BioSpectrum
the business of Bio & Health Sciences

The unsung Indian heroes of the Medicine Makers 'Power List 2015'

11 July 2015 | Features | By Aishwarya Venkatesh

The unsung Indian heroes of the Medicine Makers 'Power List 2015'

In a bid to celebrate the achievements, discoveries and leadership capabilities of influential people in the field of medicine, *Medicine Makers*, a UK-based publication had published a 'Power List'-an index of the most 100 influential people in drug development and manufacturing. The list was developed by the publication in three stages.

In stage one, it invited readers to nominate those who they thought deserved recognition. In stage two, a jury of four noted medicine makers (who prefer to remain anonymous) selected their top 100 from the slate of nominees: the results were consolidated into a list of 100 names. In the final stage, the jury ranked the list, and the average rankings were combined to provide the final power list.

The top 5 in 'The Medicine Maker Power List' are: Anthony Fauci, director, National Institute of Allergy and Infectious Diseases, USA, Kiran Mazumdar-Shaw, chairman & managing director, Biocon, Sir Andrew Witty, chief executive officer, GlaxoSmithKline, Arthur D. Levinson, chief executive officer, Calico and Heather Bresch, chief executive officer of Mylan.

The prestigious list also includes few other fellow Indian researchers and leaders who have managed to grab a place among the Top 100 global leaders through their influential work and excellence in the field of science.

Dr Vikramaditya G Yadav, assistant professor, Department of Chemical and Biological Engineering, The University of British Columbia, Canada

Dr Vikramaditya G Yadav is one of the youngest Indian-origin achiever to be recognized by Medicine Makers for his formalization of 'biosynthonics', a novel paradigm for drug discovery and development based on metabolic and enzyme engineering. Among other innovations, he and his team are working to construct artificial human brains that help in testing of neurodegenerative drugs and research on neurodegenerative disorders.

Q. Please tell us about your work and achievements in detail.

Biosynthonics' - a novel paradigm for discovering and synthesizing potent bioactive molecules - is the focus of my research group. We also focus on formulation and assembly of drugs and their translation to certain pathological conditions. We have recently embarked on the development of a brain-on-chip device for preclinical testing of anti-neurodegeneration drugs.
Biosynthonics is a response to the current drug discovery crisis in the pharmaceutical industry. The platform comprises of four principal domains - design, synthesis, exploration, and integration. In retrosynthetic analysis, a 'synthon' is defined as a structural unit, or building block, within a molecule that is the product of a specific synthetic operation. By clustering biosynthon gene combinations, permutations and mutations into biosynthetic operons to be expressed as heterologous metabolic pathways in tractable microbial hosts, one can readily generate pharmacophores which can be used in drug discovery

Apart from this, we are working to construct artificial human brains in a variety of formats, one of which is a brain-on-chip in collaboration with colleagues from the biopharmaceutical industry and the Faculty of Pharmaceutical Science.
The device mimics the human brain a three-dimensional models of human tissue that recapitulate the spatiotemporal complexities of the tissue microenvironment as they occur within the body. This provides a highly context-specific platform to test and validate lead compounds, which improves the success rate of compounds in the clinic.

We plan to utilize this device to investigate fundamental details about neurotransmission and test lead compounds targeting two prominent neurodegenerative disorders, chronic traumatic encephalopathy (CTE) and frontotemporal degeneration (FTD) in a high-throughput manner.

Q. How can this research bring about a change in current testing methods?

The number of new drugs approved by the FDA each year has remained practically unchanged during the past decade despite a doubling in R&D expenditures over this period. In fact, candidate attrition rates and development times actually rose quite markedly during this period. It now takes over a decade to discover and develop a new drug, and statistics such as the one reported recently by Sanofi, the world's fourth-largest drug company by prescription sales, which recently put its own cost of bringing a new drug to market at $7.9 billion compared to an industry average of $5.8 billion, illustrate the magnitude of the crisis.

Through Biosynthonics we can change the current scenario in drug development by leveraging the advances in science and technology. The platform could prove to be particularly effective in tapping into the chemistry of natural products, a veritable treasure chest of therapeutic compounds.

Also brain-on-chip helps in pre-clinical testing of lead compounds targeting neurodegeneration. Although this process sounds straightforward, it is anything but. Maintenance of cortical nerve cell cultures is extremely challenging, and reliable operating procedures were only established very recently. Furthermore, cortical cell cultures do not incorporate key constituent tissues of the human brain such as the blood-brain barrier. As a consequence, diffusion of the lead compounds across the blood-brain barrier, which has long been the Achilles heel of drugs targeting brain tissue, is never actually evaluated until the molecules are tested in patients - a potentially calamitous scenario.

Regulations stipulate that lead compounds exhibiting positive activity in cortical cell cultures must then be tested in whole animal models, preferably those that bear anatomical traits that are similar to humans. The greater the degree of similarity between the target organs in the animal model and human patients, the more insightful is the testing.

Unfortunately, though, results from pre-clinical animal testing using the best neurodegeneration animal model that the pharmaceutical industry has at its disposal - that of the rodent - do not translate well to the clinic, and nearly all drug candidates targeting neurodegeneration fail when tested in real patients on account of poor safety and/or efficacy. Organs-on-chips are three-dimensional models that recapitulate the spatiotemporal complexities of the tissue microenvironment as they occur within the body. This provides a highly context-specific platform to test and validate lead compounds, which improves the success rate of compounds in the clinic.

Q. Please describe your journey so far.
I currently work as an Assistant Professor in the Department of Chemical & Biological Engineering at the University of British Columbia (UBC) in Canada. I hold a Bachelor of Applied Science degree in Chemical Engineering from the University of Waterloo. My first taste of the pharmaceutical industry came during my undergraduate tenure, as a research associate with TherapureBioPharma (formerly Hemosol, Inc.) and then as a bioprocess technologist by Sanofi Pasteur. At TherapureBioPharma, I worked extensively on bioprocess development for manufacture of the company's flagship product in receptor-mediated drug delivery. At Sanofi Pasteur, I was involved with the development of an early concept modular and

disposable vaccine production platform for decentralized manufacturing. During my final year of studies at the University of Waterloo, I was invited to conduct research on tissue engineering in the laboratories of Dr Robert Langer and Dr Ali Khademhosseini at the Harvard Medical School's Division of Health Sciences of Technology. This proved to be a transformative experience for me and spurred to pursue a doctoral degree in Chemical and Biochemical engineering at the Massachusetts Institute of Technology (MIT) under the supervision of Dr Gregory Stephanopoulos.

Q. Your views on being a part of the Medicine makers List? What challenges do you foresee now?

A. I truly appreciate my recognition and would like to share this honor with three of his professors from MIT - Dr. Robert Langer, Dr. Charles Cooney and Dr. Bernhardt Trout.

I am a strong advocate of philanthropic science and hope that soon people throughout the developing world, especially in my homeland, have access to the very best therapeutics at the lowest prices. We hope to continue in similar stead and successfully translate technological innovations to the pharmaceutical industry. After all, there is no greater feeling than to put smiles on people's faces.
manish-soman

Image not found or type unknown

Mr Manish Vinayak Soman, President and CEO, Sciformix

Mr Manish Soman was recognized by Medicine Makers for his instrumental role in helping Sciformix evolve from a niche area into a leading global scientific process organization for the biopharmaceutical, generic pharmaceutical, consumer product, medical device and contract research industries.

Q. Please tell us about your work and achievements in detail?
I have worked across organizations including Deloitte, Patni Computers, HP Enterprise Services and GENPACT over the past 20 plus years and helped to facilitate their growth into successful global businesses and practices. The experience I have gained in these roles has helped me to hone my relationship, leadership, planning, co-ordination and analytical skills. I have worked in the US, Europe, India and the Far East, with special emphasis in the life sciences, banking and financial services industries.

I joined Sciformix in 2012 as President and CEO, because it gave me an entrepreneurial opportunity to grow something in a niche area and enticed me into taking the opportunity. Founded in 2007, Sciformix is a global scientific process organization (SPO), headquartered in the US, with operations in the UK, India and the Philippines. We partner with life science companies and provide them outsourcing services to help them develop, launch and sustain medical products that improve the quality of healthcare worldwide. Our services include safety and risk management, regulatory affairs & operations, and clinical research and post-approval support.

I think my strength is that I believe in building strong executive teams and getting the most out of them, as well as inspiring their loyalty and making future leaders out of them.

At Sciformix, we have made great strides in achieving our long-term strategy of focusing on evolving and enhancing our service and technology offerings, broadening our global reach and growing and diversifying our client and revenue base. Globalization, expansion and growth are key elements in client delivery and customer support. Our hearty 30-40 percent YOY revenue and employee growth are testaments to our successes. Last year we opened an office in the UK, we also organically grew in the Philippines two years ago and we continue to make key investments in strengthening our management team.

Q. Your aims and goals?
Emerging markets, such as India, China and Latin America, are becoming increasingly important for Big Pharma, generics and biologics manufacturers alike. These markets will contribute significantly to their revenue figures and this is where the majority of expenditure in medicines will come from in the future. Our aim is to help our clients proactively prepare for changes in the global environment and to penetrate these markets faster.

The world we live in is changing rapidly, and generic and chemical drugs will be replaced by drugs with heavier molecular weight i.e. biosimilars/biologics. Around a third of the biopharmaceutical industry R&D pipeline comprises biologics. By 2016, 10 of the global top 20 bestselling drugs will be biologics and sales from biological medicines are set to account for 49 percent of the world's top 100 drugs in terms of revenue by 20181. Biosimilars/biologics bring a whole new set of challenges to drug manufacturers, especially generic manufacturers, in the area of drug safety and global regulations. This is where

Sciformix can help.

Sciformix is already doing a lot of drug safety work of biologics and more than 1/3 of the company is focused on biologics/biosimilars. We are well aligned to this kind of change and can help manufacturers who want to build biosimilars mature faster. By working collaboratively with generic manufacturers, we can help them prepare for the global challenges they will face in the future. Our rich knowledge of therapeutic areas such as oncology, autoimmune diseases, Central nervous system (CNS) and respiratory diseases etc. can help these organizations get to market faster and stay compliant with the changing regulatory times.

Some other challenges our clients and the industry as a whole are facing includes: growing regulatory pressures, the ever increasing complexity of managing product lifecycles, and patient and payer pressure to get the safety, efficacy and price of the product right. Our goal is to partner with drug manufacturers and help them achieve success and lessen the burden of these dynamic and multifaceted challenges.

Q. Please describe your journey so far?
In today's global economy, traditional business models are being pushed to the breaking point and the challenges are great. Yet with these challenges come great opportunities and where successful organizations can differentiate themselves from the competition.Organizations are facing the challenge of having to find new revenues streams and are turning to emerging markets.

Additionally, they are also facing fierce competition from generics and biosimilars and are looking to have a mixed portfolio of generic and innovative products. Other pressures include expediting product time to market, supporting global distribution channels, cost pressure and of course the ever-changing and complex regulatory environment.

To stay ahead of the game and meet these opportunities head on, collaborations and partnerships are critical to a drug manufacturer's success.This is the reason how Sciformix came into being. We understand our client's needs and these global trends.
Sciformix was founded with the clear intent to deliver niche scientific knowledge-based expertise solely to the Life Science industry.

The founders of our company understood that at the core of addressing the vast challenges and complexities that were unique to the life science industry, was the science. Because of our specialized talent and focus on lifesciences (vs BPOs and KPOs who serve multiple industries), we have unique insights on what is missing from traditional service providers and are able to provide niche and customized support to our clients. By providing high quality scientific knowledge-based expertise we are able to deliver better quality outcomes and improved efficiencies across the entire lifecycle of our client's products.

At the core of Sciformix since our inception is our excellence and expertise in science. Sciformix was founded in 2007 to serve large top-tier pharmaceutical companies and fill a growing need in scientific data analysis and reporting. The company has expanded its reach and portfolio of services to help small and mid-sized biopharmaceutical, consumer products and medical devices organizations. As market demands evolved, we expanded our footprint with the emergence of biologics. By adding value-added services and talent such as medical writing, medical affairs, scientific affairs and medical safety, we have been able to expand our portfolio and offer our clients more integrated and comprehensive solutions.

Q. Your views on being a part of the Medicine makers List? What challenges do you foresee now?
It is an honor and very humbling to be in such elite company. It gives all the people on the list, a platform to come together and take steps to boost the pharmaceutical industry, collaborate on formulating long terms solutions to industry problems, and finding smarter and sustainable ways to innovate, grow and contribute to the enhancement of healthcare products and services worldwide.

One of the biggest challenges and feats that need to be addressed collectively would be to standardize regulations globally so that there is a commonality of purpose. Another area the industry needs to make great strides is in Big Data. On one end of the spectrum, we are being inundated with so many different sources of data (such as social media) in different formats (structures and unstructured), and on the other spectrum important clinical and product data is not being shared. Most of the data is of varying quality.

Whatever happens, you can be certain that Sciformix will be ready to interpret and speed up access to all data in a form that manufacturers, payers and patients can understand, as well as provide the analysis that goes into making informed decisions

throughout the product lifecycle. The industry needs to focus and spend money on big data analysis. The returns are inevitable. If we were to achieve this, it would revolutionize the Pharma industry, its entire manufacturing and commercial processes. But most importantly, it would make healthcare more inclusive than ever before in our history, and that I believe is something worth striving towards.

mr-ajaz-hussain

Image not found or type unknown **Mr Ajaz Hussain, executive director, The National Institute for Pharmaceutical Technology and Education, USA**

Mr Ajaz Hussain has previously worked for the FDA, where he became deputy director of its Office of Pharmaceutical Studies in 2000. He also held a Senior Biomedical Research Scientist position. He is widely recognized for his leadership of several FDA initiatives such as Process Analytical Technology and Pharmaceutical Quality for the 21st Century. Mr Hussain serves as an advisor to generic and biosimilar companies in North America and in India helping organizations develop programs that enhance understanding of quality and regulatory compliance, and help them reduce risk of failure, time and cost of development and manufacturing.

Q Please tell us about your work and achievements in detail?

My professional mission has remained the same for decades - making high quality affordable. I believe in competition. It is the best approach to improve quality and affordability. I devote 50 percent of my professional time to National Institute for Pharmaceutical technology and Education (NIPTE). The mission of their work is to reduce cost, improve quality and enhance confidence. There are 14 Member Universities and the faculty at these universities come together to contribute to NIPTE's mission.

I serve as an advisor to to generic and biosimilar companies in North America and in India. In today's regulatory environment, many executives and senior managers in the life science and consumer sectors are increasingly finding themselves in unfamiliar territory, even while they must continue to take rapid and assertive actions on investment strategies and development plans. Concern over these rising levels of product complexity and regulatory uncertainty is leading many executives and investors to seek reassurance that effective business processes are being established to mitigate risk of development failure and/or risk of regulatory non-compliance.

Our core focus is efficiently developing and upholding credible scientific evidence to support product development, improve manufacturing and quality assurance, and reduce overall risk and uncertainty. Via this focus, we offer services to create sustainable competitive advantage and cost savings for companies that help to de-risk investments in complex, reduce risk of failure, as well as time and cost of development and manufacturing.

We also help businesses implement processes that effectively fulfill expected management responsibility for GxP compliance and quality and ensure rigorous risk-management and effective root-cause investigations. We help in establishing knowledge management systems for effective use of prior knowledge and continual learning.

Q. Your aims and goals?

My consulting practice is also focused on 'making high quality affordable'. Primarily I serve as an advisor to generic and biosimilar companies in North America and in India. Through these efforts, I help to reduce risk of failure in development phase and reduce uncertainty companies' face in developing and seeking approval for complex generics and biosimilars. Following my career at FDA, I had the opportunity to lead the Sandoz biosimilars program before regulatory pathways were established in EU and USA.

Reducing complexity and uncertainty for complex product development in an organizational setting where each function (e.g., analytical chemist, process engineer, formulation scientist) looks at the problem from their own viewpoint is what I enjoy doing in my consulting practice. I am often pulled into advising on cGMP compliance problems, I do not mind doing so for companies genuinely interested in improving. I am also devoting significant time to teaching 'Culture of Quality' at combines in India. This is giving me an opportunity to reconnect with India at multiple levels - this effort - I call it 'Dil Se' (from the heart).

Q. Your views on being a part of the Medicine makers List? What challenges do you foresee now?

I appreciate the nomination, selection and the recognition. In my career, I have considered such recognition as way to help my children appreciate my professional passions. Now that they have grown-up, perhaps they will still appreciate this recognition.

Moving ahead, I see the need for significant efforts to be directed at improving the pharmaceutical educational system - at the college level and in continuing professional education - in India and around the globe. NIPTE is exploring ways they can contribute. NIPTE has established a Memorandum of Understanding with Sun Pharmaceutical Ltd in India to evaluate if an NIPTE - Sun Pharma collaboration is feasible to establish a Quality -by -Design training curriculum at Sun where NIPTE faculty will participate in the training of their staff.

NIPTE will look for other such collaborative opportunities - in research and education - with other companies in the US and other regions particularly regions that export medicines to the USA. Clearly, research to develop rigorous methodologies for assessing equivalence and similarity will remain important. Science based risk-assessment, efficient quality by design methodologies for Nano-, pediatric medicines and continuous manufacturing and formulation design for continuous manufacturing are areas of high interest.