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Online this Month

A Scientist Walks into a Bar...

And gives a presentation as part of Pint of Science, a global science festival. Taking place in May, the Pint of Science festival aimsto deliver "interesting and relevant talks on the latest science research in an accessible format to the public". Generally, it involves scientists speaking on a variety of topics, from medicine, to neuroscience, to robotics and more, in bars and pubs. Find out what's on near you by visiting the website.

http://tmm.txp.to/0418/pintofscience

The Power List

The 2018 Power List, starting on page 24 of this issue, features 100 of the most inspirational professionals involved in drug development. The list was compiled based on reader nominations and feedback from a judging panel – but any list will always be subjective. If there are names you would like to see on the 2019 list then let us know by nominating now.

http://tmm.txp.to/2019/powerlist

Easy as B to D?

The Trump Administration's plans to move Medicare Part B drugs into the Part D system, and to change Part D formulary standards to require a minimum of one drug per category rather than two, would mean additional delays and cost barriers for patients. Angus Worthing, Government Affairs Committee Chair, American College of Rheumatology, gives his thoughts on the matter...

http://tmm.txp.to/0418/worthing

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Balloons, representing the 2018 Power Listers, lift drug development UP!

the Medicine Maker

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In My View

Feature

Reports

Sitting Down With

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How Far We've Come

Stop, for just a moment, to contemplate the marvels that pharma has achieved

Thriving in today's world is a challenge for both individuals and companies; lower wages butt up against higher living costs, lower profits clash with higher operating costs. Add political uncertainty to the mix, and it's no surprise that depression, anxiety and low self-esteem are reaching record levels. In the midst of this turmoil, what's our reaction? Taking time out to revel in how far we have come – and celebrating the individuals that make change possible.

In March, I had the opportunity to visit Roche headquarters in Basel. As well as touring some of the labs, I also delved into the "Roche Archives" – a vault of company history, including building plans, staff photographs, published articles, and legal documents (even the original document founding the company, signed in 1896). There was also an old machine for making cough medicine, old diagnostic systems, company awards, Roche coat hangers, Roche teddy bears… Countless objects and documents, each with their own part to play in Roche's success story (photos on page 14).

Several big pharma companies apparently maintain such archives – but only rarely are they the subject of a tour. My guide, Alexander Bieri, seemed pleasantly surprised by my wonder at this room of history. But how can you not be awed by a century-old bottle of medicine (Sirolin)? Roche stores a sample of every medicine ever made by the company, from simple small molecule drugs to the more complex biopharmaceuticals that dominate global pipelines today. The result is an incredible visual reminder of how far the industry has come.

Yes, it is well accepted that manufacturing processes in pharma tend to lag behind those in other industries. It is also well accepted that the prices of medicines are spiraling beyond society's ability to pay for them. And there are many treatments that continue to elude science. But one day, I believe we will have the solutions to these problems.

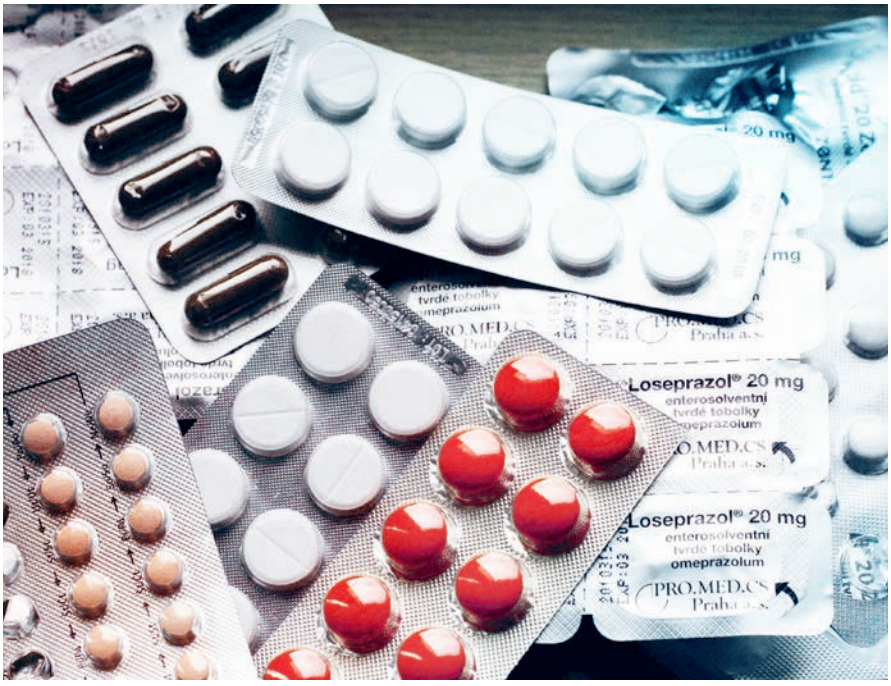
Everyone in the pharma industry today, no matter the job function, is shaping the future of mankind. After all, good medicine underpins health and wellbeing. Celebrating the great and the good within our wonderful industry underpins our annual Power List issue. And so, on page 24, we highlight 100 of the most inspirational individuals advancing drug development and working hard to overcome the trials facing the industry today – and into the future.

Stephanie Sutton
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



In the NIR Future

Could near infrared chemical imaging offer improved 'real-time' monitoring of tablet manufacture?

The pharmaceutical industry is in continuous need of improved process analytical technology (PAT) for monitoring, analysis, understanding, and control. We spoke to Himmat Dalvi, (Associate Professor, Department of Chemical Engineering and Biotechnology Engineering, and Pfizer Industrial Research Chair at the Université de Sherbrooke, Canada) about a new analytical tool – near-infrared chemical imaging (NIR CI) – that could help the manufacture of more uniform tablets (1).

What inspired your research?
Pharmaceutical dosage form manufacturing is undergoing a paradigm shift, from quality by testing to quality by design. The new approach demands more product and process understanding, process monitoring, analysis and control rather than simply manufacturing a product using predetermined fixed process parameters and "passing" or "failing" based on quality specifications. Our main purpose in this research was to evaluate the feasibility of a new process analytical tool, NIR CI (which can provide spectral and spatial information), against existing technology, NIRS (which provides spectral information only), for feed frame monitoring (1).

Why is it important to monitor powder potency inside a feed frame?
The feed frame drives powder blends into tablet moulds. It operates within a high-speed industrial tablet press, and offers the last opportunity to examine the powder blend before tablet compression. However, it also applies considerable strain onto the moving powder blends, which can lead to undesirable quality

phenomena, such as powder segregation. To protect the final product quality, we need to discover occurrences like this in real time, so that intervention is possible.

What are the limitations of NIRS?

NIRS has not yet developed into a fully robust and understood PAT tool for feed-frame monitoring, as parameters, such as spectral baseline variations and the variable location of NIR probes on the feed frame, lead to variable concentration predictions from lab to production, or batch to batch.

How did NIR CI compare?

NIR CI not only performs on a par to NIRS for concentration monitoring, but also shows potential in probing local concentration variations, thanks to the larger sample area it makes available to us.

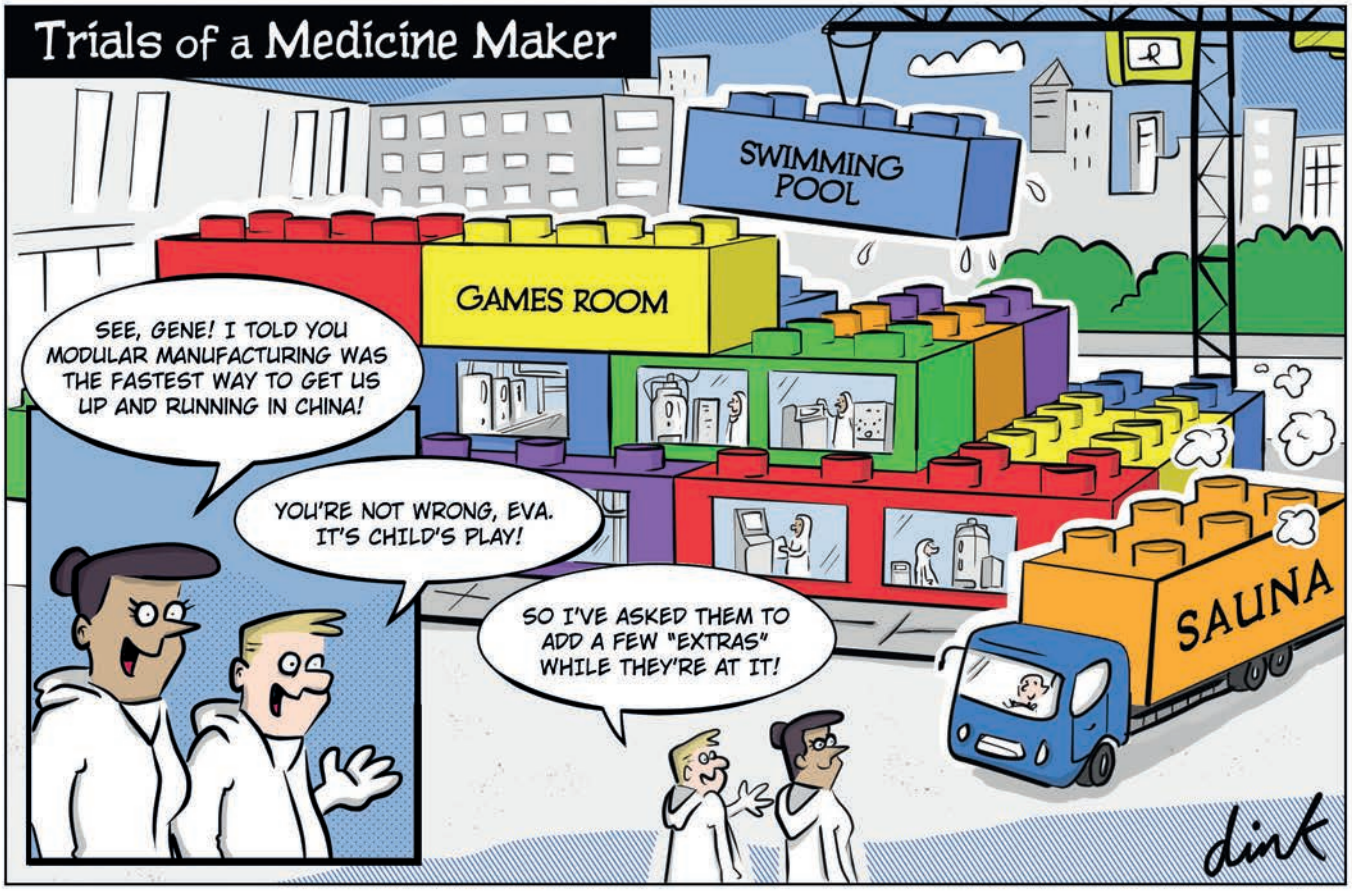
What difference could your research make?

Our research proves the feasibility of NIR CI for testing moving powder samples, while also allowing analysis of an increased sample area – thus opening doors for turning NIR CI into a robust PAT tool for feed-frame monitoring. It provides a visual presentation of the process, which could be very useful for process operators in spotting any adverse quality phenomena, such as segregation, in real time. It could also be used for similar operations involving powder samples in motion.

Reference

1. *Himmat Dalvi et al., "Concentration monitoring with near infrared chemical imaging in a tableting press", J Spectral Imaging, 7, a5 (2018).*

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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Gearing up for GDPR

New data protection regulations are coming to the EU this May – and pharma will be affected

The European Parliament adopted the General Data Protection Regulation (GDPR) in May 2016, four years after it was first proposed. This year, it will enter into force. The GDPR was created with the aim of unifying data regulations among European countries, and updating data protection laws for the modern world – as people share more personal data than ever before, new regulations are needed to give individuals more control over how their data is used and shared, both within and outside the EU.

The new regulations promise to have a far-reaching impact for businesses and organizations across the board, and have generated a significant amount of discussion. Some feel that pharma is simply not prepared for the new rules (1) – but with little time left before they begin to be enforced, the industry will have to adapt, or face some serious penalties.

Brendan Barnes Director of Data Protection, IP and Global Health at the EFPIA tells us more about the changes GDPR will bring.

Health data

- "A key concern for the industry is that the GDPR should support data-driven research and the text of the regulation does this. It is very clear that the ability to access and re-use personal health data with appropriate safeguards will be a very important driver of health system performance improvement and of pharmaceutical innovation. These benefits are already being seen."
- "The GDPR is intended to enable individuals to exercise control over their data. Companies, contractors and investigators will need to understand how to respond to access requests."

Clinical trials

- "We are seeing uncertainty regarding the impact of GDPR on clinical research. When we surveyed EFPIA members last year, it was clear that there were many areas where the interaction between the GDPR and the Clinical Trials Regulation was causing confusion. These include breadth of consent, data retention, and de-identification/anonymization obligations."
- "The standard of consent has been raised under GDPR, but this has to be understood against the context that the GDPR deals with consent across all sectors. Consent processes within clinical research are already of a very high standard and are unlikely to greatly change, although new information notices may be required. The GDPR makes extensive provision for research and acknowledges the need for specific treatment of research data. However, there is still a lot of uncertainty. An example is the right to be forgotten. While this is an important right in a general sense (for example, removing your data from a social media website), the right needs to be reconciled with the need to preserve data in a clinical trial, including data from subjects who have withdrawn from the trial. Recent guidance from the article 29 working party has again put this in question."

Companies outside the EU

- "The GDPR applies to all businesses established in the EU and to businesses worldwide who are offering services in the EU, or monitoring EU citizens."

Ensuring compliance

- "The Data Privacy regulators continue to issue guidance on specific issues which companies then need to review in relation to their internal procedures. There is a big focus on compliance as there will be for all organizations. Particular issues for life sciences companies will be to be clear about the basis on which they are processing sensitive personal data (in particular regarding the GDPR scientific research exemption) while taking into account the specific safeguards of our sector, ensuring that information notices are updated where appropriate, and assessing the basis under which they are transferring data to third countries."
- "The GDPR places a strong emphasis on accountability – a shift from the directive that preceded it – and contains very substantial sanctions for non-compliance. Companies will find that they need to embed data protection in their processes and educate staff to understand the issues. This could involve general education sessions, specific staff training and review of internal HR policies."

Reference

1. *Clinical Leader, "Pharma 'not prepared' for new EU Data Protection Regulation", (2017). Available at: bit.ly/PharmaGDPR. Accessed April 5, 2018.*

Let's Get Ready to Serialize!

One third of pharma companies claim they are "very ready" for the upcoming serialization deadlines. But are they really?

The US and EU serialization deadlines are both less than a year away, with the EU Falsified Medicines (FMD) Directive coming into force on February 9, 2019 and the US Drug Supply Chain Security Act (DSCSA) coming into force on November 27, 2018 – the latter already having been delayed by one year. So how prepared are pharma companies?

Tracelink surveyed 660 companies across segments of the supply chain, including 174 drugmakers, to find out. In their Global Drug Supply, Safety and Traceability Report, they found that only one-third of respondents believe they are "very ready" for serialization. The data also revealed that no single company has actually completed all the basic steps for serialization readiness. According to the authors, the survey proves "that the companies who feel very ready are considerably 'less ready' than they think."

Reference

1. *TraceLink, "TraceLink Publishes Full Analysis from the Global Drug Supply, Safety and Traceability Report, Industry's Largest Survey on Life Science Companies' Readiness for Serialization Deadlines" (2018). Available at: https://bit.ly/2JvuQfP. Accessed April 10, 2018.*

US DSCSA

Of the 146 pharma respondents that had DSCSA requirements, **only 33%** *responded that they felt very ready to meet the deadline.*

Some fundamental steps have been taken

90%

had taken steps to prepare for master data management

72%

felt prepared because they understand the law and have enough resources

80%

believe they will be shipping serialized product before the deadline

62%

began preparing before the deadline

Packaging lines and trade partner connections are the most incomplete

13%

of DSCSA pharma companies acknowledged that at least 20% of their volume is serialized

12%

say that most of their internal packaging lines are ready

12%

have internal packaging lines ordered and installed

EU FMD

Of the 95 pharma respondents that had EU FMD requirements, **only 33%** *believed they are very ready for the EU FMD deadline.*

As with DSCSA, none had completed all of the basic steps.

94%

had taken steps to prepare for master data management

46%

said the majority of their internal packaging lines were ordered and installed

41%

say that most of their internal packaging lines are ready

27%

believe they will be sending serial numbers to EU hub by deadline

20%

are not concerned that equipment shortages would affect compliance

Blast From the Past

Photos from the Roche Archives beautifully illustrate the industry's past

As mentioned on page 7, the Editor of The Medicine Maker, Stephanie Sutton, recently visited the Roche Archives in Basel. Roche was founded on October 1, 1896 by Fritz Hoffman-La Roche, who believed that the industrial manufacture of medicine would significantly help to fight disease. He was also keenly interested in the idea of branded pharmaceutical products. The company has been storing documents, photos, medicines, equipment and other items ever since it was founded. We thought you might enjoy some of the photos from her visit…

Clockwise from left: Airol powder wound disinfectant (one of the first products launched by Roche). Initially it was not a success, although today Airol is used to help treat acne.
Digalen heart tonic – in a heart-shaped bottle – launched in 1904 and was considered a key medical innovation at the time.
Sirolin, a non-prescription cough medicine launched in 1898, remained on the market for over 60 years – this was the first big success for the company.
Shelves showing a plethora of awards, items and equipment.

Business in Brief

Consumer unit sales, stem cell therapy approvals and beating counterfeits with blockchain… what's new for pharma in business?

Deals & acquisitions

- GlaxoSmithKline is acquiring Novartis' consumer health business for $13 billion. The business was initially a joint venture between the two companies and includes products such as Nicotinell nicotine patches, Panadol headache tablets and Sensodyne toothpaste.
- Pfizer has also been looking for a deal regarding its own consumer health business. The company has been assessing options since October 2017. Potential bidders included GSK and Reckitt Benckiser, but both pulled out in March. Now, Pfizer has been reported by many to be in talks with Procter & Gamble.
- Takeda has confirmed that it is considering an offer for Shire with the aim of boosting its footprint in gastroenterology, oncology and neuroscience. No approach has yet been made to Shire's board and Takeda stressed that the offer was at a "preliminary and exploratory stage".

Cell therapy

- A report from BCC Research, Cell Therapy process: Global Markets and Technologies, seems to confirm the high expectations for the future of the field. The reports claims that the cell therapy processing market is expected to see a compound annual growth rate of 30.9 percent through 2022 and be worth $5 billion.
- Alofisel (darvadstrocel) has become the first allogeneic stem cell therapy to receive central marketing authorization approval in Europe. The therapy is approved for patients with Crohn's disease who do not respond to current therapies.
- An encapsulated cell therapy for treating type 1 diabetes is on the cards for Eli Lilly, which has licensed the technology from Sigilon Therapeutics. Lilly will use Sigilon's Afibromar platform for islet cell encapsulation and the companies hope the treatment will restore insulin production over sustained periods without triggering an immune reaction.
- Pfizer and Allogene Therapeutics have entered into an "asset contribution" regarding Pfizer's CAR-T portfolio. Allogene will lead the development while Pfizer will participate financially through a 25 percent ownership stake in Allogene.

Emerging technology

- A collaboration between Parkinson's UK and The Cure Parkinson's Trust to identify new treatments for the disease has won the inaugural BenevolentAI Award. The award was presented through a competition run with the Association of Medical Research Charities and will give the collaboration full research support from BenovolentAI, which specializes in using artificial intelligence for drug discovery.
- DHL is partnering with Accenture to trial blockchain in pharma supply chains. In particular, the companies want to see if the technology can help prevent the distribution of counterfeit drugs by ensuring the improved accuracy of supply data.

Fame and FOYAs

ISPE announce the 2018 Facility of the Year category winners…

The International Society for Pharmaceutical Engineering's (ISPE) Facility of the Year Awards (FOYAs) are here again for 2018. Here, we highlight those companies recognized for expertise and forward-thinking innovation in healthcare manufacturing facilities.

- Project Execution - BioMarin Pharmaceutical for Project Faith, which involved creating a gene therapy manufacturing facility (the first of its kind in the world). An office and warehouse building in Novato, California, were converted into the 18,000 square foot gene therapy facility – with the buildout and commissioning of the facility finished in less than a year.
- Facility Integration – Shire, for the creation of a 120,000 square foot purification facility in Los Angeles, which was integrated alongside eight other buildings and despite significant space constraints.
- Operational Excellence – Another win for Shire in Los Angeles; for the development of their "next generation quality control lab". Lean principles were incorporated in every aspect of project execution. Organic Kaizen principles were also used.
- Facility of the Future - Vetter Pharma-Fertigung GmbH & Co.KG for the creation of its Center for Visual Inspection and Logistics. According to ISPE, the facility features a number of flexible options for utilizing space and expanding the site to fit customer needs.
- Sustainability - Wyeth Pharmaceuticals Co, a Pfizer Company, for the Pfizer Consumer Health manufacturing facility in Suzhou, China. The facility features recycling of 100% of treated wastewater for cooling tower makeup, toilets and lawn, zero nitrogen and phosphorus in wastewater discharge, rainwater harvest system, and solar-powered generation with photo-voltaic cells.

Honorable mentions were also given to Emergent BioSolutions for its BARDA Center for Innovation in Advanced Development and Manufacturing in Baltimore – a partnership between industry and government that aims to act rapidly to stop significant public health threats – and to the Government Pharmaceutical Organization (GPO) for their Rangsit Pharmaceutical Production Plant 1 in Pathumthani, Thailand, which uses quality by design and international best practices to manufacture affordable HIV medicines.

The 2018 FOYA winners will be formally recognized at the ISPE Facility of the Year Awards Banquet and Dinner in Philadelphia in November, where the overall winner will also be revealed.

Reference

1. *ISPE, "2018 ISPE Facility of the Year Award Winners Announced", (2018). Available at bit.ly/2018FOYAs. Accessed April 6, 2018.*

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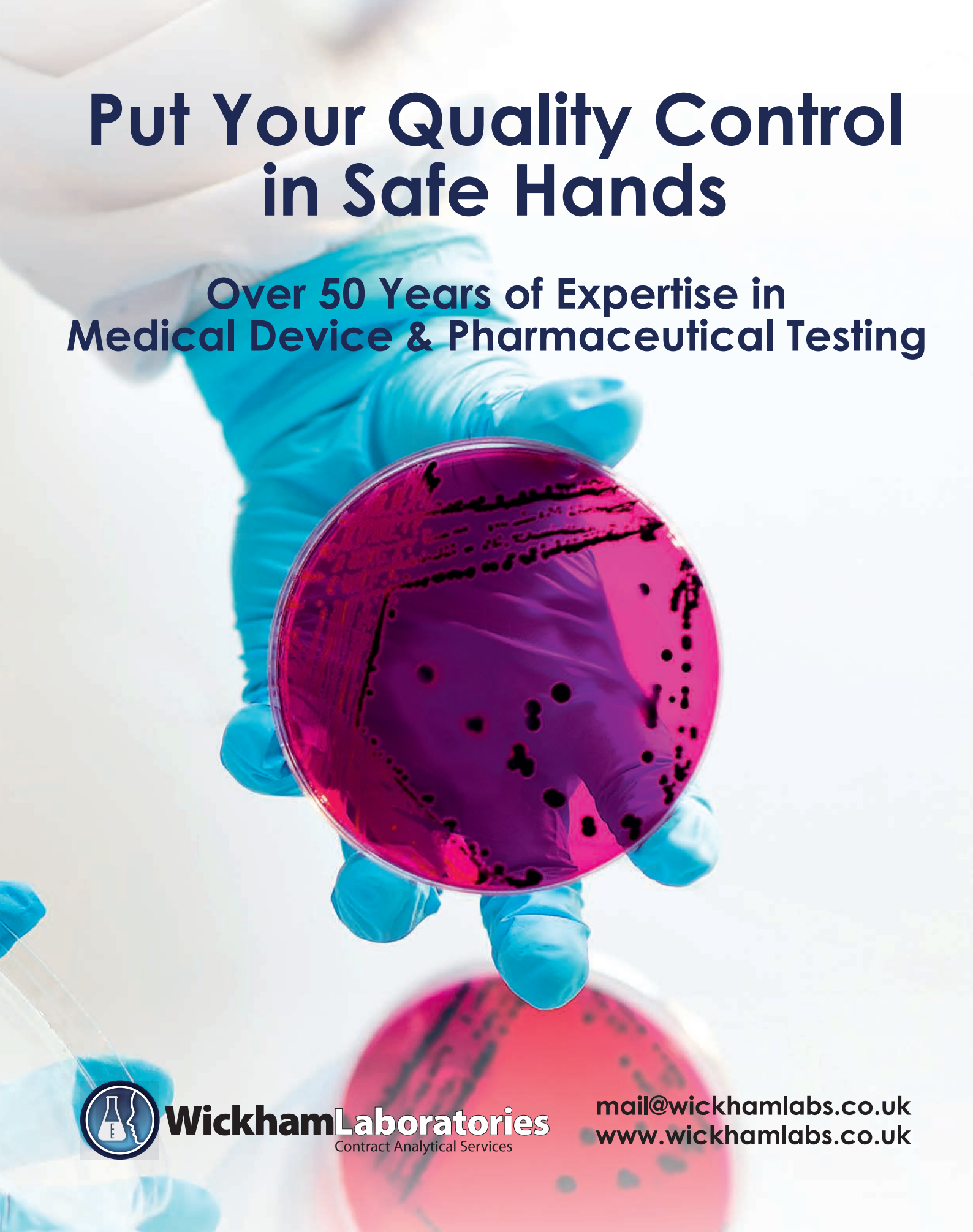

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Keeping Fit With Age

The saying goes that with age comes wisdom, but in manufacturing it can also bring about unreliable facilities and equipment. Proactive stress testing is a must to keep facilities fit and healthy.

By Allan Bream

Like everything else, sterile manufacturing facilities age and performance deteriorates over time. Many of the first and second generation biomanufacturing facilities are now 15-20 years old, so it's no surprise that sterility issues and product recalls are on the rise. One of the early warning signs that a facility is in need of some attention is an increase in batch failure rates – companies want batch failure to be less than 1 percent, but the Parenteral Drug Association has noted that it can be much higher: "Alarmingly, 80 percent of respondents to a survey conducted by the Parenteral Drug Association in 2016 had batch rejection rates of up to 4 percent due to a lack of sterility assurance or the potential thereof, and 15 percent of those respondents had rejection rates of 5-10 percent" (1).

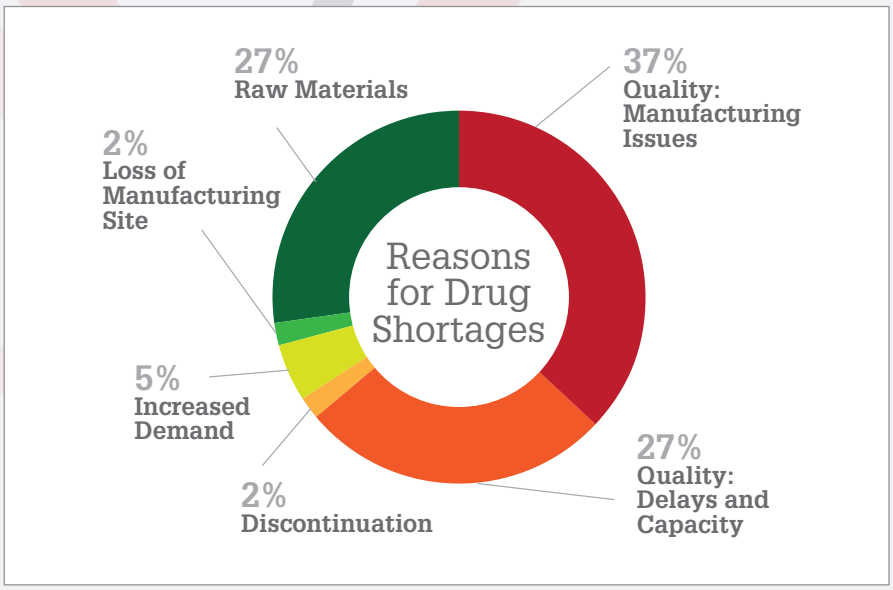
Issues with facilities and equipment can lie dormant as operators or maintenance technicians make small tweaks to compensate, but in time this can lead to other problems. Increasing contamination rates in older bioreactors are one common problem, for example, and the kneejerk reaction is often to turn up the steam cycle or temperature, but this can lead to gasket or other component failures. If equipment is becoming a source of contamination or is difficult to clean, then it is likely to be outmoded and you may need to consider replacement. Also, bear in mind that older equipment designs tend not to be the most efficient anyway – they may have nooks and crannies that complicate cleaning, or may require significant manual intervention, so it's good practice to continuously evaluate newer systems.

Sometimes it is not necessarily the age of a facility or its equipment that are a problem, but simply the fact that times and product demands have changed, and that existing equipment can't keep up. Problems in facilities of any age can also stem from lack of operator training or failure to follow standard operating procedures. If procedures and training are not adequately documented, issues can arise as companies lose legacy employees and bring in new operators or technicians – who may be eager but unwittingly undo procedures. I am sure that everyone reading this is also aware that it is all too common for one step to be skipped because it is a little troublesome or because people don't think it matters… They might get away with it the first time, but then it becomes habit – and in time, other shortcuts or small problems will culminate to form a much larger issue.

Fit facilities

When addressing a problem, you should never try to fix it in a vacuum; it must be properly socialized and vetted among all of the applicable departments, such as operations and process staff, quality assurance, validation, maintenance, quality control etc – so that you can ensure the solution doesn't cause other issues down the line. However, it can be very difficult to identify what the root cause of the problem –

"Sometimes it is not necessarily the age of a facility or its equipment that are a problem, but simply the fact that times and product demands have changed."



Reasons for drug shortages. Data from the FDA (https://bit.ly/2EqEX1I). Quality manufacturing issues and quality issues related to delays and capacity are the biggest contributors to drug shortages.

and thus the best solution – actually is. In my experience, people are very quick to assume they know what has caused the problem, but I always recommend a thorough, unbiased root cause analysis. When contamination arises, various groups within an organization will often each have their own view of the source, leading to disagreements and months of wasted time in chasing down assumptions that ultimately turn out to be incorrect. Often, a root cause is not immediately discoverable until you have performed an impartial, passion-free analysis.

I recommend using a full "stress test" to identify problems and design issues that may require remedial action. This should examine all operations and determine where the soft points may be – and whether the facility is still fit for purpose. A stress test is a comprehensive analysis that should begin with discussions and interviews with all of the different groups involved in maintaining the facility. You should examine manufacturing processes, equipment, training and history, and be on the lookout for any deviations. Also look at batch records, change control and corrective action plans for problems that may have arisen – in case they have had unexpected effects. With engineering and validation, you can get a sense of how manufacturers have been tracking equipment performance by looking at equipment alarms that have come up recently. And from there you follow the threads back… it is quite common for a problem to start with an alarm that has been ignored, or thought to be irrelevant. You also need to talk with maintenance groups and look at work orders, unscheduled maintenance, and maintenance frequency. Is it strictly time-based, or are they looking at how hard or how frequently equipment is run? In some facilities, equipment is run close to 100 percent capacity – and in that case preventative maintenance and changes may need to be made more frequently to avoid problems.

Plan and prepare

It could be that the stress test reveals no problems, which is fantastic news! But it doesn't mean you should be complacent – you still need to plan for timely repairs and replacements to ensure that your facility continues to be fit for purpose. If nothing requires immediate action then you can use the time for future planning. For instance, if you have a piece of equipment that can only perform 50 batches a year, but you're projecting the need for 75 batches in the next two or three years then you need to start planning how you will adjust. Also, don't forget that your staff will need ongoing training as new technology is integrated and as quality standards change.

Every now and then I come across someone who says, "Why don't we just let things fail and then fix them? What are the consequences of just waiting until something breaks?" My biggest advice is to always be proactive with your facility before issues arise. Once you have a problem, your capacity plan is at risk. Stress testing a facility proactively allows remediation or upgrades to be planned, meaning you can choose the best time to shut down a facility for any work and fit capital spending into budgets. And remember, the FDA expects a facility and its equipment to be designed and maintained for what you intend to produce in that facility – it is cGMP (current good manufacturing practice) for a reason. The FDA emphasizes the word "current" and grandfathering in an old approach or an old piece of equipment is no longer considered acceptable. Your technology does not have to be leading edge, but it must be accepted and you must have data to back up your approach.

In the pharma industry, all manufacturers have a duty to ensure that their facilities are up to scratch. The key goal is to supply patients – contaminations and drug shortages prevent medicines from reaching patients and can cost lives. This is something we have a duty to avoid. There is nothing worse than having a need in the market for a medicine you produce – and being unable to supply it.

Allan Bream is Associate, Lead Biopharmaceutical Specialist, at CRB Raleigh, North Carolina, USA.

Reference

1. *PDA Aseptic Processing Survey 2016*

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

Algal Boom

Algae have proven to be experts in molecular warfare with bacteria – and now is the time to apply that expertise to drug discovery and development.

By Andrew Dahl, President and CEO of ZIVO Bioscience.

Certain algal species have been cultivated in Asia as both a source of nutrition and as a traditional medicine for centuries. What most people don't realize is that algae range in size from microscopic cells floating in freshwater, to the huge kelp beds off the California coast, and everything in between. The very smallest, as you can imagine, are referred to as microalgae, and most of the green stuff people consider seaweed is technically macroalgae. About 72,000 species of algae are known – and in my view there are probably double that number yet to be discovered and classified. Of that enormous number, only about a dozen are being cultivated commercially anywhere in the world. Algae can be cultivated in natural and artificial ponds, on wooden frames set in estuaries, in photobioreactors and fermentation tanks. There's plenty of opportunity to cultivate something that has never been grown or consumed by humans or animals, and some of these could be very useful for new pharmaceuticals.

Algae are incapable of movement on their own and are completely exposed to their environment. To regulate their immediate environment and to protect themselves, algae excrete many different types of exogenous secondary metabolites. One of the biggest threats to most forms of algae is dissolved oxygen in the water, which can degrade the cell wall (even though algae produce oxygen as part of photosynthesis and excrete it into the water). One protective measure is to allow certain types of bacteria to form a plaque over the surface of the algae, but not so thick that it prevents light from reaching the algae's chloroplasts; the bacteria will absorb the oxygen and also produce a clear protective slime that protects both algae and bacteria. However, some bacteria are more aggressive and begin to attack the host algae, which responds with an arsenal of bioactive molecules that can paralyze the bacteria – sometimes killing it altogether – or fool it into thinking there are already too many bacteria on the host algae and, thus, the bacteria stop reproducing.

"Algae, much like many other natural sources, have been overlooked in current drug development initiatives."

"There's plenty of opportunity to cultivate something that has never been grown or consumed by humans or animals – and some of these could be very useful for new pharmaceuticals."

This warfare at the molecular level is why algae should be taken more seriously as a source for new and novel therapeutic agents. Algae can produce both small and large molecules – some are toxic, but most are not. The challenge is that a single strain of algae will produce dozens, if not hundreds, of different compounds over the course of a single day, and separating the active from inactive is a gigantic task. However, well-documented bioassays, as well as knowledge regarding gene signaling, histopathology and mechanisms of action can help guide researchers to particular metabolites. For the past 10 years, I've been involved in testing select algal strains both in vitro and in vivo, and the results are promising, especially with respect to immune/inflammatory modulation and hypercholesterolemia modification, both in mammals.

Algae much like many other natural sources, have been overlooked in current drug development initiatives, which instead focus on computer-generated 3D structures, predictive modeling and high-throughput screening to comb vast libraries of seemingly random molecular combinations, looking for a beneficial effect. Certainly, these are crucial developmental tools, but it is unfortunate that the field of pharmacognosy, or the study of medicines derived from natural sources, has become somewhat esoteric and uncommon in drug development circles.

In Asia, especially Japan and China, research into algae-based drug candidates has been ramping up over the past two decades, and I think we will see a pipeline developing in time. Fascinating work is also taking place in the US – particularly the work of William Gerwick at the Scripps Institute in La Jolla, and Stephen Mayfield's work at the California Center for Algae Biotechnology, also located in La Jolla, where marine algae metabolites are being investigated for new cancer drugs. As of today, there are a handful of algae-based pharmaceuticals in pre-clinical trials. As well as aiding drug discovery, algae can be modified to produce biopharmaceuticals, and in some cases, more efficiently and safely than other recombinant platforms. For example, research presented in The Proceedings of the National Academy of Sciences has highlighted how a genetically engineered strain of algae can be used to produce a complex human therapeutic drug. According to researchers at the University of California-San Diego, this particular strain, Chlamydomonas reinhardtii, can produce a wide range of human therapeutic proteins more efficiently than bacteria or mammalian cells (1). In fact, many of the algae

being investigated are modified strains designed to produce a therapeutic that's been previously produced by other recombinant platforms, such as yeast or E. coli. In the near future, popular drugs like insulin, cytokines, monoclonal antibodies and subunit vaccines may be produced by algae at a lower cost and higher purity. The variety of research being conducted with algae for the potential development of pharmaceuticals has been widely reported. For example, work on the ability of genetically engineered algae to selectively kill cancer cells has been reported in Nature Communications (2) and a more comprehensive review of the role of algae in pharmaceutical development has been published in the Journal of Pharmaceutics and Nanotechnology (3). The field is developing slowly, but I'd like to see it pick up pace and head towards more mainstream adoption.

References

1. *M Tran et al., "Production of unique immunotoxin cancer therapeutics in algal chloroplasts", PNAS. 2, 100, 14 (2013).*
2. *B Delatat et al., "Targeted drug delivery using genetically engineered diatom silica", Nat Commun (2015).*
3. *T Aditya, G Bitu, EG Mercy, "The role of algae in pharmaceutical development", Pharm Nanotechnol, 4, 82-85 (2016).*

Celebrating the Digital Age

Digital technologies could transform healthcare, including drug discovery, development, clinical trials and patient empowerment.

By Sophie Kornowski-Bonnet, Head of Roche Partnering, Basel, Switzerland.

At times, working in the healthcare industry can be very exciting, but also challenging and frustrating. You may have a very exciting drug candidate in development, and yet you won't be able to get it to patients for a very long time. One of the big focuses for Roche right now is personalized healthcare – many people in the industry, including myself, are very excited by this concept and approach. Personalized healthcare is about matching treatments to patients' individual needs, often driven by their genetic profiles – and we are seeing many advances in personalized cancer therapies in particular.

Personalized healthcare goes hand in hand with digital technologies – for example, machine learning and other advanced analytic techniques can enhance drug discovery and development by identifying new drug targets and effective surrogate markers. Research and development at Roche focuses on the therapeutic areas of oncology, ophthalmology, asthma, rheumatoid arthritis, neuroscience, inflammatory bowel disease and infections – and digital technology that allows us to deeply explore the science of disease and its genetic basis are incredibly important. As one example, we are using smart technology and genomic analyses to identify new antibiotics targeting gram-negative bacteria.

Roche's neuroscience portfolio includes several compounds for neurodegenerative diseases, including potential therapeutics for Alzheimer's disease and Parkinson's disease in advanced stages of clinical development. These could potentially become life-changing medicines for patients, but there is still the challenge of developing them in a timely manner. With digital technologies we can enhance our approach to clinical trials, making them faster, more efficient and cost effective. Data is the key here. At

"We are very impressed with their ability to build high quality, longitudinal, real world datasets, which have allowed us to better understand scientific hypotheses regarding whether people will respond to drugs or not."

"These could potentially become life-changing medicines for patients, but there is still the challenge of developing them in a timely manner."

Roche, we recently acquired Flatiron Health, a company which specializes in real-world oncology data. We have been a partner of Flatiron for a very long time, and we are very impressed with their ability to build high quality, longitudinal, real world datasets, which have allowed us to better understand scientific hypotheses regarding whether people will respond to drugs or not. We used their data to develop virtual control arms for one of our lung cancer drugs, resulting in faster patient access in Europe. I think it's fantastic to see companies like Flatiron thinking outside of the box and asking how clinical trials can be enhanced.

As head of partnering at Roche, my role is to look for innovations that could fit with the Roche pipeline – and we are spending a lot of time right now reviewing personalized and digital healthcare technologies. We aren't just looking for technologies that can aid drug development, however; mobile technologies, apps and other systems that can empower patients are also vital. Mobile apps can help collect data on patient conditions and encourage greater communication between a patient and physician – which can only lead to better health outcomes. I am really passionate about this area.

At Roche. we are not only focused on developing better medicines, but also on getting the right medicine to the right patient faster than we have in the past – and digital technologies are key to enabling this.

Read more from Sophie in this month's Sitting Down With on page 50.

Celebrating the World's Top 100 Medicine Makers

Bringing new drugs to patients is an incredibly difficult task that involves numerous indispensable actors – from pioneering entrepreneurs and CEOs, to industry experts, to dedicated researchers, to regulators who keep everyone on the right tracks. And that's why we have once again divided our annual Power List of the top 100 inspirational industry professionals into four categories: Masters of the Bench, Industry Influencers, Business Captains, and Champions of Change. The illustrious members of each group contribute, in various ways, to the life-changing, and often life-saving, work carried out by the biopharmaceutical industry.
It is our great pleasure to present to you The Medicine Maker 2018 Power List, which was compiled based on nominations from readers and the input of an expert judging panel.

MASTERS OF THE BENCH

1. ROBERT SAMUEL LANGER

INSTITUTE PROFESSOR, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, LANGER LAB

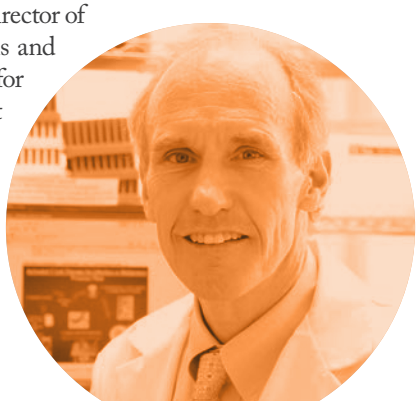
The most cited engineer in history and one of the most prolific inventors in all of medicine, Robert has nearly 1,300 issued and pending patents, many of which have been licensed or sublicensed to over 350 pharma, chemical, biotech and medical device companies. He has been honored with over 200 major 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."

3. CARL JUNE

RICHARD W. VAGUE PROFESSOR IN IMMUNOTHERAPY, UNIVERSITY OF PENNSYLVANIA

Carl is also Director of the Center for Cellular Immunotherapies at the Perelman School of Medicine, Medicine Director of Translational Research Programs and Director of the Parker Institute for Cancer Immunotherapy, both at the University of Pennsylvania. He is also Co-Founder and chief scientific advisor of Tmunity Therapeutics. Carl and his fellow "CRISPR Pioneers" were named as runners up in Time Magazine's Person of the Year. "Success is the sum of intelligence, energy and persistence – and ending the cancer epidemic is what drives me to succeed. In pharma, I'd like to see more long-term vision, rather than quarter-to-quarter milestones."



2. CHRISTOPHER J.H. PORTER

PROFESSOR AND DIRECTOR, MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

"I'm motivated by my next discovery; however big or small. I became an academic because of the excitement, wonder – and sometime panic! – that discovery can bring. I now have many different tasks to get through, but the best part of every day is still the anticipation of what the next graph might show. I realize that this is a utopian and perhaps unrealistic aim, but I'd like to see a greater emphasis on addressing unmet medical need in a manner that is not driven by market size. Philanthropy and public/private partnerships are increasingly trying to redress this balance, and have been successful in certain areas, but there is much more that can be done."

4. DAVID BALTIMORE

PRESIDENT EMERITUS AND ROBERT ANDREWS MILLIKAN PROFESSOR OF BIOLOGY, CALIFORNIA INSTITUTE OF TECHNOLOGY

David Baltimore's love for research was born after spending a summer seeing scientists at work at the Jackson Laboratory in 1955. Since then, his achievements include a National medal of Science and a Nobel Prize in 1975 for the discovery of reverse transcriptase, which implied that cancer could be caused by genetic means – a wide-open question at the time. He has played a significant role in the development of biotechnology since the 1970s.

5. RODERICK MACKINNON

SCIENTIFIC CO-FOUNDER AND CO-CHAIR, FLEX PHARMA

A Nobel laureate and an endurance athlete, Roderick's 2003 Nobel Prize was awarded for his work on ion channel activation. This work went on to become the foundation of Flex Pharma's clinical approach to muscle cramping – and the company hopes to translate their findings into treatments for patients with a range of neuromuscular disorders which cause muscle cramps and spasms.

6. NICHOLAS A. PEPPAS

PROFESSOR AND DIRECTOR OF THE INSTITUTE FOR BIOMATERIALS, DRUG DELIVERY AND REGENERATIVE MEDICINE, THE UNIVERSITY OF TEXAS AT AUSTIN

"This has been a banner year for my team, with achievements including our new treatment for hemophilia using oral delivery of hematological factor IX, and our work developing drug delivery systems of siRNA and interferons. I am driven by a continuous excitement to devise new treatments, new therapeutic agents, and new medical devices that will help patients who suffer from debilitating diseases. I am particularly interested in understanding the mechanisms and providing innovative treatments for autoimmune diseases."

7. SHINYA YAMANAKA

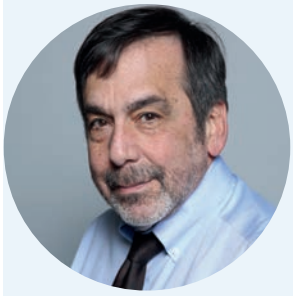
DIRECTOR AND PROFESSOR, CENTER FOR IPS CELL RESEARCH

Shinya's pioneering work on stem cells has gained him huge scientific recognition. After reprogramming adult mouse (2006) and human (2007) somatic cells into what are now called induced pluripotent stem (iPS) cells, he was awarded a Nobel Prize in 2012. "Working on the medical applications of iPS cells is still my focus," says Shinya, "and I would like to see the pharma industry collaborate more with academia to develop drugs for intractable diseases." Asked what piece of advice he would offer young researchers, he says "I wish I had improved my English communication skills in my 20s, because English proficiency is crucial for scientists to better compete or collaborate with researchers overseas."

8.MICHAEL N. LIEBMAN

MANAGING DIRECTOR AND FOUNDER, IPQ ANALYTICS LLC

"There is an increasing need to understand and address the complexities of disease in terms of clinical presentation, patient diversity and physician practice and this can only be achieved through more critical analysis and less dependency on technology. My career advice? There are no bad experiences, only new opportunities to learn and improve."



9. ANDREAS SEIDEL-MORGENSTERN

DIRECTOR, MAX PLANCK INSTITUTE FOR DYNAMICS OF COMPLEX TECHNICAL SYSTEMS, MAGDEBURG

Andreas' research focuses on developing concepts to better link the various steps involved in drug production. "I have a lot of ideas, and I am driven to evaluate their potential. This includes both theoretical concepts as well as practical implementations. I see it as a privilege that I can do this together with so many talented young people" says Andreas. "I would like to see more continuous production process applied in the pharma industry."

10. CHI VAN DANG

SCIENTIFIC DIRECTOR, LUDWIG CANCER RESEARCH

Chi is well-known for his contributions to the understanding of the Myc oncogene – his research has led to studies dedicated to the targeted disruption of aberrant cell metabolic pathways, with the aim of developing drugs to inhibit cancer. "Patients dying of cancer remind me every day why I do what I do. As with everyone else, my life has been personally touched by cancer, and as a trained medical oncologist, I am humbled by cancer as a formidable foe. A career is a journey in continuous learning – I learn something new every day."

PHIL S. BARAN

DARLENE SHILEY CHAIR IN CHEMISTRY, SCRIPPS RESEARCH INSTITUTE

Phil has racked up a number of impressive natural product syntheses, and won dozens of chemistry's highest accolades. His passion is "fundamental chemistry with rapid translational potential" and a pivotal moment was when he realized "one can't trust in public funding alone to finance a lab." Phil would like to see more partnerships with academic labs, and the appointment of chemists to leadership positions.

JONATHAN BONES

PRINCIPAL INVESTIGATOR, NIBRT CHARACTERIZATION AND COMPARABILITY LABORATORY

Jonathan joined NIBRT in 2007, and returned there in 2012 after spending some time at the University of Boston studying glycomics and proteomics for a better understanding of mammalian cell bioprocessing. "I'm still in the early stages of my career, and what's exciting is how fast the biopharmaceutical industry is moving," says Jonathan. "The industry is so dynamic, and it continually requires us to develop new approaches. Working with great people all driven by a common goal to make better, safer more effective treatments for the patients who need them is what motivates me."

CHAS BOUNTRA

PROFESSOR OF TRANSLATIONAL MEDICINE, NUFFIELD DEPARTMENT OF CLINICAL MEDICINE, UNIVERSITY OF OXFORD

Before returning to Oxford, Chas was Vice President and Head of Biology at GlaxoSmithKline. He was involved in the identification of more than 40 clinical candidates for many gastro-intestinal, inflammatory and neuro-psychiatric diseases. More than 20 of these molecules progressed to patient studies, and over five progressed to late stage development. "Pharma is building increasingly porous relations with academia. I am sure this will foster a broader appreciation of the difficulties we face, change the reputation of the industry for the better, and accelerate the development of novel medicines for society."

JONAS BOSTRÖM

PRINCIPAL SCIENTIST, ASTRAZENECA; CHIEF EXECUTIVE OFFICER, EDUCHEM VR

"I really love what I do! I can't imagine a better job than using computers and combining new (and old) technologies in innovative ways in scientific research, with the grand purpose of treating diseases. I expect, and hope, that a lot of things will become automated, with computers doing much more for us – from synthesis machines to AIs designing molecules with optimal properties, to using immersive technologies like virtual reality to gain a deeper and better understanding of the drugs we are developing. Without a doubt, embracing new technologies will allow us to push the boundaries of science, enabling new ways of working while making speedier progress."

MEINDERT DANHOF

RETIRED

Meindert was Professor of Pharmacology at Leiden University until his retirement in 2017. His research at the Leiden Academic Center for Drug Research focused on novel concepts of systems pharmacology, interfacing theories from systems biology with quantitative pharmacology. He is also a Past President of the European Federation of Pharmaceutical Sciences. He has been dubbed the "founding father" of pharmacological models for his work in developing pharmacokinetic-pharmacodynamic (PKPD) models.

CAROLYN BERTOZZI

ANNE T. AND ROBERT M. BASS PROFESSOR IN THE SCHOOL OF HUMANITIES AND SCIENCES, STANFORD UNIVERSITY

Carolyn has been recognized for both her research and teaching accomplishments, including the Lemelson-MIT award for inventors, the Ernst Schering Prize and the Arthur C. Cope Award. Her lab studies the glycobiology underlying diseases including cancer, inflammatory disorders and infectious disease, and also works to develop new ways to perform controlled chemical reactions within living systems. Several of these technologies have go on to see commercial use, and Carolyn has worked with several biotechnology start-ups.

DAVID DUNGER

PROFESSOR OF PEDIATRICS, UNIVERSITY OF CAMBRIDGE

David Dunger is a Pediatric Endocrinologist who works closely with industry to develop novel medications for children with diabetes and endocrine disorders. He is an expert on the growth hormone/insulin-like growth factor 1 (IGF-1) axis and its effects on metabolism, and his work in this area has led to the first experimental and clinical studies of recombinant human IGF-1 in type 1 diabetes.

KENNETH GETZ

ASSOCIATE PROFESSOR AND DIRECTOR OF SPONSORED PROGRAMS, CENTER FOR THE STUDY OF DRUG DEVELOPMENT, TUFTS UNIVERSITY SCHOOL OF MEDICINE; FOUNDER AND BOARD CHAIR, CISCRP

"Working with great people who share a passion for what we're doing to help patients, the public and the clinical research enterprise is what drives me. I'm on a personal crusade to see clinical trial results summaries, in plain non-technical language, provided to all study volunteers. It is the right thing to do and it sends a very strong and essential message to our study volunteers that we value their gift of participation. CISCRP is making great strides in this area, and I'm hopeful that it will become a standard practice among pharmaceutical and biotechnology companies."

CLAUS-MICHAEL LEHR

HEAD, DEPARTMENT OF DRUG DELIVERY, HELMHOLTZ-INSTITUTE FOR PHARMACEUTICAL RESEARCH SAARLAND, HELMHOLTZ CENTER FOR INFECTION RESEARCH (HZI), SAARLAND UNIVERSITY

"Being involved in various projects is a big driver of my research. This could be discussing exciting new data with my students, but also sharing and trying to give some input to the problems of my colleagues in the industry. But sometimes, I also just look forward to my next sailing trip or playing jazz with my friends!"

MICHELE DE LUCA

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

Michele is internationally recognized as a leading scientist in epithelial stem cell biology, with a focus on its clinical application in regenerative medicine. He played a pivotal role in developing epithelial stem cell-mediated cell therapy, and in demonstrating the feasibility of genetically corrected stem cell-mediated ex vivo gene therapy for epidermolysis bullosa.

GRAZIELLA PELLEGRINI

CELL THERAPY PROGRAM COORDINATOR, CENTER FOR REGENERATIVE MEDICINE "STEFANO FERRARI", UNIVERSITY OF MODENA AND REGGIO EMILIA

After studying chemistry and pharmaceutical Technologies, Graziella went on to become a leading figure in the field of epithelial stem cell biology aimed at clinical applications in cell and gene therapy. She was involved in the development of the first stem cell-based advanced therapy medicinal product approved in Europe – Holoclar.

PETER SEEBERGER

DIRECTOR, MAX-PLANCK-INSTITUTE OF COLLOIDS AND INTERFACES; PROFESSOR, FREE UNIVERSITY OF BERLIN

"Early on, I received a Fulbright scholarship to perform graduate work at the University of Colorado with Marv Caruthers, the inventor of gene synthesis machines and a co-founder of Amgen. It opened new perspectives and eventually led to my work on automated glycan assembly, which in turn resulted in novel vaccines and diagnostics. My work today focuses on creating vaccines to protect everybody from deadly infectious diseases, and new methods to produce affordable drugs."

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.

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 – I'd like to see the industry recapture its reputation as a force for good in people's lives. 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."

HAROLD VARMUS

LEWIS THOMAS UNIVERSITY PROFESSOR & SENIOR ADVISOR TO THE DEAN AND PROVOST, WEILL CORNELL MEDICAL COLLEGE

A leading cancer geneticist, Harold Varmus has previously been the director of the National Institute of Health and the National Cancer institute. He originally obtained a degree in English literature – with a desire to be a writer – before deciding to pursue a career in medicine. In 1989, he was the co-winner of a Nobel Prize (alongside Michael Bishop) for the discovery of the cellular origin of retroviral oncogenes – how malignant tumors are formed from normal cells.

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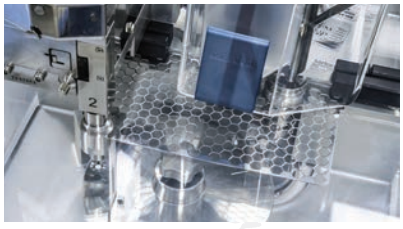

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INDUSTRY INFLUENCERS

1. RICHARD JOHNSON

CHIEF EXECUTIVE OFFICER AND PRESIDENT, PARENTERAL DRUG ASSOCIATION

"I wish I had known the importance of networking within our industry earlier on. So much of what I have learned is from colleagues, and I wish I had recognized and cultivated this earlier. 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."

2. MARTIN VAN TRIESTE

IMMEDIATE PAST CHAIR, PARENTERAL DRUG ASSOCIATION

"I would like to see a significant increase in R&D productivity, so that significant therapies get to patients faster. There are two things that most R&D organizations can do to be more effective: one, embrace productivity enhancing techniques, such as lean, which their manufacturing colleagues have embraced, and R&D professionals have resisted; two, R&D professionals must kill bad projects faster, so that valuable resources can be redeployed on projects with greater potential for success."

3. ANDY SKIBO

HEAD OF GLOBAL BIOLOGICS OPERATIONS & GLOBAL ENGINEERING, ASTRAZENECA/ MEDIMMUNE

"I am passionate about ensuring that we (both AstraZeneca/MedImmune specifically, and our biopharmaceutical industry as a whole) have a long-range biologics supply capability," says Andy. He would like to see the pharma industry work closer with regulatory agencies to find ways to dramatically reduce the cost of developing new drugs – specifically the cost of clinical trials – without sacrificing product safety or affecting patient risks.

4. MICHAEL W. 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."

5. RINO RAPPUOLI

CHIEF SCIENTIST AND HEAD EXTERNAL R&D, GSK VACCINES

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).

6. GIL ROTH

PRESIDENT, PHARMA & BIOPHARMA OUTSOURCING ASSOCIATION

"There are plenty of things I wish I'd known when I first started out in my career representing the contract manufacturing and development sector (distinct from my previous role editing a magazine covering that sector). I suppose I was most naive about how much legislative work would be involved. When I started the trade association, I thought it would primarily be FDA-facing, and would deal with improving regulations, and building bridges between our sector and the agency. I didn't realize that in a lot of cases, FDA's regulations reflect the legislation passed by Congress. It's been a rapid learning curve to understand the mechanics, personalities, and dynamics of Capitol Hill, and to help explain the sector to Congressional staff."

7. JOHN BOURNAS

PRESIDENT AND CHIEF EXECUTIVE OFFICER, 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.

8. CORNELL STAMORAN

VICE PRESIDENT, CATALENT

Cornell began his career as an accountant, before joining R.P. Scherer (now Catalent) in 1992. Cornell says he's always learning – and during his time at Catalent he has worked across a number of areas, including strategy, marketing and press relations, innovation, investor relations, and mergers and acquisitions. Cornell also represented the interests of CDMOs as a member of Pharma & Biopharma Outsourcing Association's generic industry GDUFA II reauthorization negotiation team.

9. JIM BREEN

VICE PRESIDENT, WORLDWIDE ENGINEERING AND TECHNICAL OPERATIONS, JOHNSON & JOHNSON

"Even though the world is extremely large and complex, you as an individual can make an impact each day if you 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. I would like to see the industry collaborate more and solve the unmet patient needs faster and more efficiently by utilizing new technologies such as data analytics, machine learning, robotics, and so on. I believe collaboration will aid and accelerate global pharma and drug advances, and provide more patients with cost effective solutions."

10. MONCEF SLAOUI

PARTNER, MEDIXI

Moncef, former chairman of vaccines at GSK, says he is driven by the potential impact his work has on the lives of so many.

"I would like to see a greater focus on our social responsibility in all choices and decisions we make, paralleled by a dramatic improvement in our perception as an industry by lay people," he says.

JAMES AGALLOCO

PRESIDENT, AGALLOCO & ASSOCIATES

"What drives me day-to-day is trying to bring more science into the manufacturing of pharmaceuticals. One change I'd like to see in the industry is more mentoring of younger and less experiences employees. With corporate downsizing, frequent job changes, contract employees and outsourcing, it seems to me that the development of employees is no longer a priority. Investing in employees is one of the soundest things a firm can do, yet it is increasingly hard to find that commitment in the industry."

MADHAVAN (MADHU) BALACHANDRAN

BUSINESS OWNER, MJB CONSULTANTS

Madhu spent a number of years working for Amgen and retired from the role of Executive Vice President of Operations at the end of 2016. He is considered an outstanding leader and today sits on the boards of Catalent and uniQure, among others. He also runs his own consultancy firm.

HAROLD 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.

MARC BISSCHOPS

DIRECTOR CONTINUOUS BIOPROCESSING, PALL BIOTECH

"If I had known the challenges ahead of me when I started my career, I might've chosen a different path! But overcoming challenges comes with rewards and that's something I probably would not have been able to recognize as a young scientist. I'm driven day-to-day by the ability to help – alongside my team – the industry become more efficient and agile. Continuous bioprocessing and process intensification is just one aspect of this, but it is one where a lot of advancements are happening as we speak. We still face challenges getting vital therapeutics to patients in need, however, and I look forward to a world where treatments are more accessible."

GARY CUNNINGTON

GLOBAL HEAD OF CTSU BUSINESS CONSULTANCY, 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.

MIGUEL FORTE

CHIEF EXECUTIVE OFFICER, ZELLUNA IMMUNOTHERAPY AND CHIEF COMMERCIALIZATION OFFICER AND CHAIR OF COMMERCIALIZATION COMMITTEE, ZELLUNA IMMUNOTHERAPY

"The big change our industry needs (and it's starting to happen) is the establishment and validation of a new overall business value model – a model that rests on new approaches to product development, and that is particularly attentive to patient needs, expectations and contributions; a model that brings faster and more comprehensive market access approaches, including regulatory approval, new payer and reimbursement models and customer education."

FIONA GREER

GLOBAL DIRECTOR, BIOPHARMA SERVICES DEVELOPMENT, SGS

"I wish I'd known that the career path from A to B is not always direct – it has diversions, dead-ends, circular routes and unmapped areas! This is all part of a learning process and good experience for dealing with change, both planned and unexpected. For the future, I'd really like to see an increase in the efficiency of the R&D model of research-based pharma and biopharma – not just cost reduction, but increased innovation too."

AJAZ HUSSAIN

FOUNDER AND CHIEF EXECUTIVE OFFICER, INSIGHT, ADVICE AND SOLUTIONS; PRESIDENT, NATIONAL INSTITUTE FOR PHARMACEUTICAL TECHNOLOGY AND EDUCATION

Ajaz has previously served as Deputy Director of the Office of Pharmaceutical Science at the FDA and led some of the FDA's major initiatives to develop regulatory policies. He has also held roles at Sandoz, Philip Morris International and Wockhardt. He is passionate about transforming the sector by improving assurance of quality and reliability of pharmaceutical manufacturing.

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."

DANIEL O'CONNOR

EXPERT MEDICAL ASSESSOR, MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

A medical assessor at MHRA, Daniel is instrumental in the UK's Early Access to Medicines Scheme (EAMS). "It is a privilege to work in a setting where you are contributing positively to public health on a daily basis," he says. What big change would he like to see in industry? More collaborative working across different stakeholders, including patients, regulators and industry.

CAROL LYNCH

PRESIDENT SANDOZ INC AND HEAD OF NORTH AMERICA

Carol is currently Global Head of Biopharmaceuticals at Sandoz – a business she has successfully managed since September 2014. During this time the business grew rapidly, reached $1 billion in sales annually, and the portfolio came to fruition with 5 biosimilar approvals. Under Carol's leadership, Sandoz achieved the first approval and launch of a biosimilar in the US, and last year saw the launch of the next wave of biosimilars in the EU. With the recent announcement of Sandoz's collaboration with Biocon, the company has further strengthened its pipeline. Effective March 1, Carol Lynch succeeded Peter Goldschmidt.

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.

RAM SASISEKHARAN

ALFRED H. CASPARY PROFESSOR OF BIOLOGICAL ENGINEERING AND HEALTH SCIENCES & TECHNOLOGY, MIT DEPARTMENT OF BIOLOGICAL ENGINEERING

Ram has been a professor at MIT since 1996 and served as the Director of the Harvard-MIT Division of Health Sciences & Technology from 2008-12. His research on complex polysaccharides has led to over 125 publications and over 50 patents. He is also a founder of Momenta Pharmaceuticals, Cerulean Pharma, and Visterra Pharmaceuticals.

THOMAS RYLL

VICE PRESIDENT OF TECHNICAL OPERATIONS, IMMUNOGEN

Thomas was highly commended by the judging panel for his dedication to industry and innovation, particularly in antibody drug conjugates. He has over 24 years of experience in bioprocessing, having worked for Genentech (where he was part of the first generation of large scale manufacturing processes for antibodies and recombinant proteins), Abgenix, Tanox, and Biogen, prior to Immunogen.

ANDREW WITTY

CHIEF EXECUTIVE,OPTUM (EFFECTIVE JULY 1, 2018)

Sir Andrew graduated from the University of Nottingham, UK, in 1985, with a BA in Economics, and joined GlaxoSmithKline the same year. He was appointed CEO in 2008 – a position he held until April 1, 2017. From July 1, 2018, Andrew will be chief executive of UnitedHealth Group's Optum pharmacy benefit unit.

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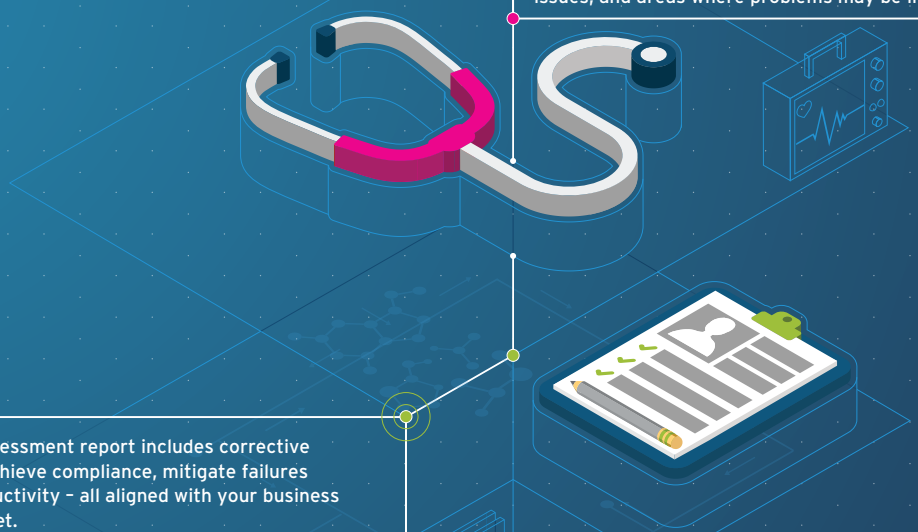

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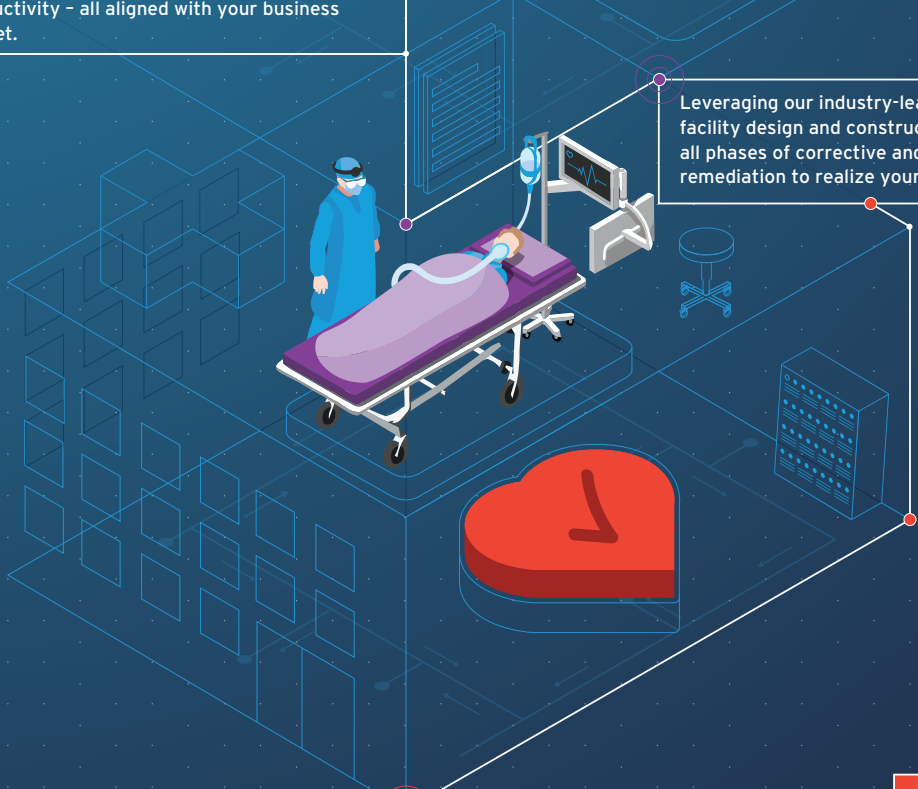

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BUSINESS CAPTAINS

1. KIRAN MAZUMDAR-SHAW

CHAIRPERSON AND MANAGING DIRECTOR, BIOCON

"There currently exists an ugly and unethical divide between the billion who have health security in the developed world and the nearly seven billion others who are vulnerable to disease and death because of little or no access to health protection. Whilst the developed world spends 12 percent of its GDP on healthcare, the developing world spends less than 3 percent. The disease burden is even more skewed. 80 percent of non-communicable diseases are in the developing world, killing 30 million and driving 100 million into poverty every year. These deaths could be prevented if only they had access to essential and life-saving medicines. For the vast majority in the developing world, life is about survival and the pharma and drug development industry needs to throw them a lifeline by developing disruptive new technologies that can bridge the resource deficit."

2. JOSEPH JIMENEZ

FORMER CHIEF EXECUTIVE OFFICER, NOVARTIS

Joseph joined Novartis in April 2007 as Division Head, Novartis Consumer Health, after spending eight years running the North American, European and then Asian operations of H.J. Heinz. He was named CEO of Novartis in 2010, a position he held until earlier this year. Joseph has served as President of the European Federation of Pharmaceutical Industries and Associations and as Chairman Elect of Pharmaceutical Research and Manufacturers of America.

4. EMMA WALMSLEY

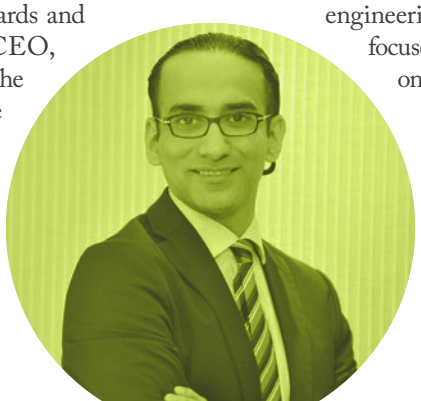
CHIEF EXECUTIVE OFFICER, GLAXOSMITHKLINE

Before heading up GSK, 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.

3. RAMAN SINGH

CHIEF EXECUTIVE OFFICER, MUNDIPHARMA, SINGAPORE

Since Raman took the helm of the company in 2011, Mundipharma says it has enjoyed growth of 40 percent every year and is now prominent in 128 countries. Mundipharma won "Emerging Markets Company of the Year" at the 2016 Scrip Awards and Raman was awarded "Best CEO, Pharmaceutical Industry Asia" at the Business Worldwide Magazine 2017 CEO Awards. Before Mundipharma, Raman served as vice-president of commercial operations for emerging markets at GlaxoSmithKline where he oversaw all aspects of the brand's commercial operations across its emerging markets. He has also held positions at Abbott as the regional director in Australia and New Zealand, and general manager for Korea, as well as various sales, marketing and strategy positions at Bayer. Raman was raised in the US and initially he expected to be an entrepreneur like his father. He has a degree in mechanical engineering but has focused his career on healthcare.



5. BELÉN GARIJO

CHIEF EXECUTIVE OFFICER, HEALTHCARE, MERCK

Belén Garijo 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. Since 2013, she also acts as President and CEO of the Biopharma business, where she started in 2011 as Chief Operating Officer. Before moving to the pharma industry, she was a practicing physician.

6. ROBERT A. BRADWAY

CHAIRMAN AND CHIEF EXECUTIVE OFFICER, AMGEN

In 2006, Robert joined Amgen as Vice President of Operations Strategy. He was appointed to the Amgen Board of Directors in October 2011, and became Chairman in January 2013, and CEO in May 2012. Before Amgen, he was a managing director at Morgan Stanley in London. In 2017, Robert was elected PhRMA board chairman-elect.

7. SEVERIN SCHWAN

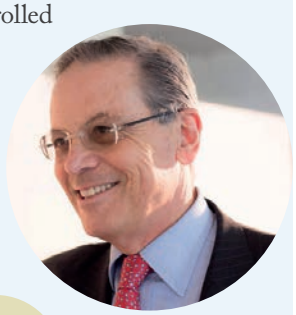
CHIEF EXECUTIVE OFFICER, ROCHE GROUP

After completing his studies 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.

8. ARIE BELLDEGRUN

EXECUTIVE CHAIRMAN AND CO-FOUNDER, ALLOGENE THERAPEUTICS

Arie has founded several successful biopharmaceutical companies, including Agensys, Cougar Biotechnology, and most recently Kite pharma, acquired by Gilead in 2017 for $12 billion dollars. In October last year, Kite Pharma's Yescarta became the second CAR-T therapy approved by the FDA. And in April, 2018, Arie raised $300 to co-found Allogene Therapeutics, which will acquire and advance a portfolio of off-the-shelf CAR-T therapies previously controlled by Pfizer.



9. JEAN-PAUL CLOZEL

CHIEF EXECUTIVE OFFICER, IDORSIA

Jean-Paul founded Actelion in 1997, together with his wife and work colleagues and friends, and has since built Actelion from a start-up to a multi-billion market capitalization company – acquired by Johnson & Johnson for €27.9 billion in 2017. As part of the transaction with J&J, Actelion spun out its drug discovery operations and early-stage clinical development assets into a newly created company, Idorsia, which Jean-Paul now heads up.

10. 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. In 2014, she was named by Forbes Magazine to the "30 Under 30" list in Science and Healthcare, and in 2016, Fortune Magazine named her to the "40 Under 40" list of the most influential young people in business.

STÉPHANE BANCEL

CHIEF EXECUTIVE OFFICER, MODERNA THERAPEUTICS

Prior to Moderna, Stéphane was CEO of bioMérieux and he has also held leadership positions at Eli Lilly. Moderna claims it can generate proteins needed to treat an array of diseases by turning cells into "drug factories" with custom-built strands of messenger RNA. In 2017, Stéphane was named Ernst & Young 2017 New England Entrepreneur of the Year.

ERIK GATENHOLM

CO-FOUNDER AND CHIEF EXECUTIVE OFFICER, CELLINK

Erik started his first biomedical device company, BC Genesis, at age 18 in Virginia USA, in 2008. Now 28, he is the CEO of CellInk, the first bioink company in the world and a leading bioprinter provider. Erik's expertise lies in commercializing biomedical technologies by disrupting industries. His drive and passion, he says, comes from the fact that he truly wants to change the world of medicine for future generations to come.

STÉPHANE BOISSEL

CHIEF EXECUTIVE OFFICER, TXCELL

Stephane says he's driven by "a passion for working in an environment with an incredible purpose: saving and improving lives. Also, making day-to-day decisions to address challenges makes you forget how long, cumbersome and random drug development can be." What big change would Stéphane like to see in pharma and drug development? "A little less greed and a lot more social responsibility."

ANNALISA JENKINS

CHIEF EXECUTIVE OFFICER, PLAQUETEC

Annalisa began her first tour of duty with the Royal Navy as a medical officer, but has since climbed the ranks of pharma to become a CEO and a member of numerous boards, including PlaqueTec – a UK diagnostics company developing a novel approach to assess an individual's risk for coronary artery disease. "I'm driven by a passion for making peoples' lives longer, healthier and happier, ensuring that great science is translated effectively into new options for patients globally, and inspiring the next generation to make a difference. In the future, I'd like to see diversity at the top recognized as a business and human right imperative, and girls in school embracing STEM. I'm also passionate about innovative and progressive business models that seek to ensure that the discoveries and products of our industry benefit every human being on the planet."

JOHN CHIMINSKI

PRESIDENT AND CHIEF EXECUTIVE OFFICER, CATALENT

"Honestly, I wish I could've known that as an electrical engineer, I would one day be working in the pharma and biotech industry. Although my engineering background has served me well, I would have spent more time learning the life sciences disciplines of biology and chemistry! What drives me? Being responsible for 1,000 customers and more than 11,000 employees at Catalent. The patient is the common factor behind both of these groups and ensures that our priorities and decisionmaking deliver safe and effective medicines. I would like to see more standardization of regulatory requirements across all global agencies. There are still significant differences in requirements, and how inspectors interpret these requirements through their inspections, that lead to 'patch-work' solutions and processes. This, in turn, leads to variability and additional costs that don't necessarily equate to better quality or control."

JEFF JONAS

CHIEF EXECUTIVE OFFICER, SAGE THERAPEUTICS

Jeff joined SAGE as CEO in 2013 and has more than 20 years of experience on both the scientific and business sides of the pharmaceutical and healthcare industries, particularly in the CNS field. He has published more than 70 scientific papers and chapters, authored more than 100 books, scientific articles and abstracts, and has received numerous awards.

ANKIT MAHADEVIA

PRESIDENT AND CHIEF EXECUTIVE OFFICER, SPERO THERAPEUTICS

Ankit was formerly a Venture Partner at Atlas Venture where he supported the formation of eight companies focused on novel drug discovery platforms and therapeutic products. He 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 has been its CEO and President since March 2015.

G. V. PRASAD

CO-CHAIRMAN AND CHIEF EXECUTIVE OFFICER, DR. REDDY'S LABORATORIES

G. V. has been a member of the board of directors at Dr. Reddy's since the year it was founded. He joined in a full-time capacity in 1990, when company revenues were less than $50 million – today they are over $2.5 billion. Prasad is a strong believer in sustainable manufacturing and business practices, and is also involved with charitable initiatives including the Andhra Pradesh chapter of the Worldwide Fund for Nature and the "Acumen Fund," a nonprofit venture that uses entrepreneurial approaches to help eliminate global poverty.

VIVEK RAMASWAMY

FOUNDER AND CHIEF EXECUTIVE OFFICER, ROIVANT SCIENCES

Vivek founded Roivant, a company that in-licenses late-stage drug candidates and develops them through subsidiaries, in 2014. Axovant, Myovant, Enzyvant, and Dermavant are some of the company's subsidiaries, developing drugs for Alzheimers disease, women's health, rare diseases and skin diseases, respectively.

RODGER NOVAK

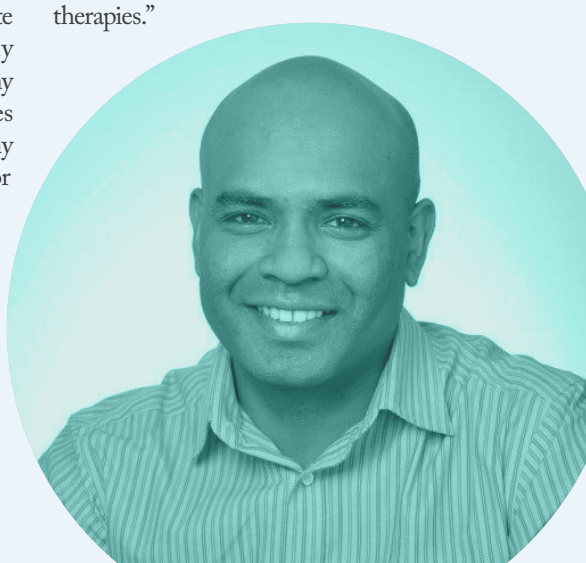
PRESIDENT AND CO-FOUNDER, CRISPR THERAPEUTICS

Rodger is one of the three co-founders of CRISPR Therapeutics, which aims to treat diseases using the breakthrough CRISPR/Cas9 gene editing technology. In December last year, the company applied for permission from the EMA to test its most advanced product, code-named CTX001, in patients suffering from beta-thalassemia.

RAVI NALLIAH

CO-FOUNDER AND CHIEF EXECUTIVE OFFICER, TRAKCEL

TrakCel is described as a clinical orchestration platform for regenerative and cell-based therapies. "As a passionate innovator working in a relatively conservative industry I thought that my passion would win over my colleagues when trying to create space for my companies to innovate. However, for innovation to flourish, passion can only get a leadership team so far. I now work hard to develop detailed cases for all activities so that my vision will appeal to all the personality types in my leadership team. TrakCel's software is primarily used to support cell and gene therapy products. And it's regrettable that, due to the complexity associated with the manufacture and administration of these products, the price tag tends to be high. But these treatments are curative, and I would like to see healthcare payers considering the accumulative reduction in healthcare costs once patients are treated with these therapies."



IAN C. READ

CHAIRMAN OF THE BOARD AND CHIEF EXECUTIVE OFFICER, PFIZER

Ian began his career with Pfizer in 1978 as an operational auditor. He is a past Chairman of the Board of PhRMA and currently serves as President of the International Federation of Pharmaceutical Manufacturers & Associations.

DAVID SCHENKEIN

CHIEF EXECUTIVE OFFICER, AGIOS PHARMACEUTICALS

David joined Agios in August 2009 as CEO and board member, after working as senior vice president, clinical hematology/oncology, at Genentech. He has been a hematologist and medical oncologist for more than 20 years and still sees patients once a week at Tufts Medical Center, where he started practicing as a doctor in 1983.

LEONARD SCHLEIFER

PRESIDENT AND CHIEF EXECUTIVE OFFICER, REGENERON

Working alongside CSO George Yancopoulos, Leonard has grown Regeneron, which he co-founded in 1988, from a small startup to one of the world's leading biotechnology companies, with a number of FDA approved medicines. Leonard is a licensed physician and worked as a practicing neurologist before founding Regeneron.

MARTIN TOLAR

FOUNDER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, ALZHEON

During his academic career, Martin served as an Assistant Professor in the Department of Neurology at Yale University School of Medicine, where he focused on movement disorders. Since then he has served as head of business development at Pfizer before founding Alzheon, a clinical-stage biopharmaceutical company focused on brain health, memory and aging.

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The Humanity in Science Award recognizes and rewards scientific breakthroughs that aim to have a real impact on humankind's health and wellbeing.

HUMANITY IN SCIENCE AWARD

the Analytical Scientist

2015

Peter Seeberger & Andreas Seidel-Morgenstern, Directors at two collaborating Max Planck institutes in Germany, developed an innovative process to manufacture the most effective drugs to treat malaria from plant waste material, air and light.

2016

Waseem Asghar, Assistant Professor at Florida Atlantic University, developed flexible sensors for the rapid and cost-effective diagnosis of HIV – and other infectious diseases – in point-of-care settings.

2017

Richard Jähnke, Global Pharma Health Fund (GPHF), developed and continuously improved GPHF Minilab – a "lab in a suitcase," enabling resource poor countries to rapidly identify substandard and falsified medicines.

Nominations will open soon for the 2018/2019 Humanity in Science Award

www.humanityinscience.com

CHAMPIONS OF CHANGE

1. TOMASZ SABLINSKI

CHIEF EXECUTIVE OFFICER AND CO-FOUNDER, TRANSPARENCY LIFE SCIENCES

According to Tomasz, it's important to challenge the status quo, as fear is the most significant barrier to progress. "The world we live in is changing constantly. As an incurable optimist, I see opportunities every single day. In drug development, specifically, there are countless opportunities to improve a 50-year old process using existing and emerging technologies that will bring life-saving medicines to patients faster. I'd like to see the same curiosity and creativity that drive software and technology development applied to drug development."

2. J. CRAIG VENTER

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

John is regarded as a pioneer in the field of genomics – founding Celera Genomics in 1998 to sequence the human genome using tools and techniques he and his colleagues developed. With Celera he also worked to sequence the fruit fly, mouse and rat genome. With his team at the J Craig Venter Institute, he created the first self-replicating bacterial cell constructed entirely with synthetic DNA. He is also founder, scientific strategy advisor and executive chairman of Human Longevity.

3. STEVE DAVIS

PRESIDENT AND CHIEF EXECUTIVE OFFICER, PATH; LECTURER ON SOCIAL INNOVATION, STANFORD GRADUATE SCHOOL OF BUSINESS

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.

4. ANDREW POLLARD

PROFESSOR OF PEDIATRIC INFECTION AND IMMUNITY, UNIVERSITY OF OXFORD

Andrew chairs the UK Department of Health's Joint Committee on Vaccination and Immunization, the European Medicines Agency scientific advisory group on vaccines, and is a member of WHO's SAGE (Study on global AGEing and adult health). His research focuses on developing and evaluating vaccines, including those for meningococcal disease and enteric fever.

5. ANTHONY S. FAUCI

DIRECTOR, US NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

Anthony first became Director of NIAID in 1984, where he oversees basic and applied research on HIV/AIDS, respiratory infections, emerging diseases such as Zika, and many more – he was also one of the principal creators of the President's Emergency Plan for AIDS Relief, which has saved millions of lives worldwide. Anthony was a clinical researcher at the NIH when the AIDS crisis began, and his interest in the disease led to seminal contributions to the understanding of how HIV destroys the body's defenses.

6. SUE DESMOND-HELLMANN

CHIEF EXECUTIVE OFFICER, BILL & MELINDA GATES FOUNDATION

After training as an oncologist, Sue spent 14 years as head of product development at Genentech – where she played a role in the development of Herceptin and Avastin. Next, she spent five years as the first female Chancellor of the University of California, San Francisco. As the first physician and research scientist CEO of the Bill & Melinda Gates Foundation, she draws on her public and private sector experience to combat infectious disease and empower people – especially women and girls.

7. SUBHASH KAPRE

CHIEF EXECUTIVE OFFICER, INVENTPRISE

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.

8. JULIE LOUISE GERBERDING

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

Julie served as Director of the US Centers for Disease Control and Prevention (CDC) director from 2002 to 2009 – the first woman to be appointed to this role. She joined MSD in 2010, and is responsible for the company's Foundation and "Merck for Mothers," a global program to prevent maternal mortality. Julie has also helped with the development of the Merck Women's Employee Business Resource Group. She was selected as 2018 Women of the Year by the Healthcare Businesswomen's Association for her contributions to advancing gender equality in the healthcare industry.

9. MARGARET HAMBURG

PRESIDENT, AAAS, FOREIGN SECRETARY OF NATIONAL ACADEMY OF MEDICINE

A former FDA commissioner, Margaret now works with the American Association for the Advancement of Science. "Partnership is so important – we need to be able to work across disciplines, sectors and borders in order to make a difference. I would like to see better alignment between the opportunities in science and technology today with unmet medical care and public health needs."

10. MARK PAXTON

MANAGING DIRECTOR, ACCELERATORX

"Day-to-day, I am driven by the excitement that there are tremendous opportunities to improve healthcare outcomes with high quality, safe and effective drugs. Educating the various stakeholders across the globe on what this actually means is very important and there is a lot of collaborative work that still needs to be done. Currently, I am working on a couple of initiatives to accelerate the adoption of digital connectivity of drug products – especially with injectables. Such connectivity allows for healthcare providers and patients to provide significantly more specificity regarding health outcomes than is currently measured in clinical trials."

STEVE ARLINGTON

PRESIDENT, PISTOIA ALLIANCE

"If I had understood the power of cross-disciplinary working when I first started my career, then I would have focused my efforts on this way of working much earlier. My aim in life is to make a real difference in everything I do. I also believe that you should focus on the things you enjoy the most, as you do much better when you are having fun at work. I am particularly passionate about the pharma industry discovering, developing, and launching affordable medicines that society really needs. In everything I do, I try to promote greater collaboration within and between industry, the regulator, the payer, and the provider. With greater collaboration, we will be able to harness the power of new science and technologies such as genomics, AI and blockchain."

THOMAS CECH

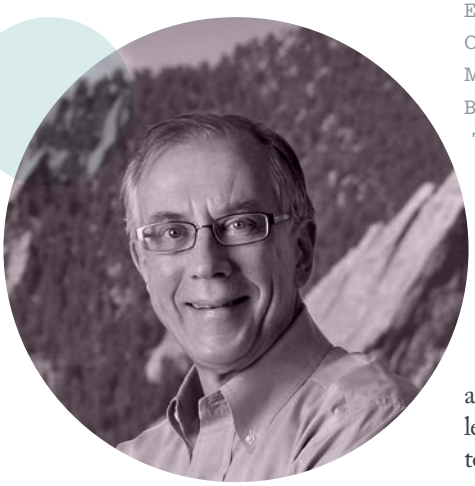
DISTINGUISHED PROFESSOR OF CHEMISTRY AND BIOCHEMISTRY, UNIVERSITY OF COLORADO

Thomas is 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. He shared a Nobel Prize in Chemistry for the discovery of the catalytic properties of RNA in 1989. Asked what changes he'd like to see in pharma, Thomas says, "We need to see more risk-taking to make the big advances in meeting unmet medical needs, not just me-too incremental improvements."

SÉGOLÈNE AYMÉ

EMERITUS DIRECTOR OF RESEARCH, FRENCH INSTITUTE OF HEALTH AND MEDICAL RESEARCH (INSERM)

Ségolène is a medical geneticist and chairs the Topic Advisory Group on rare diseases at the World Health Organization and the European Union Committee of Experts on Rare Diseases. She is also the founder of Orphanet, a portal which provides information on rare diseases and orphan drugs and the editor-in-chief of the Orphanet Journal of Rare Diseases.



DARIO CAMPANA

MRS. LEE KONG CHIAN CHAIR IN ADVANCED CELLULAR THERAPY, PROFESSOR, DEPARTMENT OF PAEDIATRICS, YONG LOO LIN SCHOOL OF MEDICINE, NATIONAL UNIVERSITY OF SINGAPORE; SCIENTIFIC FOUNDER, UNUM THERAPEUTICS, NKARTA AND MEDISIX THERAPEUTICS

"I believe there is an innate resistance to new ideas and truly disruptive technologies, and it often takes a long time before these are valued. More effective therapies are urgently needed, and I believe that better interaction between industry and academia can help to facilitate the translation of basic discoveries into clinical applications."

DALVIR GILL

CHIEF EXECUTIVE OFFICER AND MEMBER OF THE BOARD OF DIRECTORS, TRANSCELERATE BIOPHARMA

Dalvir Gill was appointed CEO of TransCelerate in January 2013 and has since pioneered a number of changes and improvements to the drug development process. As the CEO of TransCelerate and its subsidiary BioCelerate, Dalvir has led a number of initiatives that have helped to make the research and development ecosystem more efficient, safe and innovative. Through TransCelerate, he has made it a priority to not only engage with patients about clinical trials, but to also offer higher value to patients and other healthcare stakeholders through more effective use of trial information.

BEN GOLDACRE

SENIOR CLINICAL RESEARCH FELLOW, CENTRE FOR EVIDENCE-BASED MEDICINE, NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

Ben is a doctor, academic, writer, broadcaster and campaigner for greater transparency in the pharma industry. He co-founded AllTrials, a project that advocates for all clinical trials being listed on an open registry. He runs the EMB DataLab in Oxford which aims to create useful tools using academic and health data, with its first output, OpenPrescribing, providing a live view of individual practice prescribing data in the UK.

FAITH OSIER

GROUP LEADER, HEIDELBERG UNIVERSITY HOSPITAL; PRINCIPAL INVESTIGATOR, KEMRI-WELLCOME TRUST RESEARCH PROGRAM

Faith has won multiple prizes for her research into the mechanisms of immunity against Plasmodium falciparum, and she aims to translate this knowledge into highly effective malaria vaccines. She originally trained as a pediatrician in Kenya before specializing in immunology in Liverpool, later obtaining a PhD from the Open University, UK.

BRIAN OVERSTREET

PRESIDENT, ADVERA HEALTH ANALYTICS

Brian is the co-founder of Advera, an analytics company that has introduced a predictive system that analyzes real-world drug outcomes data to improve patient safety and reduce systematic healthcare costs. Recently, Advera partnered with technology consulting firm Booz Allen Hamilton to provide access to social media data on adverse drug effects to spot adverse events faster.

MIKE REA

CHIEF EXECUTIVE OFFICER, IDEA PHARMA

"I'm leading the development of a code of ethics for the industry. I wholly believe that we have to do the right things, and do them transparently, and with full input from other stakeholders. It took me a long time to realize just how cool this industry can be – we need to become more attractive to people leaving university in order to compete with tech and finance. I wish I'd realized earlier in my career that pharma is an industry looking for people to change it!"

MELINDA RICHTER

GLOBAL HEAD OF JLABS, JOHNSON & JOHNSON

"I had very humble beginnings, and as a young woman I always felt like I didn't have the same platform that other people had and that I was straying into territory where I didn't belong. Growing up with five brothers and three sisters gave me the competitive spirit and the independence to go there anyway. My favorite quote is 'courage is fear that has said its prayers'. Our mission is to make it faster, easier, cheaper and more exciting for innovators and investors to deliver real value and impact for patients. We want to make the business of health just as productive, advanced, sexy and as addictive to participate in as the tech industry."

ROBIN ROBINSON

RETIRED

During his time as Director of Biomedical Advanced Research Development Authority (BARDA), Robin developed patented platform vaccine technologies including virus-like particles and subunit protein vaccines for human pathogens – and led the development of the first avian influenza H5N1 vaccine. Robin has also served on WHO international expert teams on influenza vaccines.

ROSALIND SMYTH

DIRECTOR, UNIVERSITY COLLEGE LONDON GREAT ORMOND STREET INSTITUTE OF CHILD HEALTH

Rosalind has based her career around improving children's health, and is recognized as a leading authority in the field. Previously Professor of Pediatric Medicine at the University of Liverpool UK and Director of the UK Medicines for Children Research Network, she has also chaired the UK Pediatric Expert Advisory Group of the Commission on Human Medicines.

BRUNO SEPODES

PROFESSOR OF PHARMACOLOGY AND PHARMACOTHERAPY, UNIVERSITY OF LISBON; CHAIR OF THE EMA COMMITTEE OF ORPHAN MEDICINAL PRODUCTS

After studying pharmacy at university and then moving into toxicology, Bruno became an assessor for the Portuguese medicine regulator INFARMED before moving to the European Medicines Agency. From there, he developed a passion for the regulation of orphan diseases, creating incentives for development and therefore improving public health. He recently received the EURORDIS Rare Disease Leadership Award. "I would like to see a better and earlier dialogue with regulators in order for drug development to be as smooth as possible. There are still several missed opportunities of interaction with regulators and we simply cannot afford that, especially in some fields such as drug development for rare diseases," says Bruno.

ABBE STEEL

CHIEF EXECUTIVE OFFICER, HEALTHIVIBE

Abbe has 27 years' experience in the life sciences industry, and is the Founder and CEO of HealthiVibe, a company that helps pharmaceutical companies gather patient insights to support clinical trial design. Her passion lies in leading patient initiatives for clinical development and post-marketing programs – and she would like to see the industry change to ensure that no protocol is finalized without incorporating patient feedback first.

MATTHEW TODD

ASSOCIATE PROFESSOR, UNIVERSITY OF SYDNEY; FOUNDER, OPEN SOURCE MALARIA

Matthew would love to see a "robust and large-scale trial of open source drug development as a competing model for the pharmaceutical industry, funded through a mixed investment model of public, private and philanthropic support." His passion is to improve efficiency in R&D through working with others, and making knowledge more available.

Leading by Learning

Sitting Down With…
Sophie Kornowski-Bonnet,
Global Head, Roche Partnering.

Did you always want to work in pharma?

My main interest was actually chemistry. I come from a family with a chemistry and pharmacy background, and I always thought that chemistry had a magic touch to it. It seemed amazing that you could be sick, take a drug and then be less sick or even cured. I decided to go to pharmacy school and started working in pharmacy hospitals, but during my studies I became really passionate about the impact a company can have on health. This was reinforced when I started working for Abbott Diagnostics at the time of the launch of an HIV test. The epidemic was just starting to take shape and this test had the incredible ability to reliably/adequately diagnose people. I was determined to stay in industry and learn more of the business side after that.

How did you join Roche?

Roche asked me to run their affiliate in France. The focus was on oncology and it was really exciting because I hadn't worked in this area before. I had the opportunity to launch many of Roche's landmark medicines, including Avastin.

Eventually, I moved to Basel to take on my role in Roche Partnering to lead a group of around 80 people based in different sites around the world. Our job is to scout interesting opportunities that complement the Roche pipeline. Around 30 to 40 percent of Roche medicines are externally sourced. Opportunities may include a very early research idea in academia or a large company that already has a product on the market. We focus on specific therapy areas, but we also look at personalized healthcare and healthcare IT, where companies are working on artificial intelligence, big data, or apps that can be applied by patients. Using AI, for example, it should be possible to better understand the impact of a drug on a patient and the results from clinical trials. These are really exciting areas and should lead the industry to a whole new level of discovery and development.

How did you move into business development?

I got an MBA from the University of Chicago and then I joined a management development program at Abbott that included a number of assignments, two of which were key for my development. One was in market research, which was interesting because I learned how to evaluate a physician's perception of the impact of innovative medicines, and how they often make an immediate yes or no decision. The second was a sales representative visiting psychiatric hospitals. My focus was mainly on manic depression and epilepsy, and I was shocked by the distress that existed in psychiatric hospitals and the lack of effective drugs in this area. But the physicians were very dedicated and had a real hunger for science and new medicines. I loved working so close to physicians and the psychiatric area. I remained in that area for a number of years before going on to run the business unit for neuroscience at Sanofi.

What are the most challenging aspect of your role?

I need to empower my team so that they can find the best opportunities. If I want to empower them I should let them do what they know best and run with it. But at the same time, I have experienced a lot; it can be difficult to share your own experiences while still empowering people to make their own decisions. Sometimes I have to encourage them to be more forceful or to be aware that something is too risky and not worth pursuing. I am so proud when I see my team develop – especially when they are promoted and go on to become leaders in an area. When you are in a senior position you always end up feeling like you have a lot of children. Finally, we all work really hard and it's rewarding to see the impact it has on the company pipeline.

What is the biggest lesson you have learned over your career?

To continuously work to be a good leader. When you move into a senior role, you think you are ready to lead people – you are motivated and driven; you think that being a good leader will be spontaneous. In reality, you need to roll up your sleeves and work on it. During the first 15 years of my career, I learned how to be a pharma executive, but it took another 15 years to learn how to be a good boss. But if you work on it, it will change your life and have a huge impact on the people around you.

Some say there is a lack of women in the industry. What is your view?

I actually think there are more women in the pharma industry than in many other industries. But it is true that you tend to find less women at the top. Women and men are different; we think differently and express those thoughts differently, I think – that is the value of diversity. Of course, there are challenges – you might be the only woman in a boardroom – but if you stay focused, believe in yourself and get the right training, then you can succeed no matter what. I have tried to develop skills to be comfortable in this situation – and also to be a mentor to women. But sometimes I can't nominate women for leadership roles in my team because I don't have the right candidates at the time. I try to be neutral to gender to focus on the right person for the right job, but I'm not neutral to the gender of my interview pool. My interview pool will always have an equal number of men and women.

Why is pharma such a rewarding industry to work in?

As well as the difference you can make to patient lives, I love that I can continuously learn. Recently, I visited a school in Basel to talk to children about what they want to study – I told them that the beauty of the pharmaceutical industry is that you continuously learn. Every day, I come home smarter than when I left – but also more aware of my lack of knowledge; that's not always a great feeling, but it always helps you to progress.

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