APRIL 2019 # 52

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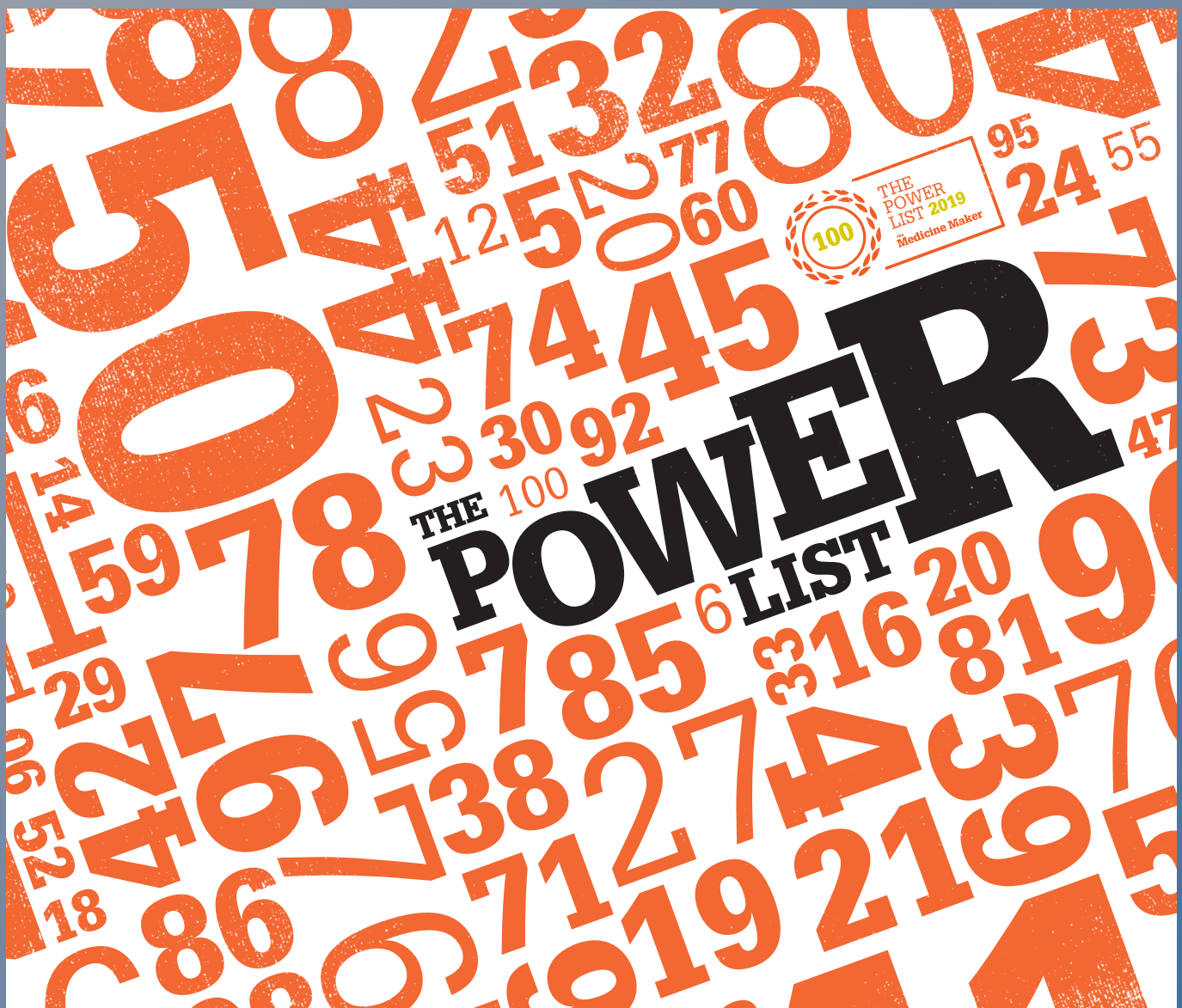

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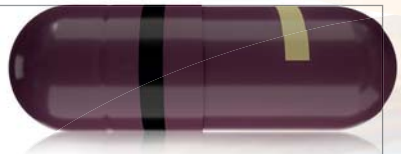
the Medicine Maker



Celebrating People and Processes

On page 18 you'll find The Medicine Maker's annual Power List, which celebrates 100 of the most inspirational professionals involved in the pharma industry. Any list will always be subjective – and if you'd like to comment on this year's list feel free to drop an email to the Editor at stephanie.sutton@texerepublishing.com.

But talent and inspiring people aren't the only essential element for developing today's breakthrough drugs – technology is also needed. In December 2019, we will celebrate some of the latest drug development and manufacturing technologies to hit the market throughout the year with our annual Innovation Awards! The nomination form for the 2019 Innovation Awards is now live.

The rules: the technology must have been released (or is planned for commercial release) during 2019; and the technology must be expected to have a significant impact on drug development or manufacture. The innovation can be a piece of equipment, IT software, formulation technology, drug delivery method or any other innovation that you think will fit the bill.

We can't wait to see all of the innovations you nominate!

http://tmm.txp.to/innovations19-noms

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Distribution:
The Medicine Maker (ISSN 2055-8201), is published monthly by Texere Publishing Limited, Booths Park 1, Chelford Road, Knutsford, Cheshire, WA16 8GS, UK.
Single copy sales £15 (plus postage, cost available on request info@themedicinemaker.com)
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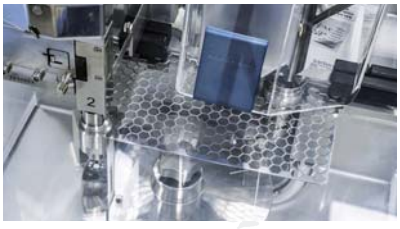

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No Hero Left Unsung

There are few things more inspirational than someone making a positive difference without the need for recognition – but you have to find them first.

When I visited Dublin for the International Society for Pharmaceutical Engineering's (ISPE) European conference, I was pleased to find a copy of W.B Yeats' collected poems sat on the bedside table in my hotel room. I've read more than one article pointing out the relevance of a famous line in The Second Coming to current times: "Things fall apart; the center cannot hold." But I think that's taking things a bit too far – after all, Yeats wrote the poem in the wake of the First World War, the Russian revolution and political upheaval in his native Ireland. Instead, I'd like to reflect on another line in the poem, "The best lack all conviction, while the worst are full of passionate intensity."

To me, Yeats' line is about how turmoil energizes and empowers the worst of us, while leaving others unsure and afraid, but it also works more generally. During my time at The Medicine Maker, I've had the pleasure of speaking to many leading scientists, thinkers, and business people passionately working to make the world a better place. Though not lacking in conviction, these people are often remarkably humble, and can be reluctant to shout about themselves.

Cornell Stamoran expresses a similar sentiment beautifully on page 25, "I'm frequently inspired by seeing the dedication of 'unsung' heroes – people who persevere and perform in important but less visible jobs every single day, without drama or the need to be recognized."

We understand that such people don't need recognition, but it's to our industry's detriment if we fail to do so – whether they like it or not! The pharmaceutical industry does deserve its bad press at times, but is the coverage fair overall? It surely won't be unless we showcase and celebrate the best our industry has to offer. And if people aren't given the recognition they deserve, how will others be inspired, as Cornell has been? These questions get to the heart of why we're proud to bring you The Medicine Maker Power List 2019 (page 18).

Clearly, there are many inspirational and talented women and men who will not appear in this years' top 100 – the limitation of a finite list. And so, I urge you to nominate your brilliant, yet underappreciated, colleagues for next year's list, by emailing me directly: james.strachan@texerepublishing.com.

James Strachan
Deputy Editor

Upfront

Reporting on research, personalities, policies and partnerships that are shaping pharmaceutical development and manufacture.

We welcome information on any developments in the industry that have really caught your eye, in a good or bad way. Email: stephanie.sutton@texerepublishing.com

Battery Powered Inspiration

A battery-like system could help enhance the manufacture of drugs

Electric cars are feats of engineering and technology that ultimately provide cheaper and cleaner transport options. And their batteries have recently become a source of inspiration for scientists at Scripp Research, who have developed a system to help with small molecule drug manufacturing (1).

The team, led by Phil Baran, a professor at Scripps Research and a member of The Medicine Maker 2019 Power List, developed the system in response to a challenge set by Pfizer to synthesize a compound at the commercial scale using a Birch reduction. The reaction has been a staple for organic chemists since the 1940s; reactive metals, like lithium, are dissolved in liquid ammonia to manipulate molecules with ring-shaped structures. "Although the Birch reaction is commonly used, the use of lithium and ammonia make it highly unsafe and malodorous," explains Baran. Birch reactions on the kilogram-scale are often avoided by chemists due to the risks that they present. Ammonia is highly corrosive and irritating to the eyes and the skin, while lithium is highly flammable and even explosive when exposed to air or water.

Though large scale Birch reactions are few and far between, the Scripps team were spurred on by a story of a successful attempt. "Our motivation to accomplish our goal peaked when we discovered Pfizer's kilogram-scale synthesis of the anti-Parkinson's F1 drug candidate sumanirole, which employed a Birch reduction. What they had achieved was a rare and remarkable achievement in chemical manufacturing! Despite the risks, we weren't prepared to shy away from the challenge," adds Byron Peters, postdoctoral associate in the Baran Lab. Pfizer used customized equipment to administer lithium metal and enough ammonia to fill three Boeing 747 airliners in the gas phase. 2300 liters of flammable hydrogen gas was liberated on quenching the reaction.

Baran's team, however, have developed a method that avoids the dangers commonly associated with the process. During their early experimentation, they noticed the build up of solids on the electrodes used in their reactions. When they consulted their collaborators, Shelley Minteer, a professor at the University of Utah, and Matt Neurock, Shell Professor of Chemical Engineering and Materials Science at the University of Minnesota, they realized that they were observing the formation of solid electrolyte interfaces (SEIs). SEIs protect the lithium within electrodes

from overcharging or being consumed by surrounding media and are used in batteries, including those used for electric cars, smartphones and laptops.

Using their newfound understanding of SEIs to their advantage, the team began to investigate a range of additives designed to manipulate the SEI layer's thickness and protect the integrity of the electrochemical cell. "With a more intuitive sense of how to improve the reaction, we identified two cheap non-toxic reagents which enabled us to carry out the Birch reaction at room temperature," explains Solomon Reisberg, Graduate Research Fellow and co-author of the paper detailing the group's research. Most excitingly for the team was the fact that they were able to scale-up the reaction to a 100-gram scale for less than $250 with the help of Asymchem, a CDMO based in China.

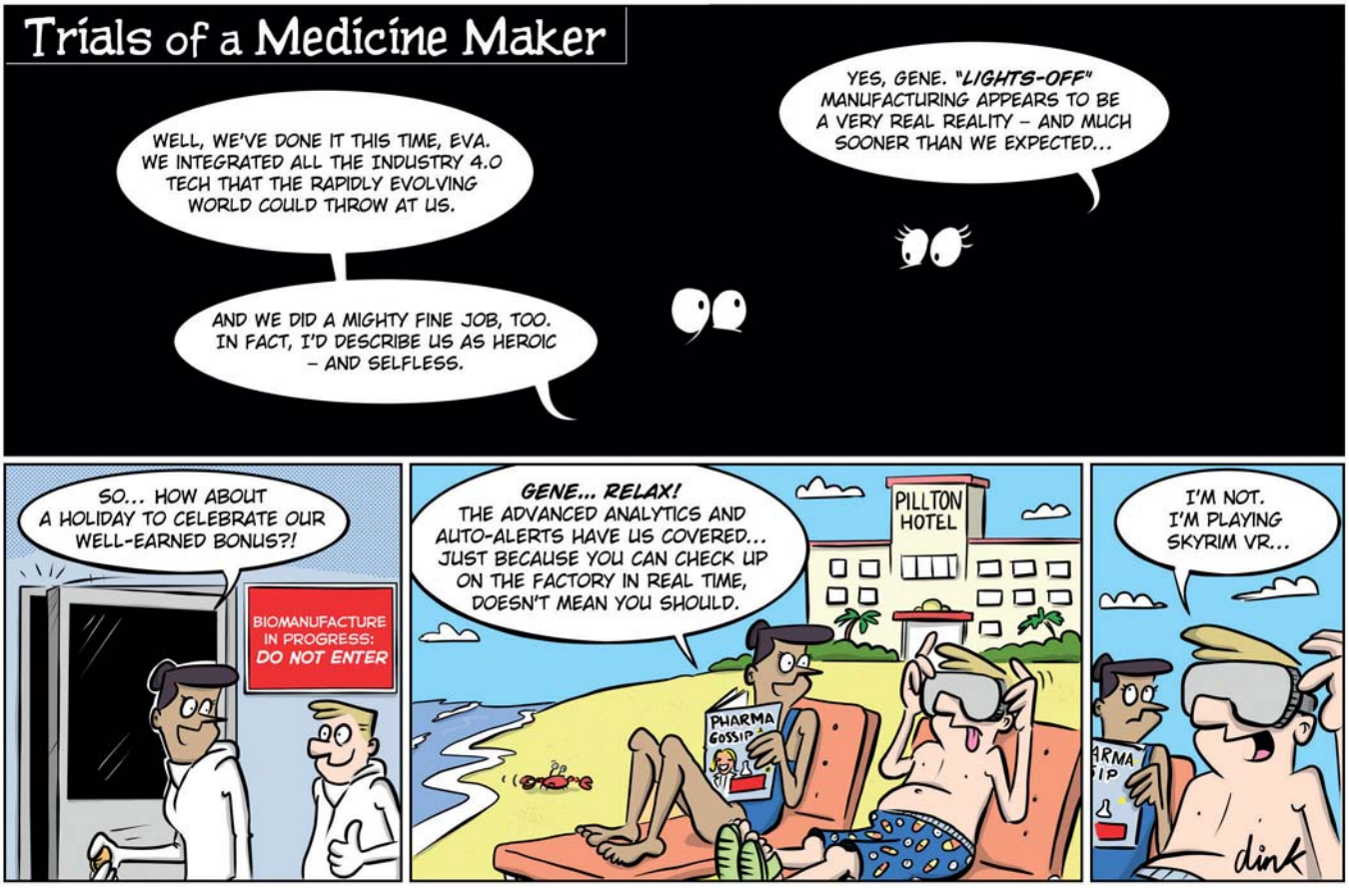
The team is looking forward to using their electrochemical discovery in other avenues of synthesis and as a draw to entice more chemists to use electrochemistry as a synthetic tool. However, they are still firmly focused on developing scalable methodologies.

"Reaction scalability was our goal from the outset. We're glad that we were able to achieve it in a safe, cost-efficient way," Kevin Rodriguez, NIH Diversity Research Fellow at the Baran Lab says. "This adventure really shows off the power of collaboration between industry and academia, especially in identifying and solving real problems that require a realm of interdisciplinary knowledge that spans beyond one's own field."

Reference

1. *P Baran, "Scalable and safe synthetic organic electroreduction inspired by Li–ion battery chemistry", Science, 363, 838–845. (2019) PMID: 30792297*

For more adventures featuring Gene and Eva check out our website themedicinemaker.com/additional-data/cartoons
If you have any ideas you'd like to see in future comic strips about bioprocessing then get in touch with us at info@themedicinemaker.com or look up #TrialsOfAMedicineMaker on Twitter.



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New Avenues

Offering scientists the opportunity to screen hundreds of millions of never-before-made small molecules is ZINC, a virtual pharmacological library

Docking is the most pragmatic approach to discover new small molecules to modulate protein function. The process enables scientists to model interactions between small molecules and proteins at the atomic level and make predictions about the preferred orientation of molecules. Researchers at the University of California, San Francisco have used the docking technique for over two decades to discover new drug-like molecules. The work of the researchers has resulted in the creation of ZINC, an enormous virtual pharmacology database, which will soon contain over a billion molecules. Could some of these be the blockbusters of the future? John Irwin a professor of pharmaceutical chemistry at UC San Francisco discusses the development of what they claim is the world's largest pharmacology platform.

What inspired the development of the platform?

In 2016, my colleagues and I learned about Enamine, a Kiev-based company that produces novel building blocks (including chemical reagents, scaffolds and intermediates) and screening libraries. By combining the various building blocks using over one hundred standard chemical reaction schemes, the company had a huge breakthrough in their ability to deliver hundreds of millions of never-before-made compounds on demand at the cost of around $100 per molecule. We were intrigued by their work and partnered with them with the hope of creating a new type of screening library.

With the support of the National Institutes of Health (NIH), we actively began to add the compounds produced by Enamine to our open-access platform, ZINC, and within the space of a few months our library had increased ten-fold in size and within the space of a year, 100-fold! ZINC now houses 750 million different compounds within its library. The hits generated from the platform can be downloaded in both 2D and 3D formats ready for docking.

How does ZINC compare with other screening platforms?

ZINC is 100 times larger than the average high throughput screening library used in pharma. And although, in principle, DNA encoded libraries (DELs) are often reported to be of a similar size, we believe our library is much more chemically diverse because ours supports over 10 times as many bond-forming reactions to build it, and it is more tolerant of diverse chemical functionality. Many medicinal chemistry programs lead to candidates that resemble the initial hit they began with. Our approach should open up entire new areas of chemical space for medicinal chemists to explore.

Has the platform identified any potential drugs through its virtual screening process?

Drug discovery is a long and arduous process, but we're pleased to say that PZM21, an opioid analgesic, is currently in preclinical development by Epiodyne (a biotech company which produces small molecule drugs). PZM21 was based on a discovery using our platform.

What's next for ZINC?

Constraints such as receptor flexibility, scoring function and ligand chemistry that once held researchers back are now gone. The platform offers them the opportunity to really make a difference within the drug development space and its rapid growth means that we are on target to have one billion commercially available 3D molecules in biologically relevant forms in ZINC by the summer of 2020. It's a huge achievement and I can't wait to see how it will contribute to improving patient lives.

Reference

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(Un) Treatable

Could an esketamine nasal spray improve the lives of people with treatment-resistant depression?

Once a club drug of a bygone era, ketamine has found a new lease of life as an FDA-approved therapy for treatment-resistant depression (TRD). According to the WHO, depression is the leading cause of disability worldwide (1) with TRD affecting 50 percent of all patients and carrying an increased risk of suicide (2).

In September of 2018, Janssen announced its New Drug Application (NDA) to the FDA for the approval of a novel esketamine-based nasal spray for the treatment of TRD - and in February the drug was recommended for approval by the FDA's Psychopharmacologic Drug Advisory Committee and Drug Safety and Risk Management Advisory Committee (3).

The drug will be used alongside conventional oral antidepressants.

"We decided to pursue development of an enantiomer - or one side of the ketamine molecule - because it could be formulated as a nasal spray, allowing appropriate patients in need to have access to it," a spokesperson from Janssen explained.

Though the mechanism of action of ketamine is not completely understood, it is thought that the drug acts upon the glutamate system allowing neurons to reconnect, thus improving synaptic plasticity (the efficiency of information transfer through synapses – the junctions between neurons). Though there were delays in the approval process due to the US government shutdown, Janssen has already filed for approval in the EU and intends to do the same in other international markets.

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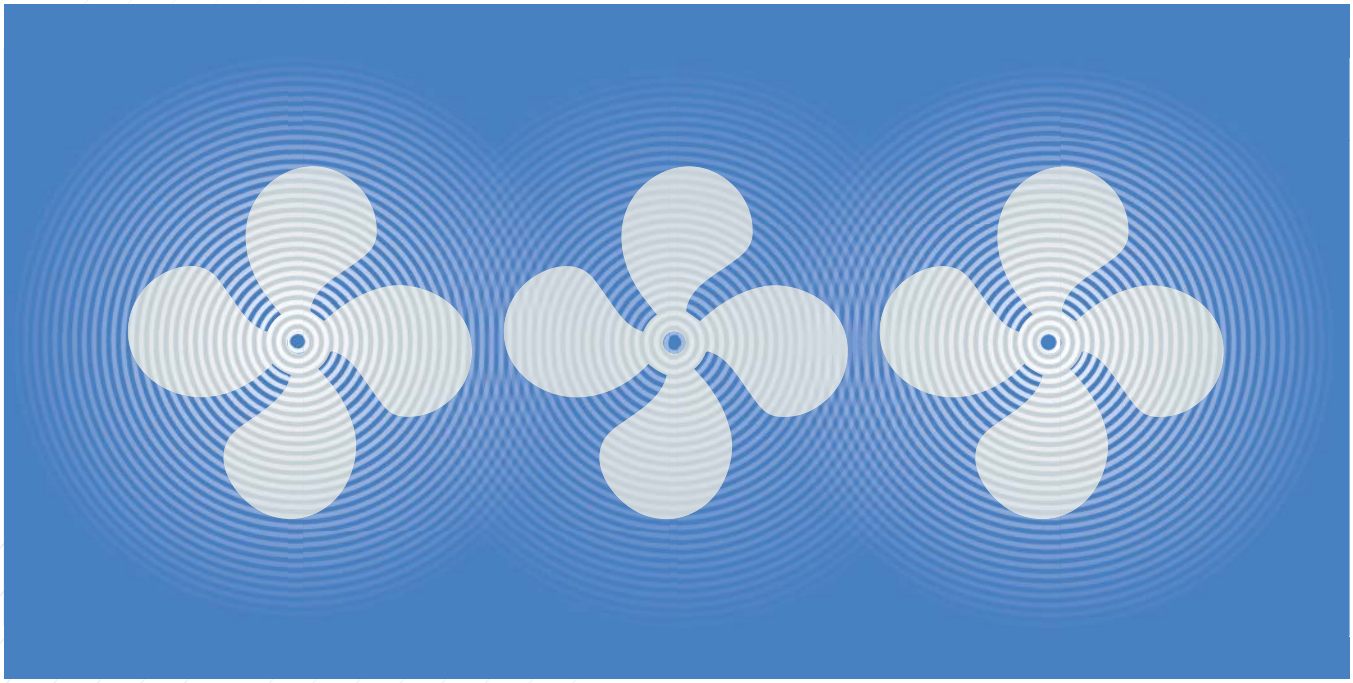
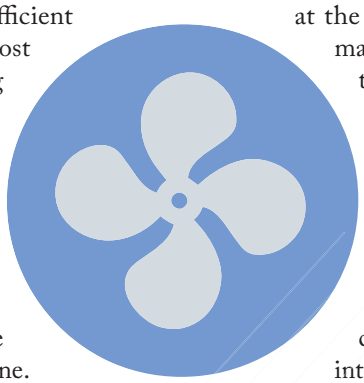


Ready, Steady, Propel!

Can micromotors give oral vaccine technology the boost it needs?

Although some oral vaccines can stimulate immune cells in the mucus layer of the intestine to produce IgA (a class of antibody), insufficient potency has prevented most of them from conferring ample protection against pathogens. Researchers at the University of San Diego, however, have developed oral vaccines with a twist: they are powered by micromotors to target the mucus layer of the intestine.



"We hypothesized that by using micromotor technology to add active propulsion to oral vaccines, we could facilitate their enhanced processing by the immune system. This would, in turn, generate a much stronger immune response (in the form of higher antibody levels) compared with formulations that lack propulsion," explains Ronnie Fang, an Assistant Project Scientist at UC San Diego.

The motor vaccine formulation, developed by the La Jolla based team, consists of several components, but at the heart of the drug is a magnesium core coated in titanium dioxide used to propel the vaccine.

"The titanium coating on the core is placed asymmetrically allowing one side of the magnesium core to be exposed to interact with the biological fluids that power the motors," explains Fang. "The motor core is then coated with a layer of red blood cell membrane to help cue the immune system and allow it to illicit appropriate responses."

To allow the motor cores to adhere to the intestinal wall lining and protect them the harsh environment of the stomach, the researchers added additional chitosan and enteric polymer layers to coat their molecules. The team were able to successfully feed their formulation to mice and found that the propulsion mechanism they had devised enabled better retention of the vaccine material on the intestine wall and greater amounts of antibody when compared with static microparticles. They believe that the concept of motor-based vaccines should be applicable to any type of infectious disease, once its safety in humans has been tested.

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In My View

In this opinion section, experts from across the world share a single strongly held view or key idea.

Submissions are welcome. Articles should be short, focused, personal and passionate, and may deal with any aspect of pharmaceutical development or manufacture. They can be up to 600 words in length and written in the first person.

Contact the editor at: stephanie.sutton @texerepublishing.com

Don't Forget About the Patient

Pharma manufacturers are not embracing patient-centric design when it comes to formulation. We need to go beyond tablets and capsules.

By Thomas Hein, Director Sales & Business Development at Hermes Pharma, Germany.

Designing products that cater to the specific needs of consumers/patients seems logical for any competitive market. In pharma, however, many companies are still not designing truly patient-centric medicines. Tablets and capsules have been the go-to dosage form for decades, but for a significant number of patients, tablets and capsules can present problems. A survey found that, of approximately 2000 people surveyed in the US and Germany, over half reported difficulties swallowing tablets and capsules, with many finding that these dosage forms were too large, became stuck in the throat, or had an unpleasant taste or odor (1). As a result, some of those questioned reported not taking their medicine in the intended way, such as by crushing conventional tablets or dissolving them in water – or not taking them at all.

These issues are particularly apparent in older patients. As explained in the February cover feature of The Medicine Maker (2), elderly patients are more susceptible to issues with swallowing. The natural aging process can cause a weakening of the muscles of the oesophagus and reduce saliva production, which makes the intuitive mechanism of swallowing much more complex. And swallowability is not the only issue to consider; a declining loss of force and dexterity can make it challenging to even open packaging. In my view, however, difficulties swallowing tablets transcend all age groups.

The idea of putting the patient at the centre of product design isn't new, and yet for many pharma companies, it is a paradigm shift from what's gone before. For example, many pain relief and cough and cold medicines available on the market today contain APIs that were developed decades ago, when usability was a minor concern for companies. Exacerbating the problem, however, is the fact that companies launching generic successors of these products often default to the same dosage forms. Many simply do not consider alternative user-friendly dosage forms that would better meet the needs of patients and consumers, and rejuvenate aging products.

Tablets and capsules are often considered the best option from a regulatory standpoint, and are also cheap and easy to formulate. There are relatively few manufacturers with the specialist expertise and technologies required to make well-designed alternative dosage forms cost-effectively. Regulatory authorities rightly require new medicines to be fully characterized and well-understood before they can be approved, but the stringent regulation has led pharma companies to adopt a cautious approach to innovation. User-friendly dosage forms, such as effervescent and chewable tablets, lozenges and orally disintegrating granules, are becoming more well known with established manufacturing methods but their use is still not the "norm". With many companies looking to bring their medicine to market as quickly as possible, tablets and capsules are often perceived as the quickest and easiest solution, despite the fact that they create challenges for

large numbers of patients and consumers.

User-friendly dosage forms present many advantages. Orally disintegrating granules (ODGs) and effervescent tablets can be combined in a single dose to overcome the issues associated with polypharmacy, for example, and coating technologies can be used to develop extended release formulations that deliver APIs over a sustained period, reducing the burden on patients who would otherwise need to take several individual doses.

Patient-centricity is particularly important for over-the-counter medicines, where patients will, undoubtedly, look for products that best match their individual needs and lifestyles. In our study, we found that around 9 in 10 people had used effervescent tablets and lozenges. In some countries, novel dosage forms are more widely accepted; in Germany, for instance, ODGs are much more widely-used than in the US and UK, while in many Scandinavian countries, the most popular dosage form for painkillers is effervescent tablets. When deciding on the best formulation route, it's very important to understand subtle market differences, but always remember that modern patients and consumers increasingly expect convenience in all areas of their life. If medicines can't be transported or fitted easily into routines then patients will look for alternatives, if available.

Of course, there are also differences when developing medicines for different age groups. Going back to elderly patients, although user-friendly alternatives may address their needs to a greater degree than traditional tablets and capsules, there can be other challenges. Orally disintegrating tablets, for example, stay in the mouth for a long duration so taste is very important, as well as mouth feel and even smell. But it takes significant expertise and experience to ensure that compatible flavoring excipients are chosen that work in harmony with the API. Appearance is also important for some alternative oral dosage forms. If you are developing an effervescent tablet that dissolves in water, for example, you must choose excipients that will dissolve fully in water leaving no residues or creating foam, and it's important to ensure the solution looks good in the glass. Developing patient-centric products that appeal to consumers isn't just essential for over-the counter medicines, it can also help patients to better comply with prescription medicine regimes by making them feel good about their medicine.

While the pharma industry may often claim to be "patient-centric", many companies are thinking in terms of molecules or brands, rather than the patients who need to take the medicines. The one-size-fits-all approach still dominates, and the needs of specific patient groups remain unmet. This is largely because the industry takes its responsibility for safeguarding health very seriously. But companies are recognizing that, with the right expertise and technologies, these hurdles can be overcome, and the benefits that come with a more patient-centric approach to product design are well worth it.

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Speak Up!

The evolving Brexit landscape provides ample opportunities for companies to position themselves as leaders and influencers. So long as they are willing to communicate.

By Neil Hunter, Life Science and Corporate Communications PR Director at Image Box PR, UK.

The biopharmaceutical industry, like many others, has felt the uncertainty surrounding the Brexit negotiations – and it's quite remarkable that, at the time of writing, we still don't know what the outcome will be. Brexit, especially a "harder" Brexit, certainly brings risk. But with an evolving landscape comes new opportunities to shape that landscape to your benefit and to the benefit of the industry, provided you're willing to communicate.

During periods of uncertainty, people look to one another for answers, for the right questions, and for leadership. Some companies will be reluctant to speak on controversial topics – especially political ones like Brexit. But you only have to look at the reception to some of the Brexit articles published in The Medicine Maker – which frequently appear in most-read lists online – and elsewhere to appreciate the opportunities available.

For example, in 2016, a group of US senators proposed a new piece of legislation on how cell and gene therapies were developed and approved. We had a client that put across their thoughts on the legislation in a press release – what its implications might be, how they felt it could be improved. And within five hours, we had the senator's office ringing us up trying to broker a meeting to work out how the legislation could be amended to suit the market better. That's the moment you realize your influence extends further than even you thought!

The key to effective communication on controversial topics is to think strategically about what value you can add to the discussion. It can be useful to benchmark what's been said before – you may well be putting forward an argument that contradicts what the market has previously put forward. This isn't a problem, but if you're planning on speaking to journalists then you'll need to think carefully about how to justify what you're saying without being insulting.

I've seen numerous examples of companies making a success of talking about controversial political topics. Another example was just after President Trump proposed a 20 percent drop in the US healthcare budget, and a number of biopharma companies made strong cases for why such a move would indirectly impact their business. Even if they weren't able to change government policy, they were able to gain some influence and profile in the market, while their competitors who declined to comment missed out.

As long as you've done your homework and what you're saying is factually correct, the risks of talking about a controversial topic like Brexit are low. In fact, the opportunity cost of not putting your position across in press releases and interviews can be quite significant. Effective communication means gaining influence and visibility in the market. That in turn can result in new customers, potential partnerships and investment – and can even impact the evolution of the landscape itself. If you're not positioning yourself as a thought leader, gaining visibility, and shaping the discussion in this way, you can be sure that your competitors will be doing so.

At the time of writing, we don't know what the outcome of the Brexit negotiations will be. In the months following April, the Article 50 negotiations could still be ongoing; the UK could in a transitional period having ratified the Withdrawal Agreement, negotiating the future relationship; or outside the EU entirely after leaving without a deal. This means there will be ample opportunities for companies to step up and make the case for what they want out of the ongoing Brexit negotiations.

Of course, the industry has largely been united in it's support of a close relationship between the UK and EU. And with the negotiators so far being unable to guarantee such an outcome, some may be feeling apathetic about the whole thing. But just remember, the benefits of communication extend far beyond the ability to influence the outcome. So don't be afraid to speak up.

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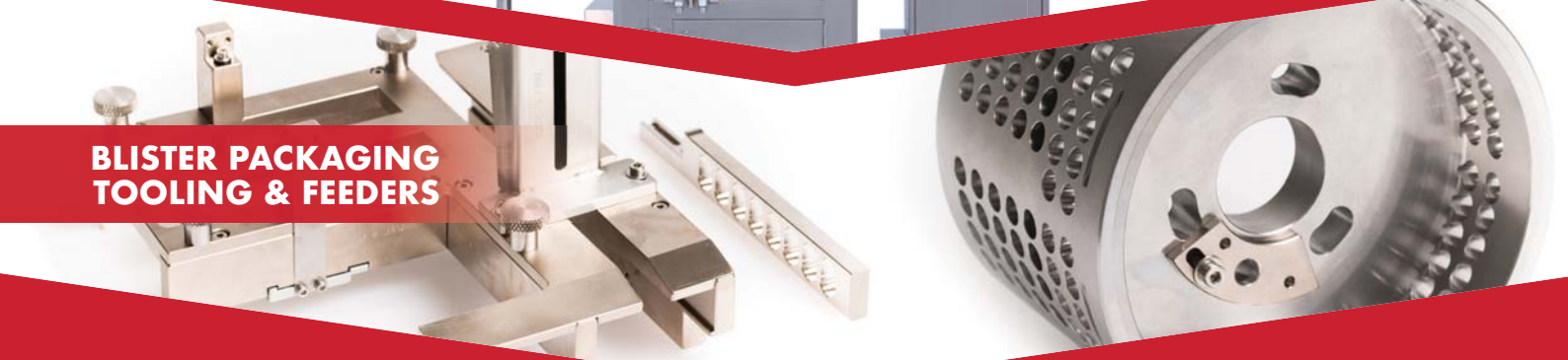

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THE 100 POWER LIST

Breakthroughs at the bench, novel technologies and groundbreaking policies and regulation have helped the pharma industry grow from strength to strength. After months of collating reader nominations and judging overseen by a panel of industry experts, we proudly present The Medicine Maker 2019 Power List, featuring 100 of the industry's pioneers across four categories: Industry Influencers, Business Captains, Masters of the Bench, and Champions of Change.

INDUSTRY INFLUENCERS

MADHAVAN (MADHU) BALACHANDRAN

BUSINESS OWNER, MJB CONSULTANTS

Since retiring from his position as Executive Vice President at Amgen in 2016, Mahdu hasn't slowed down. Alongside running his own business, mjb Consultants, he currently serves as a board member of Catalent, an independent director for the Stevanato Group, as well as a non-executive director of uniQure N.V.

JIM AGALLOCO

PRESIDENT, AGALLOCO & ASSOCIATES

Jim has over thirty years of management experience in pharmaceutical manufacturing and engineering. As President at Agalloco & Associates, he provides a wide range of technical services to the pharmaceutical and biotechnology industries in areas such as validation, serialization and facility design. Over the last five years staying active, physically, socially and mentally has become a key focus in Jim's life. "The time we are given is not infinite, so we have to make the most of it!"

HAL BASEMAN

CHIEF OPERATING OFFICER, VALSOURCE

Harold (Hal) has over 39 years of experience in pharmaceutical operations, validation, and regulatory compliance. He has been very active in the Parenteral Drug Association, including a stint as Chair. "I try to make a difference, make time to give back to the industry, and do things to help improve how industry manufactures quality drug products so that those products are safer, more affordable and available to patients," he says.

JOHN E. BOURNAS

PRESIDENT AND CHIEF EXECUTIVE OFFICER, INTERNATIONAL SOCIETY FOR PHARMACEUTICAL ENGINEERING (ISPE)

John says he wishes he'd known about the power of collaboration – sharing knowledge and doing so respectfully across cultures and geographies – when starting out. "I truly believe that we don't impart or teach these concepts sufficiently. I realize that these are softer skills than the technical and operational initiatives that we are involved in as an organization, but my sense is that we should be aware of these early on in our careers. Afterall, international cooperation among professionals, academics and companies is increasing as we confront common challenges in the global supply chain," he says.

JIM BREEN

VICE PRESIDENT, LEAD BIOLOGICS EXPANSION, JANSSEN PHARMACEUTICALS

"The pace of change in the world today is extremely fast and will only accelerate as we see the impact of technological and digital innovation. Each of us individually can make an impact each day if we are focused and want to make a difference. We all have the ability to improve the lives of patients via collaboration on the local and global level, challenging why we do things to streamline processes, and applying science to accelerate delivery of new therapies to patients. Our industry needs to collaborate more to solve unmet patient needs through faster execution and delivery to the patient. Use of industry forums to help accelerate these innovations will provide our patients with the medicines they need quicker."

JON COFFMAN

GLOBAL HEAD INNOVATION AND TECHNOLOGY, BOEHRINGER INGELHEIM

As Global Head of Innovation and Technology, Jon's expertise lies in CMC development and continuous bioprocessing. He has served as the co-chair of the Recovery of Biological Products Conference for over 16 years.

GARY CUNNINGTON

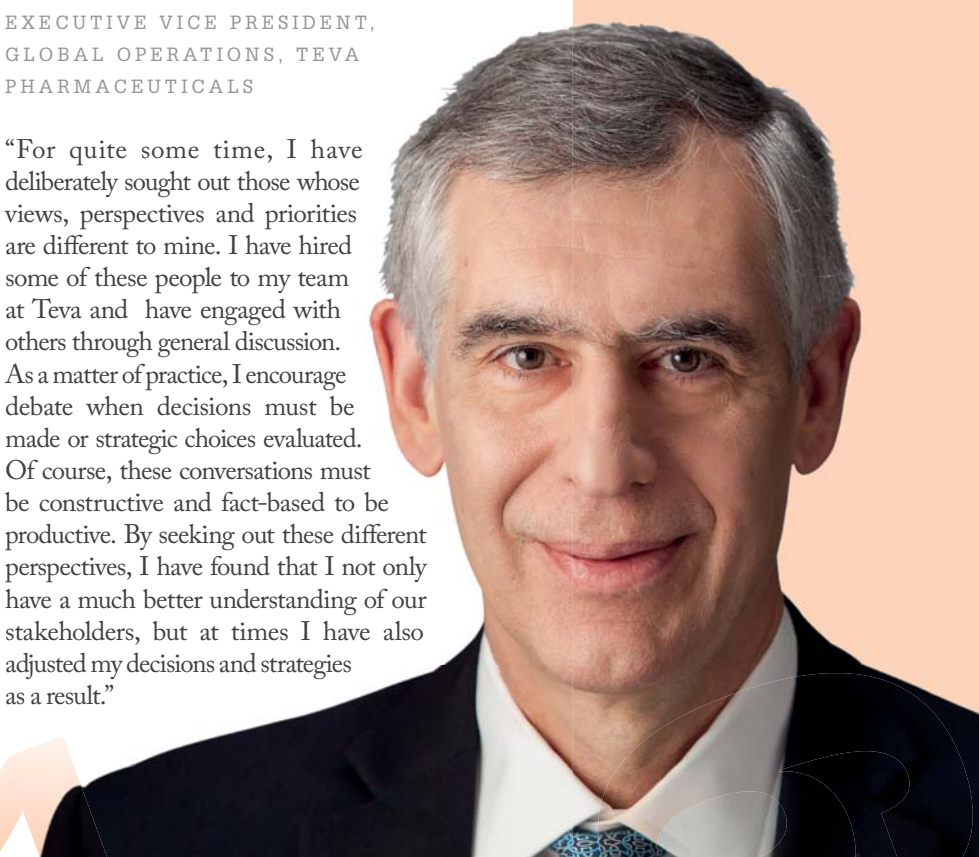
GLOBAL HEAD OF BUSINESS CONSULTANCY (CTSU), BOEHRINGER INGELHEIM

Gary regularly speaks at conferences about safeguarding patient data during clinical trial supply. Nominators praised Gary for his inspirational leadership and coaching workshops. "It's not just thinking outside of the industry confines, but changing the entire mind-set related to patient care. Inspiration is the key to empower individuals to create a change of such magnitude," he says.

CARLO DE NOTARISTEFANI

EXECUTIVE VICE PRESIDENT, GLOBAL OPERATIONS, TEVA PHARMACEUTICALS

"For quite some time, I have deliberately sought out those whose views, perspectives and priorities are different to mine. I have hired some of these people to my team at Teva and have engaged with others through general discussion. As a matter of practice, I encourage debate when decisions must be made or strategic choices evaluated. Of course, these conversations must be constructive and fact-based to be productive. By seeking out these different perspectives, I have found that I not only have a much better understanding of our stakeholders, but at times I have also adjusted my decisions and strategies as a result."



DOUG HAUSNER

ASSOCIATE DIRECTOR, C-SOPS/ DEPARTMENT OF CHEMICAL AND BIOCHEMICAL ENGINEERING, RUTGERS UNIVERSITY

Doug's work at C-SOPS has a strong emphasis on continuous manufacturing and FDA initiatives, supporting quality by design. Doug believes that "boundless energy and determination" are important when trying to gain new technical and soft skills.

TONY HITCHCOCK

TECHNICAL DIRECTOR, COBRA BIOLOGICS

Tony has over 30 years of experience in the large-scale manufacture of biopharmaceuticals. As a founding staff member of Cobra, he has been responsible for the development of much of Cobra's manufacturing technologies in the field of DNA and virus production. "A number of people have inspired me, both within the companies I have worked for and outside. A key person was David Thatcher who I worked with for over 19 years and had great scientific insight into the area of bioprocessing. I have also been fortunate to work with a wide range of customers, developing highly innovative and novel products. A key academic who has inspired me is Professor Alvin Nienow, who I have worked with for over 20 years and at 82 is still teaching and inspiring the next generation of scientists in the field."

MAIK JORNITZ

CHIEF EXECUTIVE OFFICER, G-CON MANUFACTURING

"Working for patients and hopefully making a difference to improve treatments and access to treatments is what drives me day to day. I am very passionate about the patient since this is the person we all work for – no matter what position or function you are in. To improve the industry, I think we need to be able to make technology changes much faster, especially when these changes improve the safety, quality and efficiency of manufacturing processes."

RICHARD JOHNSON

PRESIDENT AND CHIEF EXECUTIVE OFFICER, PARENTERAL DRUG ASSOCIATION

"Day-to-day, I never forget that the ultimate users of pharmaceutical products are people, including our families, friends and ourselves. Many of the biggest impacts on modern life have come through better prevention and treatment of diseases. Life expectancy and quality of life have dramatically changed in my lifetime, and any contribution that I can make is an intrinsic good! But I would like to see more focus on improving the manufacturing of pharma products. The predominant business model is to focus on new therapies, but without a corresponding focus on improving the manufacturing of these products, many patients will not receive the quality of pharma products they need. Exciting new therapies are coming into the market: cell and gene therapies, and integrated drug, device, diagnostic products. We must also continue to focus on improving the manufacture of existing therapies, that serve the vast majority of patients worldwide."

JIM MILLER

CONTENT ADVISOR AND CONSULTANT TO THE DRUG, CHEMICAL & ASSOCIATED TECHNOLOGIES ASSOCIATION (DCAT)

With a passion for the biopharmaceutical industry, Jim regularly speaks at pharmaceutical industry events including DCAT and CPhI. The industry expert founded PharmSource Information Services in 1996. The company was subsequently acquired by GlobalData 10 years later.

JOHANNES KHINAST

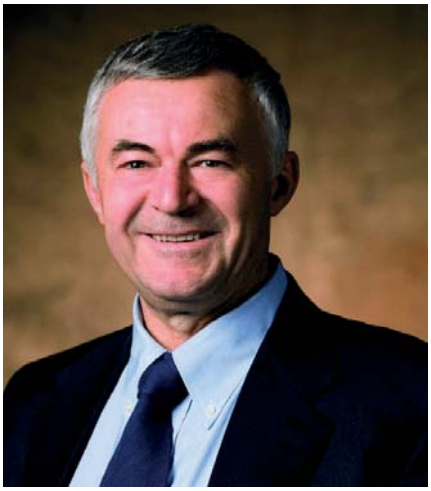
HEAD OF THE INSTITUTE FOR PROCESS AND PARTICLE ENGINEERING, THE GRAZ UNIVERSITY OF TECHNOLOGY; SCIENTIFIC DIRECTOR, RESEARCH CENTER PHARMACEUTICAL ENGINEERING GMBH

With an interest in the development of novel drug formulations, Johannes has worked with numerous pharmaceutical companies as an advisor for the implementation of such technologies. With over 120 peer-reviewed publications and awards including the NSF Career Award to his name, his passion for pharmaceutical engineering is undeniable.

MICHAEL O'BRIEN

PRESIDENT, NEXTGENTECH

Michael has held executive leadership positions for over 20 years with companies including Pfizer and Sanofi-Aventis. He has served as the President of NextGenTech since November 2017. NextGenTech is made up of a multidisciplinary team of pharmaceutical industry experts who help companies achieve their business objectives.



RINO RAPPUOLI

CHIEF SCIENTIST AND HEAD EXTERNAL R&D, GSK

Rino's contributions have had a phenomenal impact on the vaccines industry. He was involved in the development of CRM197 used in H.influenzae, N.meningitidis, and pneumococcus vaccines, and has also introduced several novel scientific concepts – genetic detoxification (1987), cellular microbiology (1996), reverse vaccinology (2000) and the pangenome (2005).

GUIDO RASI

EXECUTIVE DIRECTOR, EUROPEAN MEDICINES AGENCY

Guido is serving his second term as Executive Director of the EMA, having served as the EMA's Principal Adviser in Charge of Strategy between terms. He previously worked for the Italian Medicines Agency, the Institute of Molecular Medicine of the National Research Council in Rome, and as a physician.

ANDREW D. SKIBO

TECHNICAL ADVISOR TO EVP OPERATIONS AND IT; ASTRAZENECA

"If you lead it, you own it – no excuses." Andy has lived by this mantra throughout this working life. "It is imperative that a leader has an unflinching accountability to those in his charge. As the leader of a company you must be able to prioritize products with the most potential. Some development paths will inevitably fail but some must succeed and every sinew of enterprise energy needs to be exercised in driving to that end result."

GIL ROTH

FOUNDER AND PRESIDENT, PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

As President of the Pharma & Biopharma Outsourcing Association, Gil is trying to change the outsourcing landscape for the better by giving CDMOs a unified voice within the industry to address regulators with. Alongside his work with the pharma industry, Gil runs a podcast called The Virtual Memories Show.

DEEPAK SAPRA

SENIOR VICE PRESIDENT & HEAD OF PHARMACEUTICAL SERVICE AND ACTIVE INGREDIENTS, DR REDDY'S LABORATORIES

"My parents have been my biggest inspiration; my mother for her belief in the goodness of people and that empathy should be a key aspect of all our interactions and my father for his continuous commitment to learning and improving (he is in his late 70s and pursuing a PhD in an area he feels deeply about)."

MONCEF SLAOUI

PARTNER AND MEMBER OF SCIENTIFIC ADVISORY BOARD, MEDICXI

During his nearly 30-year career at GlaxoSmithKline, Moncef was an industry powerhouse who championed advances in drug discovery and development. He now sits on the advisory boards of Medicxi Ventures, the Agency for Science, Technology and Research, and the Qatar Foundation, helping to support the global industry with his pharma know how.

CORNELL STAMORAN

VP OF CORPORATE STRATEGY AND GOVERNMENT AFFAIRS, CATALENT PHARMA SOLUTIONS

"I'm frequently inspired by seeing the dedication of "unsung" heroes – people who persevere and perform in important but less visible jobs every single day, without drama or the need to be recognized. The sense of mission that drives them to persevere despite large obstacles and relatively low return has truly influenced the way I have approached my career."

JAMES N. THOMAS

CHIEF EXECUTIVE OFFICER AND FOUNDING PARTNER, JUST BIOTHERAPEUTICS

Over the course of his career, Jim as contributed to the advancement of many important therapeutics including Activase, Vectibix, Enbrel, Prolia/Xgeva and Repatha, as well as numerous biosimilar programs. Jim has built teams, departments and functions passionate about creating and using innovative technologies to deliver to the needs of patients. Just Biotherapeutics was set up to improve the access of medicine to patients worldwide.

BERNHARDT TROUT

RAYMOND F. BADDOUR, SCD, (1949) PROFESSOR OF CHEMICAL ENGINEERING, MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Bernhardt has been a professor of chemical engineering at MIT since 1998. His work on small molecule crystallization, formulation, and manufacturing has had a significant impact on the pharma industry. He sights Margaret Rousseau, the mind behind the first commercial plant for penicillin production, as his inspiration.

MICHAEL VANDIVER

VICE PRESIDENT OF MANUFACTURING & PLANT DESIGN, JUST BIOTHERAPEUTICS

Michael has over 30 years of biopharmaceutical process development and manufacturing experience. At Just Biotherapeutics, he led efforts to bring the company's J.Plant and J.Pod clinical and commercial biomanufacturing facilities online. "I would like to see the cost of biologics driven down, as well as the expansion of global access to medicines, where cost savings are passed onto patients rather than increasing profit margins." Looking back, Michael wishes he'd realized earlier that, "you will fail more times than you will succeed, but failure is how you will learn."

STÉPHANE BANCEL

CHIEF EXECUTIVE OFFICER, MODERNA THERAPEUTICS

Prior to Moderna, where he has served since October 2011, Stéphane was CEO of bioMérieux and has also held leadership positions at Eli Lilly. Moderna currently has 20 messenger RNA development candidates in its portfolio, with 11 in clinical studies.

BUSINESS CAPTAINS

OLIVIER BRANDICOURT

CHIEF EXECUTIVE OFFICER, SANOFI

Oliver started his career as a physician working primarily on malaria – practicing medicine in the Republic of the Congo for two years. In addition to his responsibilities at Sanofi – he became CEO in April 2015 – he is also Chairman of the Board of Management for PhRMA, Vice President of EFPIA, and an Honorary Fellow of the Royal College of Physicians in London.

ROBERT A. BRADWAY

CHAIRMAN AND CHIEF EXECUTIVE OFFICER, AMGEN

Robert was appointed CEO of Amgen in May 2012. Before Amgen, he was a managing director at Morgan Stanley in London. Today, Robert is also the chairman of the CEO Roundtable on Cancer, a member of the American Heart Association CEO Roundtable, and a member of the PhRMA board of directors.

MINZHANG CHEN

CHIEF EXECUTIVE OFFICER, WUXI STA

Minzhang Chen joined WuXi AppTec in 2008 and currently serves as CEO of WuXi STA, the small molecule process development and manufacturing subsidiary of WuXi AppTec. Under his leadership, WuXi STA has grown from an early phase process research focused organization to a world leading contract development and manufacturing organization for small molecule APIs and finished dosage forms from preclinical to commercial. Prior to joining WuXi, he served as Director of Technical Operations at Vertex Pharmaceuticals where he led a team who successfully supported the process R&D, API contract manufacturing and commercialization of Incivek.

JOHN CHIMINSKI

CHAIRMAN AND CHIEF EXECUTIVE OFFICER, CATALENT PHARMA SOLUTIONS

Scheduling time to think and asking for reports over PowerPoints are two notable changes John has implemented in recent years. “For most of my 30 year career, I aggressively scheduled meetings and rarely gave myself enough ‘block time’ to take a breath and work on more thoughtful and strategic activities that create long-term growth or future opportunities. Now, I have a better balance of an aggressive schedule with four-hour block times seeded throughout the week,” he says. “And when something is important, I ask for a written report. Nothing is better for demanding clarity from the writer, and attention from the reader. For our strategic plans, and other critical activities, I request written narratives constrained by number of pages to force clarity and thoughtfulness. If you can explain your business strategy in a couple of pages, and sell it to investors, you have something to invest the companies scarce capital in!”

KENNETH C. FRAZIER

CHAIRMAN AND CHIEF EXECUTIVE OFFICER, MERCK SHARP & DOHME.

A lawyer by training, Ken joined MSD in 1992 as general counsel. He held a range of senior management positions before being appointed CEO in 2011. In 2018, Ken was named on the Time 100 most influential people list for his decision to leave President Trump’s manufacturing council.

STANLEY CROOKE

CHAIRMAN AND CHIEF EXECUTIVE OFFICER, IONIS PHARMACEUTICALS

“I am now fully convinced that the only major difference between humans and other intelligent species is that humans can dream collectively. In fact, for most humans, I think there is a great need to be a part of shared or collective dreams. So to me, the most valuable commodities in life are big dreams and the leaders who can share their big dreams with others galvanically creating a collective with a higher, more noble purpose. This is how the present was created and how a better future will come to be.”

BELÉN GARIJO

CHIEF EXECUTIVE OFFICER, HEALTHCARE, MERCK

Belén has been a member of the Executive Board of Merck since January 2015. She is responsible for the Healthcare business sector, comprising the Biopharma, Consumer Health, Allergopharma and Biosimilars businesses. Before moving to the pharma industry, she was a practicing physician for six years.

ERIK GATENHOLM

CO-FOUNDER AND CHIEF EXECUTIVE OFFICER, CELLINK

Benjamin Franklin's famous words, "Don't put off until tomorrow what you can do today," resonate well with Erik: "We're proud of the hard work we do – it's very demanding, but the change we are doing in the field of medicine is extremely rewarding," he says. On the question of luck, Erik believes that to do amazing things, stars need to align and things need to happen simultaneously. "It's challenging to predict these things and even explain them in retrospect," he says. "But the thing with luck is that the harder you work, the luckier you are."

RACHEL HAURWITZ

PRESIDENT AND CHIEF EXECUTIVE OFFICER, CARIBOU BIOSCIENCES

Rachel has a research background in CRISPR-Cas biology and holds several patents covering CRISPR-derived technologies. She co-founded Caribou in 2012 and Intellia Therapeutics in 2014, both of which are developing genome editing therapies.

JEFF JONAS

CHIEF EXECUTIVE OFFICER, SAGE THERAPEUTICS

Jeff joined SAGE as CEO in 2013 and has more than 20 years of experience in the pharmaceutical and healthcare industries. In 2019, the FDA approved SAGE's Brexanolon, the first new drug developed for women with postpartum depression.

STEVEN M. KLOSK

PRESIDENT AND CHIEF EXECUTIVE OFFICER, CAMBREX

"My luckiest break has been to join Cambrex early in my career, because the experiences I have had and the people I have shared my time with have given me 28 years of steady personal and professional growth. What's most improved my life? Building a strong team of experts within Cambrex to ensure our success, and spending quality time with family."

SANDY MACRAE

PRESIDENT AND CHIEF EXECUTIVE OFFICER, SANGAMO THERAPEUTICS

Sandy has twenty years of experience in the pharmaceutical industry, having served at Takeda Pharmaceuticals from 2012 to March 2016, and GlaxoSmithKline from 2009 to 2012. Sandy took the top job at Sangamo in June 2016.

ANKIT MAHADEVIA

CO-FOUNDER AND CHIEF EXECUTIVE OFFICER, SPERO THERAPEUTICS

Ankit co-founded Spero Therapeutics – a clinical-stage biopharmaceutical company focused on identifying, developing and commercializing novel treatments for multi-drug resistant bacterial infections – in 2013. He values "being mindful about listening first before speaking in all situations," and considers "the opportunity to work with great mentors and great teammates who have enabled me to grow professionally and personally" his luckiest break.

KIRAN MAZUMDAR-SHAW

CHAIRPERSON AND MANAGING DIRECTOR, BIOCON

Kiran says that over the past five years, her understanding of risk management has greatly deepened. "I believe that I can now invest with greater confidence in some of the exciting new areas in immuno-oncology and digital technologies that will augment the pace of research and innovation." She considers her luckiest break discovering the "ability to transform my original enzymes business into biopharmaceuticals by leveraging the various microbial and rDNA technologies in a strategic way."

VASANT NARASIMHAN

CHIEF EXECUTIVE OFFICER, NOVARTIS

Vas was appointed CEO in February 2018 after previously serving as Global Head of Drug Development and Chief Medical Officer at Novartis. In 2018, four additional Novartis products reached blockbuster status, and the company further invested in advanced therapy, including acquiring AveXis gene therapy, AAA and Endocyte radioligand therapies, and expanding global manufacturing capacity for Kymriah.

RODGER NOVAK

CO-FOUNDER AND PRESIDENT, CRISPR THERAPEUTICS

Rodger is one of the three co-founders of CRISPR Therapeutics, which aims to treat diseases using CRISPR/Cas9 gene editing technology. The company recently announced that the first patients had been treated with CTX001, a CRISPR/Cas9 therapy β-thalassemia and sickle cell disease.

RAVI NALLIAH

CHIEF EXECUTIVE OFFICER, TRAKCEL

In 2009, in the midst of the economic downturn, Ravi decided to resign from a successful role as a senior manager with a leading regional accountancy to join a very small pharma contract services company as an early stage employee. "Within the first six months, I found myself on the board of directors and thereafter quickly lead a management buyout along with fellow executives," he says. The company grew quickly and was acquired by one of the largest global contract services organizations. Ravi also credits his extensive travel over the past five years with turning him into an avid reader. "I have diversified my reading material to cover all aspects from career and work-related material to autobiographies of my influencers and general life and wellbeing literature. This has all in some shape or form impacted my approach to life either consciously or subconsciously and in the main in a very positive way."

JESSICA RICHMAN

CO-FOUNDER AND CHIEF EXECUTIVE OFFICER, UBIOME

Jessica's background (in addition to competitive bodybuilding) is in analyzing large-scale data sets, and the idea behind uBiome was to transfer those same skills to the realm of healthcare and emerging genomics. In 2019, the company launched the world's first sequencing-based clinical microbiome testing.

LEONARD SCHLEIFER

FOUNDER AND CHIEF EXECUTIVE OFFICER, REGENERON PHARMACEUTICALS

"My luckiest break was convincing George D. Yancopoulos, Regeneron's President and Chief Scientific Officer, to partner with me to found and build Regeneron. At the time, he was heading toward a prestigious career in academia but, somehow – with a little help from his father – he made the decision to instead pursue breakthrough science at our entrepreneurial biotech, through which we have helped millions of patients since."

RAMAN SINGH

CHIEF EXECUTIVE OFFICER, MUNDIPHARMA, SINGAPORE

"I joined the healthcare industry without knowing the implications at the time, but because it offered me the opportunity to establish a healthcare business in Phnom Penh, Cambodia, from scratch. Little did I realize it would lead me to where I am today, allowing me in my own small way to play a role in impacting the human race."

SEVERIN SCHWAN

CHIEF EXECUTIVE OFFICER, ROCHE GROUP

After completing his studies in economics and law at the University of Innsbruck in Austria, Severin, joined the Roche Group in 1993 as a trainee in corporate finance. Thirteen years later, he was appointed CEO of Roche's Diagnostics Division, and in 2008 he became CEO of the Roche Group. The company's cancer immunotherapy Tecentriq (atezolizumab), a PD-L1 inhibitor, this year became the first immunotherapy approved for breast cancer in the US.

EMMA WALMSLEY

CHIEF EXECUTIVE OFFICER, GLAXOSMITHKLINE

Before heading up GlaxoSmithKline, Emma worked at L'Oreal for 17 years where she held a variety of general management and marketing roles. Emma holds an MA in Classics and Modern Languages from Oxford University. She also co-chairs the Consumer, Retail and Life Sciences Council, a business advisory group for the UK Government.

MARTIN TOLAR

FOUNDER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALZHEON

During his student days, Martin helped organize the Velvet Revolution that toppled the communist regime in the former Czechoslovakia. Since then, Martin served as an Assistant Professor in the Department of Neurology at Yale University School of Medicine, where he focused on movement disorders, and as head of business development at Pfizer, before founding Alzheon – a clinical-stage biopharmaceutical company focused on brain health, memory and aging.

CLAUDIA ZYLBERBERG

CO-FOUNDER, CHIEF EXECUTIVE OFFICER AND PRESIDENT, AKRON BIOTECHNOLOGY

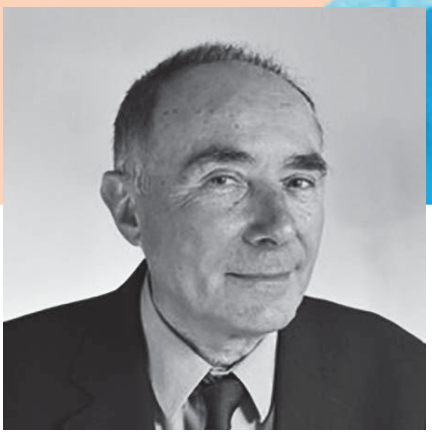
Claudia sits on numerous boards and is also a member of ISCT's Strategic Advisory Council, the National Academy of Sciences' Regenerative Medicine Forum and the Florida Organization of Regenerative Medicine. In her spare time, Claudia writes children's books and kayaks. "The solitude and the closeness to nature opens up my mind to new thoughts and ideas. It creates a space without any background noise, where I can reach into my reservoir of creativity and look for solutions to pressing issues or alternatives to road blocks," she says.

MASTERS OF THE BENCH

PHIL BARAN

DARLENE SHILEY CHAIR IN CHEMISTRY, SCRIPPS RESEARCH INSTITUTE

For his contributions to both industry and academia, Phil Baran has received numerous awards and accolades. The professor, who has worked at Scripps Research Institute since 2003, lives by the advice of his dearly departed friend, Professor Carlos Barbas: to pursue more translationally meaningful projects in the lab and to make more time for family.



PAOLO COLOMBO

EMERITUS PROFESSOR, UNIVERSITÀ DEGLI STUDI DI PARMA

"Collaboration on the basis of transparency, friendship and mutual consideration is key for anyone interested in fostering positive foreign partnerships. It is becoming increasingly evident that more needs to be done to combat orphan diseases. The deep involvement of international partners repurposing old drugs for new medicines using shared pharmaceutical technologies is of crucial importance."

LISA BRANNON-PEPPAS

OWNER AND CHIEF EXECUTIVE OFFICER, PEPPCHEM CONSULTING

Lisa is an internationally recognized researcher for her contributions to nanoparticle research, biomaterials, controlled drug delivery, and structure-property relationships of biomaterials. As an independent consultant at PeppChem Consulting, Lisa believes that "being kind, patient and working towards saving a life every day" are the essential ingredients to a positive working life.

CHARLES COONEY

ROBERT T. HASLAM (1911) PROFESSOR OF CHEMICAL AND BIOCHEMICAL ENGINEERING, EMERITUS, MASSACHUSETTS INSTITUTE OF TECHNOLOGY

As a chemical engineer, Charles has always been interested in reaching new frontiers and tackling unresolved issues within the remit of his field. However, over the past five years he has greatly diversified his reading of both scientific and nonfiction literature. "I came to the realization that innovation takes place more often at the interfaces of multiple scientific disciplines, policy, business and society, and that without a deeper understanding of history as the context one cannot appreciate the implications of discovery."

LLOYD CZAPLEWSKI

DIRECTOR, CHEMICAL BIOLOGY VENTURES

Lloyd has over 20 years of R&D experience under his belt across various therapeutic areas. He is the current Chief Scientific Officer at Persica Pharmaceuticals, a company dedicated to the development of novel therapeutics for Chronic Lower Back Pain, and Director at Chemical Biology Ventures Limited.

CHI VAN DANG

SCIENTIFIC DIRECTOR, LUDWIG INSTITUTE FOR CANCER RSEARCH; PROFESSOR, WISTAR INSTITUTE

"As a biomedical researcher, the emergence of immunotherapies for cancer patients has provided me and others across the industry with such opportunities. The tangible impact on clinical outcomes of these treatments is evident. However, we are still challenged by why many patients don't have durable responses and additional research will be critical to overcoming this barrier and achieving more cancer cures."

MEINDERT DANHOF

RETIRED

Dubbed the "founding father of pharmacological models," Meindert's research focused on novel concepts of systems pharmacology and interfacing concepts from systems biology with quantitative pharmacology. After retiring in 2017, he received the Emeritus Professor Status at Leiden University. In March 2018, Meindert set up MD Pharmacology Advice which provides training and scientific support on pharmacological models and intellectual property disputes.

MICHELE DE LUCA

DIRECTOR, CENTER FOR REGENERATIVE MEDICINE "STEFANO FERRARI", UNIVERSITY OF MODENA AND REGGIO EMILIA

Michele has been involved in epithelial stem cell biology for regenerative medicines for 20 years. His pioneering work has included the use of human epithelial stem cells for repigmentation of vitiligo, life-saving treatment of massive full-thickness burns, and piebaldism.

KENNETH A. GETZ

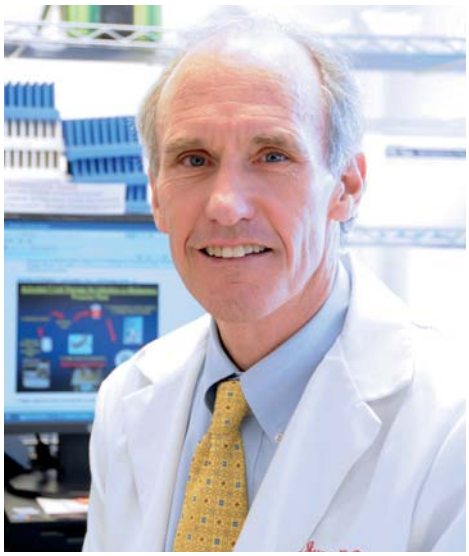
DIRECTOR OF SPONSORED PROGRAMS AND ASSOCIATE PROFESSOR, TUFTS UNIVERSITY SCHOOL OF MEDICINE; FOUNDER AND CHAIRMAN,CISCRP

"The development, continued regulatory approval and commercialization of immunotherapies will have the biggest impact on patients. The impact is expected to continue to grow exponentially as immunotherapies extend into disease conditions other than cancer."

MICHAEL JENSEN

DIRECTOR, BEN TOWNE CENTER FOR CHILDHOOD CANCER, SEATTLE CHILDREN'S RESEARCH INSTITUTE

Renowned for his work in pediatric cancer research, Michael has served as the director of the Ben Towne Center for Childhood Cancer at Seattle Children's Research Institute since 2010. Prior to his tenure at the hospital, he conducted the first FDA authorized trial of T-cell therapies for children with recurrent neuroblastoma at City of Hope National Medical Center.



CARL H. JUNE

RICHARD W. VAGUE PROFESSOR IN IMMUNOTHERAPY, UNIVERSITY OF PENNSYLVANIA

With more than 350 published manuscripts to his name and numerous awards, including the American Academy of Arts and Sciences and William B Coley awards, Carl's passions have always been geared toward lymphocyte biology. His lab primarily focuses on developing new CAR therapies and new vectors for current and proposed indications.

ROBERT LANGER

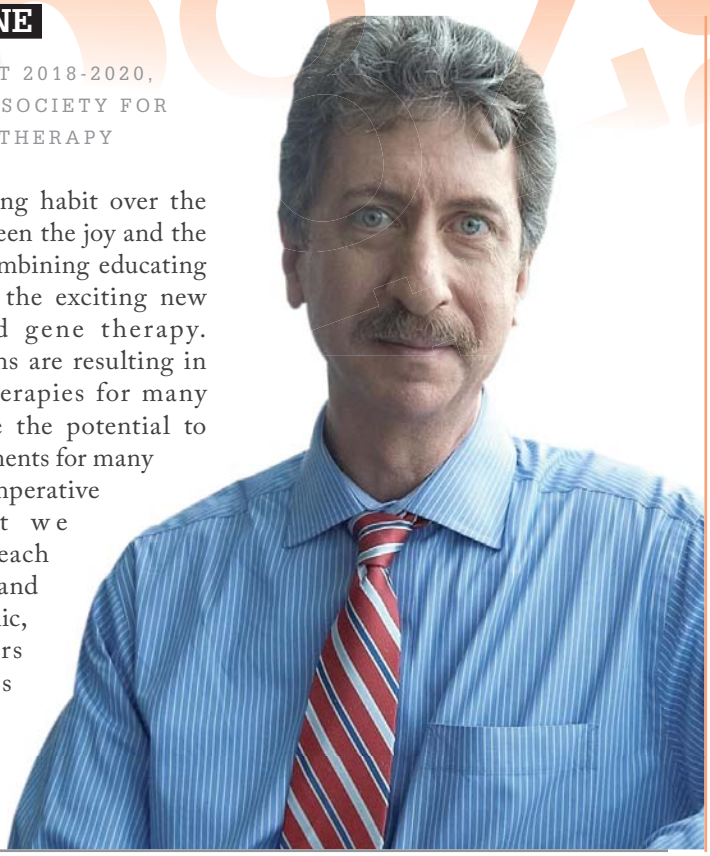
DAVID H. KOCH INSTITUTE PROFESSOR, MASSACHUSETTS INSTITUTE OF TECHNOLOGY

The most cited engineer in history and one of the most prolific inventors in all of medicine, Robert has nearly 1,300 issued and pending patents, many of which have been licensed or sublicensed to over 350 pharma, chemical, biotech and medical device companies. He has been honored with over 200 major scientific awards, including the United States National Medal of Science, and the 2002 Charles Stark Draper Prize (often considered the equivalent of the Nobel Prize for engineers).

It has been estimated that as many as two billion people may have had their lives touched by the technologies created by Robert and his fellow researchers, and many of his former students have gone on to great success in academia and industry. "Working with wonderful students and doing work that can make the world a better place is what drives me," says Robert. "If I could change one thing about the industry, it would be to find a way to get more funding for basic research that could help pharma."

BRUCE LEVINE

PRESIDENT-ELECT 2018-2020, INTERNATIONAL SOCIETY FOR CELL AND GENE THERAPY

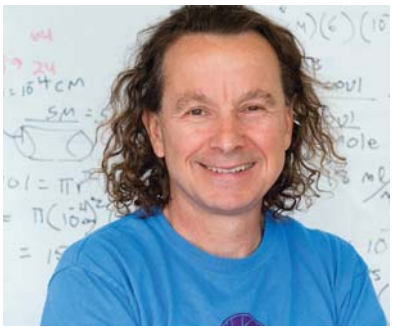


"My most rewarding habit over the last five years has been the joy and the responsibility of combining educating and mentoring in the exciting new field of cell and gene therapy. Medical innovations are resulting in transformative therapies for many patients, and have the potential to revolutionize treatments for many conditions. It is imperative however, that we augment our outreach and communicate and connect to the public, patients, regulators and governments to make our work more accessible."

RODERICK MACKINNON

CO-FOUNDER AND CHAIR, FLEX PHARMA

Winner of the 2003 Nobel Prize for Chemistry and co-founder of Flex Pharma, Roderick has had many career highs. He currently serves as an Investigator at the Howard Hughes Medical Institute and the John D. Rockefeller Jr. Professor, Laboratory of Molecular Neurobiology and Biophysics at The Rockefeller University.



JOAN MANNICK

CO-FOUNDER, CHIEF MEDICAL OFFICER AND MEMBER OF THE BOARD OF DIRECTORS, RESTORBIO

"Aging is the biggest risk factor for most diseases. Recent scientific discoveries in the field will help in the development of drugs that target the biology of aging and may lead to new therapies to improve immune function and reduce infection rates in the elderly."

CHRIS MASON

FOUNDER AND CHIEF SCIENTIFIC OFFICER, AVROBIO; PROFESSOR OF CELL AND GENE THERAPY, ADVANCED CENTRE FOR BIOCHEMICAL ENGINEERING, UNIVERSITY COLLEGE LONDON

With over 25 years experience, Chris has had a massive impact on the field of cell and gene therapies. He is currently a Professor of Cell and Gene Therapies at UCL and Founder and Scientific Officer of AVROBIO, a clinical stage company with a focus on developing disruptive lentiviral-based gene therapies.

GRAZIELLA PELLEGRINI

DIRECTOR, CELL THERAPY PROGRAMME, CENTRE FOR REGENERATIVE MEDICINE "STEFANO FERRARI," THE UNIVERSITY OF MODENA AND REGGIO EMILIA

Holocar, the first ATMP containing stem cells to be approved by the European Commission was produced by Graziella and her team. She believes that a cohesive team is the key to success.

NICHOLAS A. PEPPAS

COCKRELL FAMILY REGENTS CHAIR IN ENGINEERING #6; PROFESSOR OF CHEMICAL ENGINEERING, THE UNIVERSITY OF TEXAS AT AUSTIN

"Over the course of the last 30 years, we have seen developments that have ultimately led to improved drug delivery, which was previously unimaginable. To continue along this path it is essential that we remember that we are serving patients first and foremost. All the research we do and the novel therapeutics we produce would be meaningless without the intention of improving the quality of life of our patients."

CHRISTOPHER J.H. PORTER

DIRECTOR, MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES, MONASH UNIVERSITY

Chris has always had a strong interest in drug delivery systems and was awarded the American Association of Pharmaceutical Scientists lipid based drug delivery outstanding research award in recognition of his efforts in this area in 2009. However, he realizes that there is much to be gained from multidisciplinary approaches. "The insight available from those outside your main area of focus can be remarkable."

DOLORES SCHENDEL

CHIEF EXECUTIVE OFFICER AND CHIEF SCIENTIFIC OFFICER, MEDIGENE

Dolores has been a member of the German Research Foundation, German Cancer Aid and the European Research Council, and developed her interest in tumor immunology while working at the Sloan-Kettering Institute in New York. She joined Medigene as Chief Scientific Officer in 2014, when the company acquired Trianta Immunotherapy, and was appointed CEO in 2016.

PETER SEEBERGER

MANAGING DIRECTOR, MAX-PLANCK INSTITUTE COLLOIDS AND INTERFACES

With a focus on creating novel vaccines, Peter aims to help protect patients against infectious diseases and improve the accessibility of drugs. "New technologies such as continuous manufacturing to produce known drugs and vaccines will make them affordable to broader parts of the world's population."

ADRIAN WILDFIRE

SCIENTIFIC DIRECTOR, SGS

"Self-belief is a person's strongest asset. You come to a time in your life where you have to nail your colors to the mast. Looking over the remarkable discoveries made in the last 20 years from CRISPR-Cas9 to organ-on-a-chip and meeting the people behind some of them I am struck by how they never gave up believing and how they took dreams and theory and made them into something accessible and practical. I like pragmatism and momentum – if you stop or spend too much time looking backwards then the world has moved on."

JOHN TALLEY

CHIEF SCIENTIFIC OFFICER, EUCLISES PHARMACEUTICALS

"My passion is unraveling the role prostaglandins play in immune surveillance within the tumor microenvironment. I would also like to see a return to the highly-regarded reputation of the pharmaceutical industry. This might be accomplished by promotion of the many tangible benefits to individuals that are a consequence of the industry's research and development initiatives."

SHINYA YAMANAKA

DIRECTOR AND PROFESSOR CENTER FOR IPS CELL RESEARCH AND APPLICATION (CIRA), KYOTO UNIVERSITY

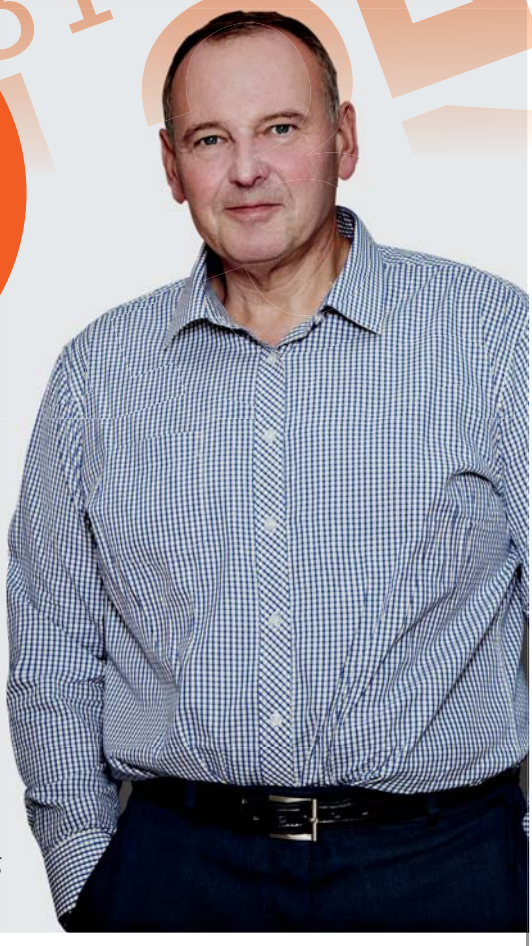
As a 2012 Nobel Prize Laureate, Shinya Yamanka's work on stem cells has gained him international recognition. Discovering the medical applications of induced pluripotent stem cells has been a major focus for the researcher since he first reprogrammed human cells in 2007.

HAROLD VARMUS

LEWIS THOMAS UNIVERSITY PROFESSOR, WEILL CORNELL MEDICAL COLLEGE

A leading cancer geneticist and co-winner of the 1989 Nobel Prize, Harold Varmus has previously been the Director of the National Institute of Health and the National Cancer Institute. Before training as a physician, he studied English Literature with the hopes of becoming a writer. Alongside his work in cancer research, Harold takes an active interest in biomedical enterprise and consults companies and academic institutions.

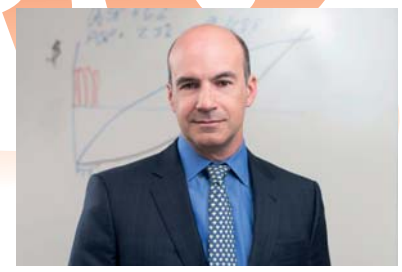
CHAMPIONS OF CHANGE



STEVE ARLINGTON

PRESIDENT, PISTOIA ALLIANCE

"Professionally, I would say the most significant thing that has improved my career is that I am continually finding the power of many far exceeds trying to do things alone. Whilst it can be challenging in the beginning to get alignment and coordination, the time invested when collaborating is repaid many times over."



PETER B. BACH

DIRECTOR, CENTER FOR HEALTH POLICY AND OUTCOMES, MEMORIAL SLOAN KETTERING CANCER CENTER

Peter is a physician, epidemiologist, researcher, and respected healthcare policy expert whose work focuses on the cost and value of anticancer drugs. When asked what could be done to improve access to medicines he responded, "The price of medicines should align with the benefits they provide so that patients' limited financial means are not used as a counterweight to higher than justified prices."

JOHN ARNOLD

FOUNDER AND CO-CHAIR, LAURA AND JOHN ARNOLD FOUNDATION

In 2010, John and his wife Laura, established the Laura and John Foundation. The Foundation invests in sustainable change in the US through its engagement in public conversation, the creation of new policies, education and advocacy.

MICHAEL A. ARNOLD

SENIOR DIRECTOR, INVESTIGATIONAL PRODUCTS BUSINESS PROCESS OWNER, PFIZER

Michael has worked in the pharmaceutical industry for 36 years. He is a licensed pharmacist in the state of Connecticut and was named "Pharmacist of the Year" by the Connecticut Society of Health Systems Pharmacists in 2012.

DARIO CAMPANA

SCIENTIFIC FOUNDER, UNUM THERAPEUTICS, NKARTA AND MEDISIX THERAPEUTICS; PROFESSOR, DEPARTMENT OF PEDIATRICS, NATIONAL UNIVERSITY OF SINGAPORE

"There is an innate resistance to new ideas and disruptive technologies in pharma. I believe that better interaction between industry and academia can help to facilitate the translation of basic discoveries into clinical applications."

THOMAS CECH

DISTINGUISHED PROFESSOR, UNIVERSITY OF COLORADO BOULDER

In 1989, Thomas won the Nobel Prize in Chemistry along with his colleague, Sidney Altman, for their discovery of the catalytic properties of RNA. Thomas is currently an Investigator with the Howard Hughes Medical Institute, and also a Distinguished Professor at the University of Colorado and Director of the university's BioFrontiers Institute.

MASSIMO DOMINICI

ASSOCIATE PROFESSOR, MEDICAL ONCOLOGY, UNIVERSITY HOSPITAL OF MODENA AND REGGIO EMILIA

While Massimo's professional passions lie in cell and gene therapies, running has helped changed his personal life. "I have been running all my life, since 2017 I have been taking this very seriously: last year I did four marathons! Running is a way to leave unnecessary fears and concerns on the road and go back to family, lab, patients and friends with a renovated enthusiasm for life and its obstacles."

STEVE DAVIS

CHIEF EXECUTIVE OFFICER, PATH

As president and CEO of PATH, Steve combines his experience as a business leader, health advocate, and innovator to drive change and save lives, especially in low and middle-income countries. PATH believes that social innovation is the key to changing the world. A strong proponent of gender equity in leadership roles and a social and gay activist, Steve spent part of his career using his law degree to advance human and civil rights. He is a member of the Council on Foreign Relations, serves on the board of InterAction, and is a trustee of the World Economic Forum's Global Health Challenge.

JULIE GERBERDING

EXECUTIVE VICE PRESIDENT & CHIEF PATIENT OFFICER, STRATEGIC COMMUNICATIONS, GLOBAL PUBLIC POLICY AND POPULATION HEALTH, MERCK SHARP & DOHME

Julie has served as Merck's Executive Vice President since 2016. Her career has seen her previously work in advisory capacities to the National Institutes of Health, the American Medical Association, CDC, the Occupational Safety and Health Administration, the National AIDS Commission, the Congressional Office of Technology Assessment, and the World Health Organization.

SUE DESMOND-HELLMANN

CHIEF EXECUTIVE OFFICER, BILL & MELINDA GATES FOUNDATION

Dedicated to improving the quality of healthcare and the eradication of disease, Sue is the current CEO of the Bill & Melinda Gates Foundation. She is a trained physician and takes pride in her philanthropic efforts.

DALVIR GILL

CHIEF EXECUTIVE OFFICER, TRANSCELERATE BIOPHARMA

"People need access to accurate information to make informed decisions. In today's highly-connected world, people are not as informed about their healthcare as they should be. Information on diseases and medicines is readily available with a few clicks, but we need to do a better job at providing accurate information to combat the misinformation that exists online. Empowering people with information will allow them to take better control of their health and ultimately improve access to medicines."

BEN GOLDACRE

SENIOR CLINICAL RESEARCH FELLOW, NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES, UNIVERSITY OF OXFORD; CO-FOUNDER, ALLTRIALS

A trained physician and member of the Royal College of Psychiatrists, Ben is best known for his work as on Bad Science, a weekly column featured in the Guardian newspaper from 2003 to 2011. This work discussed the misuse of science and the issues of the pharmaceutical industry, particularly its relationship with medical journals.

MARGARET HAMBURG

CHAIR OF THE BOARD, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE

Margaret is the current President-elect of AAAS. She was the longest-serving FDA Commissioner (from 2009 to 2015) after being nominated by President Barack Obama for the position. She is the current foreign secretary of the National Academy of Medicine and chair of the Nuclear Threat Initiative.

JOHN HAMMERGREN

RETIRED. FORMER CHAIRMAN AND CHIEF EXECUTIVE OFFICER, MCKESSON CORPORATION

John retired from his position as CEO at McKesson in March 2019, after nearly 20 years. The American company focuses on the distribution of pharmaceutical products and technologies. During his leadership, the company quadrupled its revenues to $208 billion dollars.

JACKIE HUNTER

CHIEF EXECUTIVE OFFICER, BENEVOLENTBIO; BOARD DIRECTOR OF BENOVOLENTAI

Jackie is a board member and Chief Executive, Clinical Programmes & Strategic Relationships of BenevolentBio, the AI unicorn disrupting the pharma industry through its approach to mining and analyzing biomedical information. In addition to her role at the company, she serves a professor at St. George's Hospital Medical School.

AMIR KALALI

CHIEF CURATOR AND
CHAIRMAN, CNS SUMMIT

Recognized for his contributions to life sciences and clinical research, Amir has authored over 200 peer-reviewed publications and advised several pharmaceutical companies. As chair of the CNS Summit, he brings to together like-minded individuals from industry with a passion for innovation in the clinical development space. He believes that focusing on kindness makes all the difference in life.

SUBHASH KAPRE

CHIEF EXECUTIVE OFFICER,
INVENTPRISE LLC

Subhash established Inventprise in 2012 with the aim of developing cheaper, safer vaccines. A previous board member of the Serum Institute of India, he has over 44 years of experience in research and development. Under a project grant from the Bill & Melinda Gates Foundation, Inventprise has created a liquid heat-stable Rota virus vaccine that can withstand temperatures of 50°C for 5 months.

FAITH OSIER

PRINCIPAL INVESTIGATOR,
KEMRI-WELLCOME TRUST
RESEARCH PROGRAM;
PROFESSOR OF MALARIA
IMMUNOLOGY, UNIVERSITY
OF OXFORD

For her research into the mechanisms of immunity against Plasmodium falciparum, Faith has won multiple awards. As a trained physician, Faith has specialized in pediatrics in both Kenya and the UK. In 2014, she was awarded the Young African Scientist Award by EVIMalaR, and won the Merle A Sande Health Leadership Award and the Royal Society Pfizer Award.

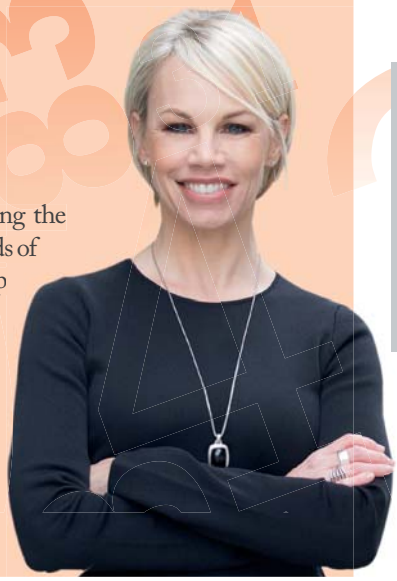
MIKE REA

CHIEF EXECUTIVE OFFICER,
IDEA PHARMA

Mike cites a number of people who have inspired him over the years, including the authors Michael Schrage, Steven Johnson, Stephen Jay Gould, Clifton Leaf, who took the time to capture their wisdom and insights for all to benefit. He'd like to see more medicine launches. "If we launched more medicines, we'd create a genuinely competitive environment, where success is driven by more than exclusivity – by innovation in commercial models and truly reflecting unmet need in choices of outcome measures and patient relevance."

MELINDA RICHTER

GLOBAL HEAD OF JLABS, JOHNSON & JOHNSON INNOVATION



"Improving access to medicines starts with shortening the amount of time it takes to get a therapeutic into the hands of the patient or consumer. Typically, that process can take up to ten years and millions or even billions of dollars. This has to change! I've worked tirelessly to streamline this process for healthcare entrepreneurs, via our Johnson & Johnson Innovation – JLABS model, and will continue to work to shorten that development cycle and to make it more affordable to ultimately get medicines into the hands of those who need them most."

MARTIN VAN TRIESTE

PRESIDENT AND CHIEF EXECUTIVE OFFICER, CIVICA RX

"From a professional perspective, I recognize now more than ever the importance of using my experience and expertise to help improve the safety and availability of vital medicines for patients. I feel a deep responsibility to give back and influence improvements to the pharmaceutical supply chain in innovative ways – and that is incredibly fulfilling."

ROS SMYTH

DIRECTOR, UCL GREAT ORMOND STREET INSTITUTE OF CHILD HEALTH

Ros has a strong interest in systematic reviews of treatments for childhood respiratory disease. In addition to her work at Great Ormond Street, she has chaired the Paediatric Expert Advisory Group of the Commission on Human Medicines and played an advisory role in drug regulation in the UK.

ABBE STEEL

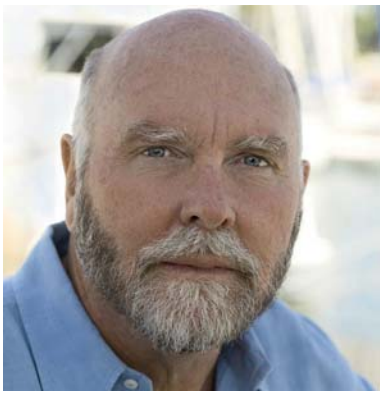
CHIEF EXECUTIVE OFFICER, HEALTHIVIBE, LLC

"By far, having more empathy and compassion for patients and their families has improved my life. This has made me a much better life science executive and, even more importantly, a more patient, caring person."

MATTHEW H. TODD

CHAIR OF DRUG DISCOVERY, UNIVERSITY COLLEGE LONDON

As founder of the Open Source Malaria program, Matthew has a strong interest in providing affordable and accessible medicines to patients globally. The project is supported by Open Source Pharma.



J. CRAIG VENTER

FOUNDER, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, J. CRAIG VENTER INSTITUTE

J. Craig Venter is the founder, chairman and CEO of the J.Craig Venter Institute. He is also the co-founder of Synthetic Genomics Inc and Human Longevity Inc, a genomics and cell therapy-based diagnostic and therapeutic company focused on extending the healthy, high performance human life span.

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Life Science Integrates is delighted to introduce the inaugural Bio Integrates conference And you're invited!

This one-day gathering of start-ups, SMEs and emerging companies will provide a platform to discuss the major challenges impacting the pharma and biotech sector, bringing together subject matter experts from the biotech and wider stakeholder community to examine and address the drivers and hurdles of today and resolve the critical business issues of tomorrow.

Addressing topics such as precision medicine, cell and gene therapy, artificial intelligence, in silico and virtual trials, the focus will be on collaboration, involving stakeholders such as patient advocates, clinicians, CDMOs and CROs, charities, manufacturers, academics and medtechs.

Delegates will benefit from updates on industry wide initiatives, alternative business models, innovative deal structures, partnering with CROs, CDMOs and the wider supply chain. With dedicated networking sessions throughout the day providing an opportunity to engage with these experts, we together, as an industry can collaborate, innovate and share insights.

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Profession

Your career
Your business
Your life

The Art of Writing

Publications are vital to building your profile, but for many scientists it's less of an art and more of an afterthought. Here, we present a straightforward guide to preparing papers and posters that will get you noticed.

By Paul R. Haddad, Emily F. Hilder and Frantisek Svec

We have presented the "Scientific Writing and Publishing" course at a number of analytical science conferences across the world, over the years. The origins of the course lie in discussions between the editors of several major journals in the field about the common mistakes made by authors, especially young scientists. Here, we distill the course into a straightforward guide to creating journal articles and posters that are clear and concise – but that also catch the reader's attention.

The Write Stuff

How to prepare a manuscript for publication.

Before you type a single syllable, ask yourself: are my results suitable for publication?

Publications are one of the important outputs of any scientific researcher. Results that stay "in the drawer" and are not shared with the community are of little value to you or others. Publishing papers and presenting at scientific meetings serves not only the outside community, but your own career, especially when you are starting out. Defending a PhD theses with no published papers is exceedingly difficult at best, and your publication record is scrutinized by granting agencies when reviewing project proposals.

Clearly, publishing your work is of utmost importance. But first you have to be sure that your research is sufficient. The first and most important question is whether you have discovered something new and interesting. Good journal editors and peer reviewers will quickly see through attempts to publish papers that present only an incremental development, such as separations of different compounds using a well-known method, or jumping on the bandwagon of a hot topic to publish a "me too" paper. You should also spend some time thinking about the major challenges of the work you carried out and whether you solved a difficult problem. If the answers to all these questions are "yes", then it is time to grab a coffee, settle down at your desk and...

Select a journal

Once you have decided to write a paper, the next step is to select the journal in which you want to publish. All journals are not created equal. It is critical to make sure that your research lies within the scope of the journal, which is typically found in the "Instructions for Authors" on the journal's website. It is also a good idea to look at a few current issues of that journal to get a feel for the type of research that is being published. Submitting a manuscript to a journal that covers a completely different field is a complete waste of time.

A frequently mentioned parameter used to differentiate journals is the impact factor (IF), which indicates how often papers published in that journal are cited over a defined period. Publishing in high IF journals contributes to the personal prestige of the author and improves the image of their institution, so a spot in one of these journals is much sought after. However, journals with a high IF are often highly selective in the manuscripts they choose to publish and their rejection rate is usually very high. Plus, some of these journals favor certain topics. After all, how many chromatographic papers do we see in Science or Nature, for example? Remember that the impact of the work you publish should prevail over the impact factor of the journal in which it is published. Therefore, you should choose a journal that is read by a large number of people in your own field

Great on paper

Each journal has specific requirements for submitted manuscripts, which should be read by all authors before they start writing. Many authors have the impression that the journal editors will correct their poorly formatted manuscript to make it publishable, but editors handle hundreds of manuscripts each year (the vast majority of which are formatted incorrectly). Improper formatting will instead lead a submitted manuscript to be immediately returned to the authors for reformatting, causing a delay before the article can even be processed.

While writing, authors should always keep in mind the potential readers. For example, though the use of abbreviations makes the writing faster (and the manuscript slightly shorter), too many abbreviations make the manuscript difficult to follow and can cause readers to lose interest. A particularly common error is the use of abbreviations in the title or abstract. Who would understand the title "Development of an analytical method to quantify PBDEs, OH-BDEs, HBCDs, 2,4,6-TBP, EH-TBB, and BEH-TEBP in human serum"? Most readers would not care to read even the Abstract. A better title would be "Development of an analytical method to quantify polybrominated diphenyl ethers flame retardants in human serum"

Choosing the right keywords is also important, as these are typically used in computerized literature searches. A keyword such as "Ultra-high performance liquid chromatography-Q_Exactive hybrid quadrupole-Orbitrap high-resolution accurate mass spectrometry" is completely useless. Instead, consider what keywords you would use when searching for your paper in PubMed or similar databases.

Figures are an important part of any manuscript, but there are a number of

pitfalls for the unwary. As some journals restrict the length of a printed paper, too many authors try to condense their manuscript by combining several figure panels into a single figure until each panel is so small that it is difficult to see the details, rendering them next to useless. A better approach is to show only the most important figures in the published paper and include all other figures in the electronic Supplementary Information. Despite the obvious importance of graphics, authors continue to submit completely inappropriate, uninformative and unnecessary figures.

Finally, don't forget the references. It is easy today to generate a large number of references using computerized databases. Thus, manuscripts including more than 50 references are becoming commonplace. Unfortunately, not all authors read the references that they cite and it is not uncommon to find some that are completely irrelevant to the paper, which is unlikely to leave editors or reviewers with a favorable impression. Also, avoid including an excessive number of self-references – you are more likely to irritate than impress. Authors should also keep in mind that each journal requires a specific format for references. It is sometimes possible to recognize where a manuscript has been submitted previously just from the format of the references, immediately telling the editor that this manuscript has been rejected previously. So be sure to re-format the reference list before submitting to a new journal.

Once More with Feeling

How to navigate the review and revision process.

For many authors, the details of peer review are opaque, making the process confusing and disheartening, particularly for young scientists. Read on as we attempt to demystify peer review and equip authors with the tools to participate constructively as both author and reviewer.

Submission

Most journals use similar online submission platforms, structured to guide authors through the submission process. Just as it is important to format your manuscript to meet the journal's specific requirements, it is essential that the journal's instructions are followed concerning the information and files required. Without this information it can be difficult or impossible for a manuscript to be reviewed fairly and a lack of information can also delay publication if the manuscript is ultimately accepted.

Authors should be aware that most journals now undertake an electronic check of the manuscript for plagiarism – a process that will identify any sections of text that have appeared in previous publications or on the internet. If the overlap with previously published work is considered to be excessive, the manuscript will be rejected. Take extreme care to avoid plagiarism as this is considered completely unacceptable – even if you are "borrowing" your own words from previous work.

Why is the cover letter important?

In addition to providing the core documents, including the manuscript text, figures and any supporting information, a critical and often underappreciated aspect of the submission process is the cover letter or justification statement. Almost all journals receive many more manuscript submissions than they can reasonably publish. Each journal will also have a defined target audience and thus will consider not only the novelty of the work but also the fit and interest for their target audience. For this reason, it is very important that the authors carefully consider the aims and scope of the journal and provide a strong justification as to why their work will be of interest to readers; most journals now require the authors to submit a cover letter and/or justification along with the manuscript. Rather than a chore, it is an opportunity for the authors to communicate directly with the editor and explain why their work is novel, what contribution it makes to the field and how it fits within the scope of the journal. Editors will not reject a manuscript because the cover letter is bad. However, a cover letter that piques the Editor's interest may accelerate the editorial progress of your paper.

Nominated reviewers

Many journals ask authors to recommend possible reviewers, which is an important opportunity to contribute to the fair review of your manuscript by appropriate experts in the field. By suggesting inappropriate reviewers, you send a clear message to the editor: you are not familiar with the literature in your field or not confident in your work. Here are some general guidelines for choosing appropriate reviewers.

Inappropriate reviewers are:

- Editors of the journal (or editors of other journals)

Manuscript Mistakes

Ten of the most common errors made by authors.

1. Submission of papers that are clearly out of scope
2. Resubmission of a rejected manuscript (to the same or different journal) without revision
3. Not sticking to the format required by the journal
4. Typos and grammar errors
5. Overzealous use of (undefined) abbreviations
6. Poor selection of keywords
7. Plagiarism, especially of small parts of a paper
8. Too many figures
9. Poor legibility of figures
10. Too many references and excessive self-referencing

- The top scientists in the world
- Your research collaborators
- People from your own institution
- A group of reviewers drawn solely from your country
- People without a publication record in the field.

Appropriate reviewers include:

- People who publish actively in the field, especially in the journal
- People whose work you have cited and discussed in the Introduction of your manuscript
- Members of the advisory board of the journal where you submit your manuscript.

Though authors may be asked to recommend potential reviewers, the editor will ultimately decide who will review a manuscript. The reviewers will provide both a recommendation on whether the manuscript should be published, and comments supporting this recommendation. It is a common misconception that the final decision by the editor will always directly follow the recommendations of the reviewers. Editors certainly do rely on reviewers to provide expert advice on manuscripts and their suitability for publication, but the final decision will be made by the editor, who must balance feedback from multiple reviewers.

For each manuscript that you submit for publication, a number of other scientists will give their time to review and provide feedback. To allow this system to continue, it is critical that if you publish in the scientific literature, you also actively support the peer review process. For younger scientists, providing high quality and timely reviews is an excellent way to increase your visibility. And it also provides a very effective way to engage with editors and experts in your field. In our experience, young scientists are often very well informed in their area of specialization and can be very effective reviewers.

Responding to reviewer comments

One of the most challenging aspects of the publication process is that you must open your work to critical feedback – and this feedback is not always positive. Remember that all authors, even the most senior in the field, must respond to criticisms of their work as part of the publication process. Read the reviewers' comments dispassionately and don't take offence – after all, the reviewers have taken time to read your manuscript and provide suggestions to improve it. In many cases, you will be asked to address the feedback from the reviewers and revise your manuscript accordingly. Be sure to address all comments, including any specific instructions from the editor and/or editorial office. We suggest preparing a document that lists each reviewer's comment, your response to that comment, and what specific changes have been made in the manuscript, each in a different color font. If a particular reviewer's comment is not clear you may request clarification through the editorial office.

In some cases, you will receive a decision that your submission has been rejected for publication. Though never welcome news, rejection is something that almost all scientists experience in the course of their career – including the authors of this article! In some cases, the editor will reject a manuscript without review – sometimes referred to as a desk rejection – but it is not necessarily a reflection on the quality of the research. Rather, the rejection may be based on other factors, such as the manuscript being presented in the incorrect form or written in poor English that prevents proper understanding of the work.

When a manuscript is rejected following peer review, remember that you have received the benefit of the reviewers' time; don't ignore the advice they have given. If you choose to submit your manuscript elsewhere, you should revise the manuscript appropriately before resubmission and never resubmit the manuscript unchanged. The scientific community within a specialized area can be small, and it is very likely that the same reviewers may see your manuscript again. We suggest that when resubmitting a previously rejected manuscript to a new journal, you should declare the history of the previous submission in your cover letter and also include the reviewers' comments and your response showing how you have addressed these comments. This makes the new editor's job much easier and in many cases will greatly speed up the review process – it may even result in your manuscript requiring no further review.

Parting Words

Getting a manuscript published in a good journal is never easy; most journals have high rejection rates. There is no secret recipe for success – just some simple rules, dedication and hard work. Authors should remember that editors are very busy people, so it is in everyone's interests to make the editor's job as straightforward as possible. Authors should cherish their work and take the greatest care in preparing their manuscripts properly. Finally, authors must expect some of their submissions to be rejected. Rejection is a statistical inevitability – the important thing is to understand why the article was rejected and incorporate this knowledge into future submissions. Success will come if you persevere.

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Poster Haste

How to create and present an eye-catching poster.

For most young scientists, the first opportunity to present work to the scientific community comes in the form of a poster presentation at a scientific meeting. Posters are a unique and important form of scientific communication because they allow direct and personal communication between the presenter and the audience. However, there are some major challenges associated with poster presentations. First, poster sessions at major conferences are often crowded and very limited on time, so the primary challenge is to attract an audience by preparing a poster that is arresting, visually appealing and scientifically exciting. Second, a poster must be able to convey its major findings in 1–2 minutes through a logical and clear layout and focused interaction between the poster presenter and audience.

Attracting an audience

A primary feature of poster sessions is that attendees can be selective about which posters they will read and discuss with the presenter. So how can you get people to stop at your poster rather than walking by? These five points will help you to stand out:

1. Posters are a visual communication tool, so graphic design is essential. Think about the overall impact of your poster in terms of layout, photographs, figures, schematics, and so on, to convey information without words. Suitable use of color throughout the poster is also essential. If you have a colleague or friend (whether or not they are a scientist) who is skilled in graphic design, it is a good idea to get their opinion and feedback on your poster layout.
2. A clear and logical layout is also essential. Start with an informative and brief title and then include clearly delineated sections showing background, aims, experimental, results, conclusions, references and acknowledgements. The logical flow of the poster should be immediately apparent so that the reader can easily move from one section to the next in the correct sequence. To assist this process, each section should be numbered and you might also wish to include arrows to guide the reader to each successive section.
3. Include a photograph of yourself (as the poster presenter) in a top corner of the poster so that you can be easily identified amongst the crowds of people at the poster session.
4. Don't forget to carefully check the poster size requirements for the particular conference that you are attending. Poster boards vary widely and it is your responsibility to ensure that your poster fits on the poster board which will be provided. Avoid landscape formats as most poster boards will not accommodate this format. The safest approach is to use a portrait format printed in A0 size. Laminating your poster improves its durability but the resulting shiny, reflective surface can be hard to read.
5. Legibility is the chief concern, so keep text to an absolute minimum. Given that most posters are printed in A0 format (841 mm wide x 1189 mm high) and are viewed from a distance of approximately 1m, a good way to check legibility is to print your poster on an A4 sheet and hold it 25 cm from your nose. If you can read the A4 version easily from this distance then your A0 poster will be easily legible from 1 m.

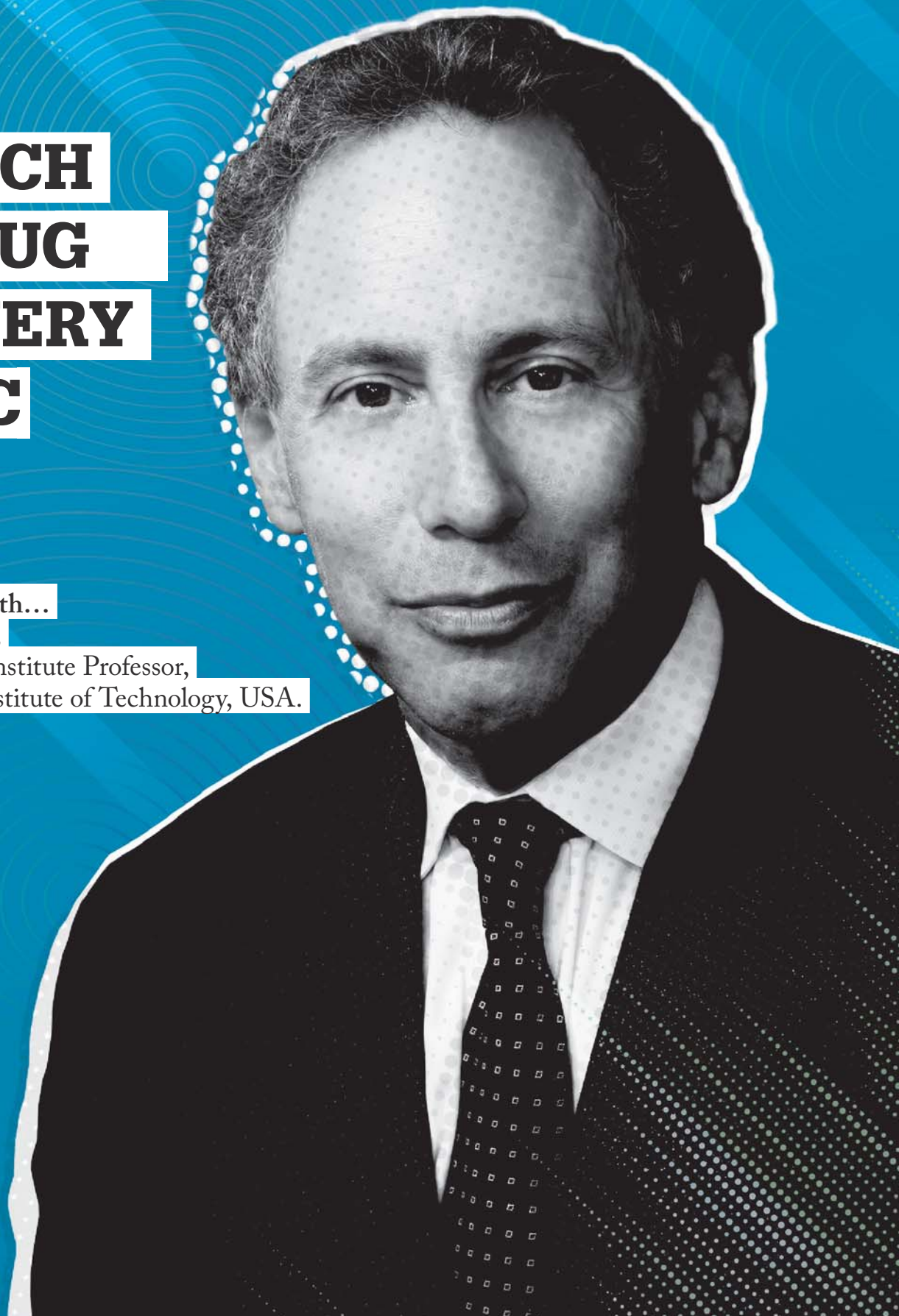
Getting your message across

Once you have managed to attract an audience for your poster (remembering that the audience will normally be one person), you must be ready to engage with that audience in a friendly and open manner. The following considerations might assist in these tasks.

1. Ensure that you attend your poster at the designated time. Most conferences will assign each poster to only one or two poster sessions so the audience will expect you to be present at your poster for the entire designated time.
2. Prepare a 1–2 minute overview of the aims and major findings of your poster and be ready to guide the audience through your poster. When someone stops at your poster you can ask politely "May I give you a 1 minute overview of my work?" People will rarely refuse this offer as it is generally faster than trying to read the poster themselves. This oral presentation must be focused and clear, and you should rehearse it carefully. The audience can then extend the discussion, or move on to the next poster.
3. You may wish to provide an A4 copy of your poster for people to take away and read in more detail later. It is also useful to have an open envelope at the bottom of your poster (many conferences provide this) so that people can leave their business cards to request further information or a reprint of your poster.

A TOUCH OF DRUG DELIVERY MAGIC

Sitting Down With…
Robert S. Langer,
David H. Koch Institute Professor,
Massachusetts Institute of Technology, USA.



How has drug delivery research held your interest for so long?

Over the years, the field has grown tremendously and there are now a lot of journals devoted entirely to this space. Ever since I started out in drug delivery, new questions kept popping up. Can we synthesize optimal biodegradable materials? Can we target different cells? Would non-invasive delivery, like aerosols work? Can transdermal patches deliver complex molecules? I kept going and my lab continues to keep going! We've recently published a paper in Science about a pill that could possibly deliver proteins orally, which has caused a lot of excitement. But beyond proteins there are even more challenges – what about delivering RNA-based drugs or gene editing therapies? Challenges keep arising and we will keep trying to solve them.

What have been the main turning points of your career?

Working with Judah Folkman at Boston Children's Hospital was the first major turning point. By training I'm a chemical engineer. Almost all of my friends went into the oil industry, but I wanted to do something different that would really help people. I applied for post doc positions in medicine and I was turned down a lot. I ended up working with Judah in the 1970s. I didn't know much about biology or medicine and I was the only chemical engineer at the hospital; the experience was eye opening. Judah was a visionary scientist and I was so lucky to have him as a mentor. He had the idea that if you could stop blood vessels then maybe you could stop cancer. And the work eventually led to the world's first angiogenesis inhibitors (although they weren't used in approved drugs for many years). One of my jobs was to develop a drug delivery system to deliver the molecules. I had the idea of using a slow release polymer in the body to release the molecule.

This work was another turning point. At the time, the literature suggested you couldn't use polymers to deliver large molecules, but I didn't read any of those articles and so I tried anyway! I found hundreds of ways of getting it not to work, and one way to make it work. I discovered a way to create microspheres, which could deliver molecules of any size. We published a paper in Nature in 1976 saying how we could do it and a paper in Science on the isolation of the first angiogenesis inhibitors, but there was a lot of scepticism; many said the papers were wrong and didn't make sense.

After my post doc, I applied for a lot of different chemical engineering jobs, but no one wanted to hire me! Eventually, I got a job at MIT, but then the guy who hired me left. And the rest of the faculty told me that I should leave too! It wasn't a great start but I persevered!

Since then, you've won dozens of awards and accolades. What moments stand out the most?

I've had a lot of honors (I sometimes think some of them were given to me by mistake!). I've been to the White House several times to receive national medals and I've also won international awards. One really nice moment was when I won a Queen Elizabeth Prize for Engineering in 2015 for my work on controlled release drug delivery for large molecules. This is a wonderful honor and I also got to spend time with the Queen of England.

What are you working on now?

There are a lot of different projects going on in the lab and we're always publishing new papers. I never expected the lab to grow as it has done! A few years ago, the Gates Foundation approached us to ask about working together. We have a big effort in the lab now on creating drug delivery systems for the developing world, ranging from long-acting oral systems to new types of ways of delivering nutrition, to aerosols, to vaccines. Working with the Gates Foundation meets all the criteria I ever wanted for my career – I always wanted to see science do good and to help people.

How do you encourage industry to adopt your research?

I try to give companies as much data as we can, and we also file a lot of patents, which really helps on the business side. I enjoy working with industry. In academia, we publish papers and try to develop new principles and ways of doing things, but you can only go so far in academia. We need industry to develop our work into commercial products that really help people.

How do you work with young scientists?

I'm really proud of my students. We have over 300 that are professors now both inside the US and internationally. When I work with young scientists, I don't tell them what to do. At school, students are judged by how good their answers are, but when you grow up it's not just about the answers but also about the questions you ask. I want to help my students cross the bridge from people who can give good answers to people who can ask good questions. I try to do that by encouraging them to ask questions, and to strike out on their own to tackle problems. Of course, I am there to help as a guide. We have over 100 people in the lab so there are lots of different people to talk to, which helps generate more ideas that we all get excited about. Everyone works together and pulls together to help each other.

If you weren't a scientist, what job would you have?

Maybe I'd be a businessman – I've enjoyed setting up companies over the years. But I really love magic. It's entertaining to watch and I've done shows for kids at MIT, which was great fun! So perhaps I'd be a magician!

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