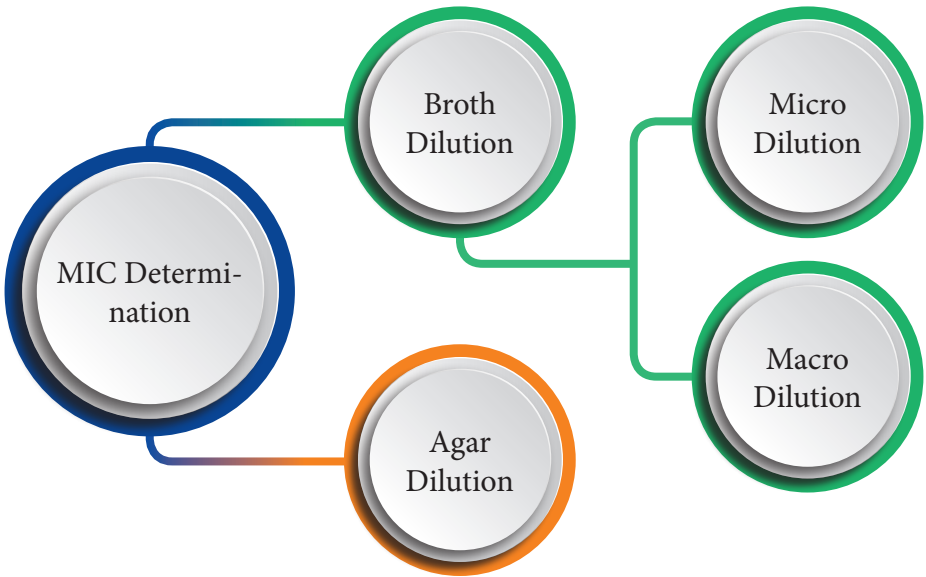
Gradient Strip Method:

The system comprises of gradient technology which is based on dilution and diffusion principle of susceptibility testing. The predefined antibiotic gradient concentrations in mcg/ml are coated on a porous paper or polymer strip. The gradient covers a continuous concentration range across 15 two-fold dilution of conventional MIC method. These strips quantifies antimicrobial susceptibility in terms of discrete MIC values. These strips are able to reproduce MIC values that obtained by Broth Micro Dilution method complies as per CLSI and EUCAST guidelines.

Broth Micro Dilution Kit:

These are the ready to use kit which determines hassel free broth micro dilution method. Gradient of antibiotics are coated into the wells of the microtiter plate. The gradient covers breakpoint scale which helps in reliable interpretation of Sensitive, intermediate and resistance detection. These kits provides minimum 3 to maximum 11 fold dilution in a single kit format without performing tedious steps and complies as per CLSI and EUCAST guidelines.

Other than these methods some automated techniques are also available in the market. But the high cost and regular software updation, is not affordable for small scale laboratories. Even though many rapid technologies are available in the market, newer technologies need to develop to tackle the upcoming resistance mechanism.
















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 INTERPHEX JAPAN	13 Jul 2022 15 Jul 2022	Interphex Japan, Japan
 fime	27 Jul 2022 29 Jul 2022	FIME, Miami Beach, Florida, USA
 International Association for Food Protection,	31 Jul 2022 3 Aug 2022	IAFP Annual Meeting, Pittsburg, Pennsylvania, USA
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