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Welcome to a Wild New Year

And welcome to our first issue of 2025!

Is it me, or did January seem to last much longer than usual? It's perhaps because so much happened in a short space of time. Many acquisitions, new collaborations, and lawsuits have been announced in the industry, bird flu is back in headlines, and there has been change and unpredictability in the US as Trump takes office. He immediately withdrew the US from the WHO and rescinded executive orders made during the Biden administration, including those focused on strengthening Medicaid and the Affordable Care Act, and tackling prescription drug costs. A temporary pause on federal funding also caused widespread confusion and panic, with scientists worried that grants for research would be affected. There will no doubt be many more changes to come – some of which may be welcomed by drug developers; several companies have already called for a rethink of the Medicare price negotiation process.

Just prior to Trump's inauguration, the HHS announced that 15 new drugs had been selected for Medicare drug price negotiations, including Ozempic and Wegovy. For now, the Inflation Reduction Act and the price negotiation process remain intact. In Trump's first campaign, drug pricing was a key theme, but it seems to be significantly lower on the agenda for his second term as he instead focuses on climate policies and diversity.

This print issue provides a snapshot of the trends and conversations shaping the industry. To get the latest, as it happens, please visit our website: *www.themedicinemaker.com.*

If there's a topic you want to read more about – or even write about – please get in touch: *stephanie.vine@conexiant.com.*

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Understanding the H5N1 Threat

With new cases of avian influenza appearing, what does this mean for global health and what are drug developers doing about it?

Credit: Adobestock.com

Avian influenza has been making waves in media headlines. At the start of January, the first human death in the US from H5N1 was reported. US authorities have also detected the first outbreak of the H5N9 strain in ducks in California, while in the UK a case of H5N1 was detected in a human for the first time since 2022.

Concerns have been growing since the virus was identified in cows in the US in March 2024. The more it mutates and affects new species, the more likely it is that it will gain the ability to transmit between humans. The global population will have little to no immunity against an avian flu because most humans have never encountered it before.

Although mutations in the virus are causing concern, many scientists emphasize that the imminent danger is low. Ed Hutchinson, Senior Lecturer at MRC-University of Glasgow Centre for Virus Research, explains, "Because viruses are closely adapted to particular host species, it's really hard for a bird flu virus to infect a human. This is why, despite the very high levels of H5N1 currently infecting wild and farmed birds, human infections with this virus are extremely rare, and normally only occur in people who have close contact with birds."

Scientists are calling for tests, vaccines, and drugs that can control the spread of the virus in poultry and livestock, as well as close surveillance. Efforts are also ongoing across the industry to develop pandemic influenza vaccines and therapeutics.

One of the most high profile companies active in the pandemic vaccine space is Moderna, which has received $590 million in funding from the US Department of Health and Human Services for the development of mRNA-based pandemic influenza vaccines. A phase I/II study was started in 2023 to generate safety and immunogenicity data for pandemic vaccine mRNA-1018. The study results will be shared soon and Moderna is now preparing for phase III.

Meanwhile, at an earlier stage of development, InvisiShield Technologies has announced that it is accelerating development of its H5N1/pan-influenza program. The company is working on intranasal antibody candidates for influenza, SARS-CoV-2 and RSV. Preclinical studies have demonstrated potent efficacy against H5N1.

Another company, Arcturus Therapeutics, is moving into a phase I clinical trial of its self-amplifying mRNA vaccine candidate for H5N1. The first trial participant was dosed in December 2024, with the work being funded by BARDA.

BARDA is also funding other projects related to pandemic preparedness. The agency recently selected four Concept Stage winners for its Patch Forward Prize, with a focus on microneedle technologies for RNA vaccines for COVID-19, seasonal influenza and pandemic influenza. Each winner (Micron Biomedical partnered with Zipcode Bio; LTS Lohmann partnered with BioNet; Vaxxas partnered with BASE; and PopVax partnered with LTS Lohmann) will receive $2 million to help advance their technology. BARDA will also be launching the preclinical stage of the Patch Forward Prize later this year.

The world is not being complacent, but continued research is a must.

Experimenting in a Most Peculiar Way

Flight Engineer Jasmin Moghbeli retrieves media bags for the Emory Health Sciences Study from inside the Kibo Japanese Experiment Module.

Credit: NASA

QUOTE *of the month*

"For over seven decades, WHO and the USA have saved countless lives and protected Americans and all people from health threats. Together, we ended smallpox, and together we have brought polio to the brink of eradication. American institutions have contributed to and benefited from membership in WHO."

Quote taken from the WHO statement following the US's announcement of intent to withdraw

Our Hearts in the Stars

Study aims for stronger cardiac cells

An Emory Health Sciences study (DOI 10.1016/j.biomaterials.2024.123080) explored the effects of microgravity on heart cells by sending 3D human cardiac spheroids, derived from induced pluripotent stem cells, to the International Space Station. After a period of exposure to microgravity, the spheroids were analyzed for changes in protein levels and gene expression. The findings revealed significant alterations in proteins and genes linked to stress responses and metabolic processes that could make the cells stronger.

"The idea behind cell therapy is to regenerate new muscle," says lead researcher Chunhui Xu. "But survival is the issue. For the heart muscle specifically, once it's damaged, it cannot regrow. After you inject new cells into the injured area, many of them are lost."

Understanding the molecular changes that enhance cell survival in microgravity could allow the researchers to apply these insights to improve the way cells for therapy are prepared on Earth and lead to more effective, resilient heart cells for regenerative treatments.

Managing Change in Devices for Patients

We need to step away from assumptions on device interchangeability and find out what patients really want

By Alex Fong, Head of Insight at Owen Mumford Pharmaceutical Services

An increasing number of patents for biological medicines are now expiring – driving new growth in biosimilars. This, in turn, is throwing a spotlight on the issue of drug delivery device switching.

Developers of biosimilars need to differentiate their offerings from originator products – and a novel drug delivery device can be an attractive option. After all, patients are used to changes in the brands of drugs they are prescribed so it's tempting to think they won't be fazed by a new delivery device from a different manufacturer.

But it's not as simple as that. If a patient has been using the same auto-injector for years, they may struggle to cope with a new one – or they may be afraid of unfamiliar features. Patient confidence is key – otherwise there's a danger they won't use the new device and will miss out on vital doses of medication.

The stakes are high – particularly given the growing trend for self-administration by patients at home (and, therefore, away from the watchful eyes of healthcare professionals). But if you get it right, it's a win-win situation; patients are more likely to adhere to their treatment regimen if they find it easy to use their drug delivery device. This isn't just good for the patient – it also benefits the healthcare system and pharmaceutical companies.

So how much change can patients cope with when it comes to their drug delivery device? The only way of knowing is to put a new device to the test with real patients. However, there is a surprising shortage of studies on the ease of switching devices – and that's why we decided to commission an independent study to evaluate the ease with which patients were able to switch between two different auto-injectors.

The two devices chosen for the study were SHL Medical's three-step, button-activated DAI auto-injector and our own OMPS two-step, spring-powered Aidaptus device, which does away with the push-button and is activated by the patient simply pressing the device onto the injection site. As well as making it easy for patients to use, we designed Aidaptus to accommodate both 1 mL and 2.25 ml prefilled glass syringes in the same base device – with stopper sensing technology and a self-adjusting plunger that automatically adapts to the different fill volumes in each syringe.

We believe our device brings benefits, but what about the patients who will – quite literally – be at the sharp end? To be clear, our aim wasn't to compare the two devices (all study participants had already been using the DAI auto-injector for at least three months). We simply wanted to know how easy it was for the patients to switch from their familiar device to a new auto-injector.

There were 52 participants (34 women and 18 men) with an average age of 51 (age range 16–75) split equally between the UK and the US. They were each asked to carry out four injections into an injection pad on a table – starting with the DAI auto-injector and then alternating with the Aidaptus.

They were given no help with the new device – just the instructions for use (IFU) in the box containing the device. We wanted to see if they could successfully carry out injections with the new Aidaptus auto-injector without any external prompting or training. We were also interested to see how long they took to do the injections, whether they actually read the IFU (or even looked at them!), and how confident they were in performing the injections. Watching the participants handling the new device certainly provided us with some clues as to how easy to use they found it.

All the injections were carried out successfully – even with the unfamiliar device. Most participants only needed to examine Aidaptus once to deliver injections successfully, with the ability to switch between the two devices not affected by gender. Those aged over 40 took slightly longer to deliver the injections with both devices – but still completed them successfully. Interestingly, by the second use, the injection times – calculated from when a participant placed the auto-injector on the injection pad and started the injection process through to when the device was removed from the pad – were similar for both devices.

Of course, although these results are interesting, they are obviously just a start – we need many more user studies to really understand all the potential pitfalls when it comes to asking patients to switch to an unfamiliar drug delivery device. Nevertheless, it was reassuring for us to see that the study participants managed to take it all in their stride – even when under pressure in an artificial test environment.

And I'll cheekily add that our results suggest that choosing an innovative two-step auto-injector for biosimilars instead of a traditional three-step device may not be a step too far after all!

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Celebrating the best and brightest companies in pharma

The Medicine Maker Power List celebrates influential individuals in the pharmaceutical industry; our Innovation Awards celebrate breakthrough manufacturing technologies. But what about companies as a whole?

Welcome to The Medicine Maker Company of the Year Awards 2025! Each year, we select the top contenders for each category based on market share, financial performance, and technology offerings. However, we leave it up to readers to decide on the final winners. For several weeks, visitors have had the opportunity to vote for their favorite companies. Here are the companies you chose for 2025.

Credit: Novo Nordisk

BEST BIG PHARMA COMPANY AND BIG "TALKING POINT": *Novo Nordisk*

DOUBLE WINNER!

HEADQUARTERS:
Bagsværd, Denmark

There's an interesting story of competition in the history of Novo Nordisk. In 1923, Nordisk Insulinlaborium began commercializing insulin. In 1925, former Nordisk employees established their own company: Novo Terapeutisk Laboratorium. Both spent the next several decades competing in the diabetes field, until they merged in 1989 to form Novo Nordisk A/S.

It was hardly a surprise to see so many votes for Novo Nordisk. At industry trade shows and events, everyone is talking about this company and its semaglutide products: Ozempic and Wegovy. Some analysts have predicted that Wegovy could become one of the best selling drugs ever because of the huge demand for weight management solutions. With Novo Nordisk struggling to manufacture high enough product quantities, its parent company, Novo Holdings, launched an unexpected acquisition of CDMO Catalent for $16.5 billion in 2024. Three of Catalent's fill-finish sites were then sold to Novo Nordisk.

Novo Nodisk is also investing in capacity for other drug areas. In mid-December, it announced an investment of 8.5 billion Danish kroner (approximately $1.18 billion) to create a brand new modular production facility in Odense, Denmark, that will span over 40,000 m^2. However, it's not all smooth sailing. Recently, the company announced results from a phase III trial of CagriSema (a fixed dose combination of cagrilintide and semaglutide). Trial participants lost around 22.7 percent of their body weight, but share prices in Novo Nordisk dropped – because many in the market had been expecting a weight loss benchmark of 25 percent.

Honorable mention: Pfizer

BEST PROVIDER OF BIOPROCESSING SOLUTIONS AND BEST CDMO: *Merck KGaA, Darmstadt Germany*

Credit: Merck KGaA, Darmstadt Germany

DOUBLE WINNER!

HEADQUARTERS:
Darmstadt, Germany

This German multinational took the crown in two categories. Merck KGaA, Darmstadt Germany, has a long history stretching back to the 1660s – making it one of the oldest chemical and pharmaceutical companies in the world. Today, its life science division supplies a broad range of solutions, consumables, and services for discovery, development, manufacturing (both upstream and downstream), and testing and analytics. In the US and Canada, the life science business is known as MilliporeSigma.

Several big announcements were made in 2024. A single-use reactor specifically designed for antibody drug conjugates was launched. On the CDMO side of the business, the company also announced a €70 million expansion of its ADC manufacturing capabilities at its Bioconjugation Center of Excellence facility in St. Louis, Missouri. This investment will triple existing capacity. In October 2024, a €290 million biosafety testing facility was opened in Rockville, Maryland, to meet growing global demand, and in late December it emerged that Merck had signed an agreement to acquire HUB Organoids Holding in the Netherlands. In a statement, Merck said that the promise of organoids contributes to the company's sustainability, diversity, and inclusion ambitions.

Best Provider of Bioprocessing Solutions Honorable mention: Thermo Fisher Scientific

Best CDMO Honorable Mentions: Thermo Fisher Scientific & Catalent

BEST API & EXCIPIENTS SUPPLIER: *BASF*

Credit: Pixabay.com

HEADQUARTERS:
Ludwigshafen, Germany

This was a hotly fought category, reflecting the number of quality suppliers in the sector, but BASF emerged as our winner for 2025 (after also taking the crown in this category in 2023). Founded in 1865 in Mannheim, Germany, the company was originally called Badische Anilin- und Sodafabrik. One of the company's most famous innovations is PVP, which was first used in the textile industry, but gained use in medicinal applications in the 1940s as a synthetic blood plasma substitute.

BASF has since turned into a global leader across multiple industries, and is well known in pharma for its wide range of APIs and raw materials, as well as excipients for parenterals, orals, topicals, and biopharmaceuticals. The company also offers quality, regulatory, and digital services, including its virtual pharma assistants.

In 2024, the company launched the Kolliphor P188 Cell Culture – a poloxamer with a lower than average molecular weight designed to offer shear protection. The company has also introduced Kollipro Urea Granules, which can help enhance flowability, minimize agglomeration, and reduce preparation and handling time in downstream processing.

Honorable mention: DuPont

BEST PROCESSING EQUIPMENT SUPPLIER: *IMA Group*

Credit: IMA Group

HEADQUARTERS:
Ozzano dell'Emilia, Bologna, Italy

IMA launched its first blister machine for the packaging of pharmaceutical products in 1976. Today, the company's portfolio includes machines for solid dose manufacturing, aseptic processing, freeze drying, packaging, end of line equipment and more, but IMA prefers to view itself as a solutions provider rather than a machine supplier. Thomas Fricke, Commercial Director at IMA Pharma, has said that it's easier to tell a pharma customer what machines the company doesn't supply rather than to list all the solutions available. As such, the company has adopted an "All-In-One" strategy where it can provide full solutions as a single supplier.

One of IMA Active's latest innovations is AQUARIA, a component washer designed to maximize washing chamber volume while minimizing machine size. It offers flexible configurations, optimizing efficiency, reducing consumption, and respecting the environment with a compact design. IMA Life has released TILE-X for fill-finish processing for small batch production. Designed to respond to Annex 1 requirements and based on electromagnetic levitation, TILE-X is a compact, Grade A, gloveless modular processing unit for high-value pharmaceuticals such as ATMPs. Another new launch from IMA Safe is the GIANT5-A96, a blister line with speeds of up to 1,300 blisters and 500 cartons per minute.

Honorable mention: Syntegon

BEST PRIMARY PACKAGING SPECIALIST: *West Pharmaceutical Services*

Credit: West Pharmaceutical Services

HEADQUARTERS:
Pennsylvania, USA

You voted for West – which delivers around 43 billion components and devices every year, and recorded net sales of $2.95 billion in 2023. The company focuses on containment, delivery systems, and services for injectable medicines, and has over 10,000 employees globally. Its expertise includes analytical services, regulatory support, fill-finish, assembly and packaging, contract manufacturing, and more. It is also well known for its expertise in extractables and leachables – a topic that West's Diane Paskiet has spoken with The Medicine Maker about before – and its knowledge of materials and their compatibility with drug products.

In 2024, West launched its Daikyo Crystal Zenith (CZ) Nested Vials in Tub – a containment solution designed for cell and gene therapies, radiopharmaceuticals, and sensitive molecules. The company also recently won the Heart of Pharma Award at CPhI for its partnership with the Fox Chase Cancer Center in Pennsylvania. The award recognizes companies for philanthropic, ethical, and community-based ventures. In February 2024, the company was named by Newsweek and the Plant-A Insights Group as one of America's Greatest Workplaces for Diversity.

Honorable mention: Corning

CELL AND GENE

The Synergy of Science and Business

Developing science is good; developing successful commercialization strategies is great

By Stella Vnook, CEO, Likarda

Science is at the heart of cell and gene therapies (CGT), but business strategy is the lifeblood that ensures its survival and success. As a former healthcare provider and scientist with over 25 years of experience in biotechnology and pharmaceuticals, I learned early on that scientific breakthroughs alone do not guarantee market success. After transitioning into leadership roles, I realized that developing and executing the right business strategies is critical, particularly in a landscape like CGT where investment is scarce, competition is fierce, and failure is not an option. For innovation to shine in the real world, it must be paired with a robust understanding of business drivers, market needs, and strategic planning.

Since taking the lead at Likarda, my objective has been to fully harness the power of cutting-edge technology by aligning a thoughtful business strategy of encapsulating cells and delivering them effectively. The science is groundbreaking, but it was the revised strategic approach that realized the potential. By analyzing market trends, evaluating unmet needs, and taking a hard look at where resources and investments were headed, I began to see broader applications based on the versatility of the technology, which we positioned in cell therapies, biologics, small molecules, and even cryopreservation logistics. Diversifying our product pipeline also ensured that we weren't dependent on a single market segment.

Below are the key strategic pillars that every scientist and entrepreneur should embrace when venturing into the commercial world.

Know the market needs and gaps

Hypothesis generation is crucial in business strategy. You need to continually ask: "What do patients, clinicians, or industry leaders need that isn't being met?" Understanding the broader healthcare ecosystem and identifying the true pain points is critical to shaping a product or technology that will stand out. For Likarda, a deep-dive into unmet needs led us to understand that our Core-Shell Spherification technology had the potential to disrupt multiple sectors.

Expand your view beyond your original vision

Once you have proof-of-concept, it's essential to ask "What else?" Expanding applications into new markets is a vital business strategy, especially when resources are limited. In the CGT space, funding often falls short. Having a diversified approach allows companies to build resilience.

Assess the financial landscape early and often

Every entrepreneur needs to learn the language of finance. Knowing how to read a balance sheet, understanding capital efficiency, and projecting ROI are just as important as understanding the science behind your technology. Set realistic financial goals, secure the right funding partners, and deploy resources wisely.

Anticipate market shifts and adapt

A business model that works today might not work tomorrow. Whether it is regulatory shifts, technological advancements, or emerging competition, you must stay nimble. Be prepared to pivot to a platform play to avoid becoming a one-product company.

Focus on execution and scalability

Every great scientific breakthrough must eventually commercialize to benefit society. Can you manufacture at scale? Can you deliver consistent results across different markets? Ensure you have the operational infrastructure in place and think about the path to commercialization early on.

Build strategic partnerships

Forming partnerships with larger corporations, academic institutions, or even competitors can help you scale faster and more efficiently. For instance, our collaboration with pharma companies and other partners allowed us to explore new pipelines while leveraging their expertise and resources.

In closing, successful leadership in CGT space demands more than scientific acumen – it requires a fusion of visionary strategy and practical business insights. By knowing the market's unmet needs, diversifying the applications of core technology, maintaining financial discipline, anticipating shifts, and forming strategic partnerships, we not only position our company to thrive but also ensure that the innovations we pioneer have the greatest possible impact on patients' lives. These strategies collectively form a roadmap for bringing therapies to market that are not only groundbreaking in their science but sustainable in their execution. At the heart of all we do remains the ultimate goal: delivering transformative, life-improving solutions to patients worldwide. In this fast-paced and competitive landscape, it is this blend of science and strategy that will define the leaders of tomorrow.

By combining cutting-edge technology with strong business foundations, we don't just aim to survive – we aim to shape the future of medicine.

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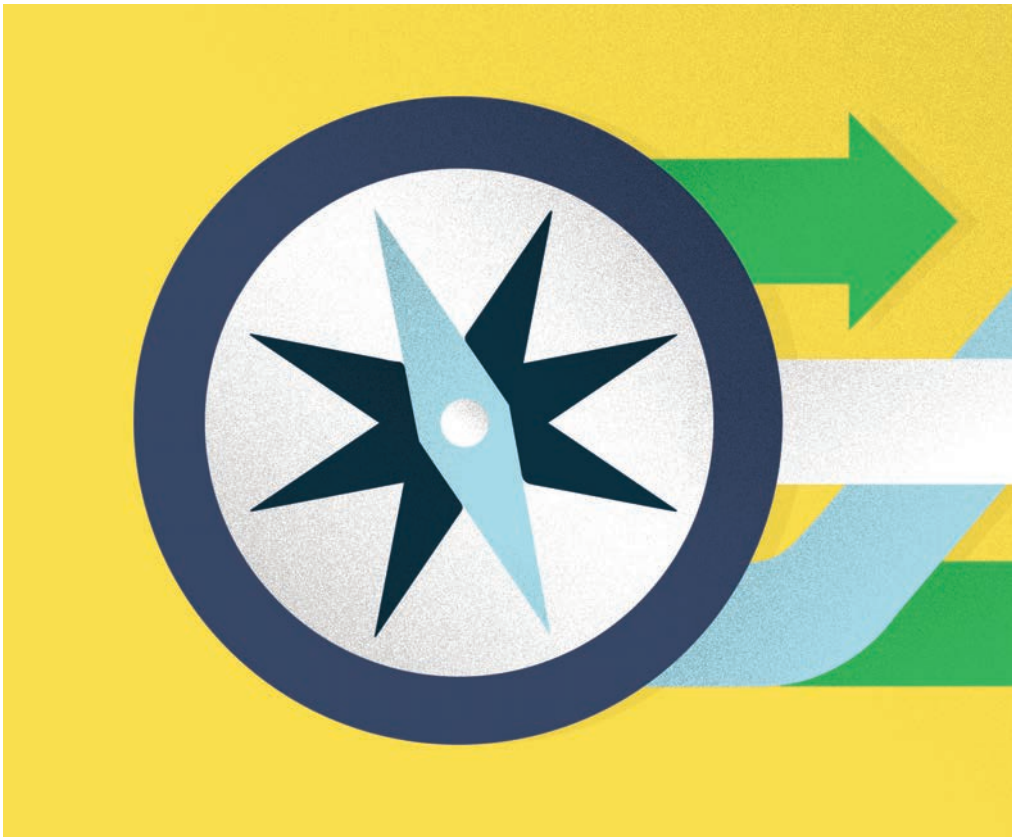
BIOPROCESSING

Navigating the Challenges and Complexities of ADC Development

ADC development is a complex process that can be streamlined – and optimized – by taking the right partnerships and strategies into consideration

By Erika Kovacs, Senior Director, Bioassays, Abzena



In the intricate and highly specialized arena of targeted oncology therapies, ADCs hold promise for safer and more effective treatment options. Developed as "biological missiles," ADCs are composed of a monoclonal antibody covalently attached to a cytotoxic drug, aiming for high specificity in targeting and potent effects in eliminating cancer cells.

The maturation of ADC technologies has broadened their scope of use, with a growing number of ADCs being approved or in late-phase clinical trials for various tumor types. These developments are driven by the increasingly diversified antigen targets and bioactive payloads, as well as enhancements in intratumor distribution and activation, which can potentially improve the anticancer activity for difficult-to-treat tumor types (1).

However, the development of effective and safe ADCs is complex and requires a multidisciplinary approach (2). One of the key terms that guide the ADC development process is developability. This term encapsulates a range of considerations that go into finding the best lead molecule for targeting a specific disease. It's not just about creating ADCs; it's about rigorously assessing them from various angles, including functionality, specificity, safety, and stability.

The right candidates

When discussing the functionality of ADCs, we must not merely consider their ability to target and destroy cells; we need an all-encompassing evaluation using a range of methodologies. High-throughput screening quickly distinguishes promising ADC candidates by assessing important parameters, such as binding affinity and payload release, while cytotoxicity assays provide insights into cell viability post-ADC exposure, revealing both lethal and sub-lethal effects.

Advanced imaging techniques, such as confocal microscopy, offer real-time visual insights into an ADC's interactions with cells, highlighting uptake and internal trafficking processes. These tools, combined with 3D viability assays on spheroid cultures as solid tumor models and real-time viability assays to monitor the kinetics of cell killing, offer a comprehensive perspective on an ADC's functionality. By integrating data from these methods, researchers can not only confirm an ADC's efficacy, but also thoroughly grasp under what conditions it performs optimally.

Another crucial aspect of ADC development is specificity. Because of the potent cytotoxic agents they carry, ADCs need to be highly specific to their target to minimize off-target toxicity (3). Flow cytometry and tissue profiling through immunohistochemistry (IHC) can be used to evaluate this specificity. IHC allows for the localization and visualization of the ADC within tissue samples, thus confirming that the ADC is binding exclusively to its intended target. Combining both flow cytometry and IHC helps mitigate risks associated with off-target effects that could compromise safety.

Of course, safety is paramount in the

development of any therapeutic agent. With ADCs, developers should assess interactions with Fc gamma receptors, and conduct off-target profiling. One specific area where safety comes into play is the "bystander effect" – a phenomenon that relates to how an ADC impacts not just the target cells, but the surrounding non-target cells, either enhancing or mitigating its overall therapeutic effect depending on the disease context.

Keep it stable

Stability and formulation development are also crucial for success. The ADC must remain stable during its journey from manufacturing to delivery within the patient; it is vital that the ADC does not release its payload prematurely, causing systemic toxicity. In this regard, lyophilization has emerged as a popular technique to improve the stability of ADCs, especially during shipment (4).

One common method of evaluating stability is "ex vivo serum stability" where the ADC is incubated with either human or animal serum for various time points. After incubation, the sample undergoes analytical processes to assess whether the ADC retains its original composition or has started shedding its payload. This type of ex vivo serum test provides critical insights into the ADC's behavior in a biological environment.

"Using a strategic blend of efficacy, safety, and stability assessments will help ensure the eventual success of your ADC."

The ADC can be reconstituted in different buffers, subjected to varied temperatures, and left for specific durations to evaluate its stability. In this manner, researchers can understand how different formulations affect the ADC and make informed choices for long-term storage. When a candidate ADC reaches a mature development stage, it moves into larger-scale manufacturing and, eventually, clinical studies. Ensuring that the product remains stable during these phases is paramount, as any instability can derail both the manufacturing process and clinical trials.

A holistic approach

To conclude, the development of ADCs is a complex but incredibly promising field that requires a multi-layered approach for success. A one-size-fits-all approach is not appropriate. The complex interplay between an ADC's antibody, linker, and drug payload means that each component requires meticulous consideration. The biological precision in targeting the correct antigen or receptor is paramount – and so is stability, where considerations regarding linker chemistry and delivery methods may necessitate tailored solutions.

A holistic approach for ADC design, development, and manufacturing should include experts from various research areas, including chemistry, analytics, bioassay, and process development from the very beginning. With this approach, you can maximize the likelihood of finding the most promising candidate and design. However, don't be afraid to lean on external experts when needed. Collaboration can be an accelerator for success in the complex journey of drug development. Partnering with another company that excels in a desired methodology, such as state-of-the-art analytics or advanced imaging techniques, can streamline the development process, ensuring that the ADC is rigorously tested under varied conditions.

Using a strategic blend of efficacy, safety, and stability assessments will help ensure the eventual success of your ADC. With each step meticulously planned and executed, the chances of developing a successful ADC increase, bringing us one step closer to more effective and safer cancer treatments.

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SMALL MOLECULE

The Liquid Challenge

Regulators want more pediatric formulations. Companies often turn to liquids, but there are specific challenges that need to be considered.

By Louise Carpenter, Head of Pharmaceutical Development, PCI Pharma Services

Credit: PCI Pharma Services

Credit: PCI Pharma Services

In 2023 the FDA released Guidance for Industry, Pediatric Drug Development Under the Pediatric Research Equity Act and the best Pharmaceuticals for Children Act: Scientific Considerations, in which sponsors are advised to provide plans for developing age-appropriate formulations of drug products in cases where an adult formulation is not appropriate for pediatric patients (1). With many medicines, this can translate to a fairly straightforward formula: children = liquids.

This move from the FDA is not only vital to ensure availability of the right drug products for the right patient demographics and reducing off-label use in children; from a business standpoint, it presents a useful tactic towards sustaining and maintaining growth. Given that the market for oral liquids is predicted to increase at a compound annual growth rate of around 6.5 percent in the coming decade (2), the outlook for substantial gains in this segment are as promising as they are important. Crucially, pediatric exclusivity typically extends intellectual property protection by 180 days, providing nearly six additional months of branded drug sales.

Liquid formulations offer some advantages over traditional oral solid dose (OSD) products, particularly in terms of ease of administration. Liquid formulations are easier to ingest compared to tablets or capsules, which can be particularly challenging for children (as well as seniors) who may struggle to swallow solid forms. They are also good for dosing flexibility. The same bottle of liquid medication can be used to administer different doses, simply by adjusting the volume given with a spoon, syringe, or dosing cup. This variability is good for supply chains too because it eliminates the need to develop a new stock-keeping unit for each dose variation, simplifying inventory management and reducing production costs.

Liquids also have increased drug absorption and bioavailability that can lead to faster onset of action, and allow for incorporation of sweetened or flavoured vehicles to mask the bitterness or unpleasant tastes of APIs.

So why don't more companies develop liquid formulations from the onset?

"Given the formulation-specific challenges, it's perhaps unsurprising that a pediatric dosage form "cottage industry" has sprung up to help pharma brand owners expand into liquids."

There are challenges. One key issue is the inherent instability of liquid formulations compared to their oral solid dose counterparts. Liquid forms are more susceptible to physical and chemical degradation, and the potential for microbial growth is significantly higher, necessitating rigorous preservation and/or sterilization processes to maintain product integrity.

Liquid formulations also require robust packaging solutions capable of preventing both breakage and formulation interaction. A broken container can result in the total loss of the product, posing significant logistical and financial concerns.

The containers are also relatively bulky and inconvenient for patients. Single-use sachets can be an attractive alternative for bolstered convenience, but this packaging format incurs its own obstacles; most notably ensuring dose accuracy. (It is worth noting here however, that a single-use sachet does have the added benefit of the option to nitrogen blanket, decreasing any potential oxidative issues with the formulation).

We also can't overlook the high potency angle. More than 25 percent of drugs on the market today are classed as highly potent, with 60 percent of oncology drugs in development involving highly potent active pharmaceutical ingredients (HPAPIs) (3). As more and more ADFs in development contain HPAPIs, this escalated high potency ratio will ultimately carry over into the development of pediatric formulations. The approach to handling such molecules requires stringent controls to ensure safety and efficacy, ideally involving contained engineering solutions to ensure drug product integrity and operator safety – including the use of dedicated facilities, HEPA filtration systems, rigorous cleaning validation procedures, and personnel highly trained in handling potent molecules.

Once the HPAPI is fully wetted, the risk to the operator is significantly reduced, but getting the HPAPI fully wetted safely can be a challenge. This is primarily because of the risk of airborne contamination, as HPAPIs are typically fine powders and can easily become airborne, posing a serious inhalation hazard to operators. The powder's propensity to accumulate static electricity further increases the likelihood of dusting, where particles can disperse into the air, especially during handling or transfer. Controlling the wetting process is therefore crucial; if the liquid is added too quickly or inappropriately, it can cause splashing or aerosolization, potentially releasing the HPAPI into the air. Effective containment is essential, requiring specialized equipment like isolators or closed systems to prevent any escape of the powder before it is fully wetted. Additionally, the variability in the physical properties of HPAPIs, such as particle size and hydrophobicity, can make the wetting process unpredictable, sometimes leading to prolonged periods of risk as the powder may resist wetting or form clumps.

Given the formulation-specific challenges, it's perhaps unsurprising that a pediatric dosage form "cottage industry" has sprung up to help pharma brand owners expand into liquids. If you choose the route of a CDMO, make sure they have dedicated expertise in liquid dosage formulation development and manufacturing, as well as the knowledge to navigate the regulatory landscape. Also look for advanced analytical testing and taste-testing facilities such as electronic tongues (e-tongues), which are a great way to help a product achieve patient compliance. The right taste masking is crucial for pediatric formulations because any disagreeable flavours are more pronounced in liquid form compared to solid dose products.

In summary, oral liquid dosage forms present unique benefits and challenges with additional considerations when the drug product is classified as being potent, but with the right expertise and technology, these hurdles can be effectively overcome and managed to deliver high-quality, patient-centric therapies.

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Left: Andrew Lewis
Right: Marwan Alsarraj

NEXTGEN

Multifaceted Views on Manufacturing

In 2024, we introduced you to our special 10-year anniversary feature on the future of pharma. Here, we share more views from that feature – this time focusing on manufacturing, technology, and automation. One key trend? AI will shape the future.

What we asked: "Looking ahead to the next 5–10 years, what will be the key disruptors and/or what can be improved upon in the pharma industry?"

Welcome to Biopharma 4.0

– with Andrew Lewis, Chief Scientific Officer, Quotient Sciences

"Biopharma 4.0, which has focused on digital transformation within the pharma/biopharma industry over the past decade, is well underway. In silico tools are transforming drug development at every stage and we are seeing small molecule drugs being discovered using generative AI even faster. It has been just over a year since we saw the first fully generative AI-created drug enter human trials (Insilico Medicine's INS018_055) and the excitement about AI and its potential has far from waned.

"Physicochemical properties of novel NCEs can be predicted from their structure to help inform candidate selection before generating experimental data. Such tools are not limited to small molecular weight drugs, as it is now possible to predict protein structure and function from its sequence of amino acids. In early development, physiologically based pharmacokinetic and pharmacokinetic/pharmacodynamic models can be continually refined as data becomes available to support decision making and maximize the chances of clinical success. In manufacturing, digital twins are increasingly used to de-risk and remove waste (e.g. time and cost) from processes for enhanced process control and improved product quality.

"If the last few years indicate what the future will hold, I anticipate AI and ML continuing their explosive path, impacting every stage of drug development. The continual linkages that we can build between AI and other in silico tools will lead to tremendous improvements in productivity across our industry, advancing the next frontier of medicines."

Accelerated Approval

– with Robert Hughes, Research Fellow, Grace

"One of the primary reasons that many of us – myself included – embarked on a career in the pharma industry was to help people. Whether for a mild ailment or a debilitating disease, medicines are one tangible way that we can help relieve a patient's suffering. However, in my 25 plus years in this industry, we have not seen a significant change in the time that it takes to get a new drug to market; the timeline from discovery through commercial launch is still in the 10-15 year range. While some medicines receive accelerated approval via fast-track, orphan, or breakthrough status to serve unmet medical needs, in general, patients in need must wait entirely too long for them to come to market.

"In the next ten years, I hope to see a reduction in the time it takes to get a new

medicine to market, and I believe that the application of AI and ML in all areas of drug development represents our best hope for shortening the average to under 10 years. A few of the ways AI/ML tools can make a material impact on the time it takes to get a new drug to market include:

- Analyzing large biological datasets to identify potential drug targets more quickly and accurately than traditional methods.
- Generating and screening millions of potential drug compounds; predicting their properties and efficacy before entering the lab testing phase; and predicting a drug's toxicity, side effects, and interactions, potentially reducing the need for extensive animal testing.
- Analyzing patient data to identify ideal candidates for clinical trials; optimizing clinical trial protocols and analyzing results more efficiently.
- Identifying new uses for existing drugs by analyzing mechanisms of action and potential effects on different diseases.
- Using data to improve drug manufacturing processes, potentially reducing costs and increasing efficiency.

"We've seen how ML can significantly reduce the time it takes to realize a scalable manufacturing process. While AI is unlikely to reduce the lengthy clinical trial and regulatory review phase in the near term – and as tools improve and become more integrated into all stages of drug development – the cumulative impact could become more significant over time.

"We have only scratched the surface when it comes to AI and ML applications in the drug development and manufacturing process. I'm energized by the possibilities that we can uncover for accelerating change in the next decade and beyond."

A Personalized and Sustainable Future

– with Marwan Alsarraj, Associate Director, Marketing Programs, Digital Biology, Bio-Rad Laboratories

"Several transformative changes would significantly impact the future of drug development, but three stand out as particularly exciting.

"Firstly, the potential of personalized medicine, and the shift towards treatments tailored to individual patients or genetic profiles, are not just promising, but are poised to revolutionize healthcare. In response, the International Consortium for Personalised Medicine (ICPerMed) predicts that the implementation of personalized medicine will lead to the next generation of healthcare by 2030. This approach promises earlier diagnosis, reduced adverse effects, and ultimately improved patient outcomes by leveraging developments in the biomedical, social, and economic sciences, together with technological advancements.

"Secondly, I would like to see a greater focus on sustainability in drug manufacturing to reduce our environmental impact. It's crucial that we recognize the current resource-intensive and waste generating processes in the production of APIs. By increasing manufacturing efficiency, we can simultaneously reduce material and energy wastage, ultimately minimizing manufacturing costs.

"There are several proposed solutions to this challenge, including the repurposing of used solvents for incineration to generate heat, or performing oil recirculation to support the operation of essential processing equipment, such as vacuums, pumps, and compressors. Using recirculating oil, these systems can operate more efficiently, reducing energy consumption and associated emissions. Many companies are also seeking to reduce their physical footprints – opting for benchtop and flexible equipment, reducing requirements for large laboratories and manufacturing facilities to minimize environmental impact.

"The third change that would significantly impact the industry is the increasing role of AI and machine learning ML in drug development workflows. The potential of AI tools to predict drug efficacy and safety

quickly and accurately is truly exciting, accelerating target discovery and accelerating preclinical testing. To fully realize this, we need comprehensive, reliable datasets and a collaborative approach to drug discovery. Open resources and communication between scientists and manufacturers would facilitate data sharing, unlocking the full potential of AI in drug development."

Digitalize and Automate

– with Michael Mrachacz, CSO & Managing Director, Uhlmann Pac-Systeme

"The pharmaceutical industry is affected by regulations like almost no other industry. Regardless of the requirements for ecological and social sustainability, we always have to fundamentally focus on patient safety. Furthermore, we are facing a rapidly changing world with a multitude of crises that will not disappear in the near future.

"We will not be able to meet these challenges with current production strategies, aimed primarily at optimizing existing processes from a cost perspective. Therefore, a fundamental revision of production strategies to find new solutions is essential to meet the challenges of sustainability, the increasing uncertainty of supply chains, and the disruptive changes in the industry. At the same time, therapies are being increasingly tailored to the individual needs of patients. This means smaller production batches and faster process conversion.

"To address all of these challenges, we must, above all, drive digitalization and automation forward. Digital production processes and smart factory concepts will enable us to respond more efficiently to the demands of personalized medicine. At the same time, digitized data analysis will help to process the large volumes of data arising from personalized medicine more quickly and to feed the results into production more efficiently. Both digitalized and automated production processes and the ability to process large amounts of data, also enable companies to operate in a more sustainable and resource-efficient manner and to respond with greater flexibility to crises.

Michael Mrachacz

"Flexibility is the bottom line. This also brings us to the concept of local4local, the second lever. In many manufacturing and production industries, we are seeing a shift towards local production. This is not least because of experiences surrounding the COVID-19 pandemic, though environmental disasters, trade conflicts, and geopolitical shifts also play a significant role. Local production for local markets and collaboration with local suppliers enables companies to be independent of supply chains, helps to monitor and comply with regulations, and makes sustainability easier.

"In a world facing profound changes, these are the decisive changes that we need in the next ten years."

Optimizing Processes With AI

– with Chad Telgenhof, Chief Commercial Officer, Sterling Pharma Solutions

"As the pharmaceutical industry strives to create the drugs of the future, it is looking to open up new molecular space, and explore the potential of new modalities. Patient safety and quality remain paramount, and technology plays an important role in both the design of new drugs and their manufacture.

"A significant improvement within the industry could be achieved through the widespread implementation of AI and ML."

"A significant improvement within the industry could be achieved through the widespread implementation of AI and ML throughout the lifecycle of a molecule. These would allow the design of new drugs to be undertaken much quicker, with the virtual evaluation of numerous parameters to assess physical properties,

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potential side effects, and efficacy.

"Process optimization could be significantly enhanced, building on information from numerous sources to reduce the time spent undertaking real-time experiments. Screening processes in terms of hazard evaluation, and finding the optimal parameters with which to safely and efficiently manufacture products requires – and generates – vast amounts of data, and being able to concentrate the time spent by scientists and engineers to key steps will accelerate processes towards scale-up manufacturing.

"In manufacturing, these technologies could monitor processes in real time to ensure quality control of products during synthesis, as well as the reactors and equipment being used, reducing human involvement in maintenance schedules. Supply chains and procurement could be automated to avoid stock availability issues for key reagents and intermediates, reducing delays and potential shut down of manufacturing, and maintaining operational and delivery schedules.

"These technologies can dramatically accelerate the process of identifying and optimizing drug candidates, predicting clinical trial outcomes, and personalizing treatments, ultimately reducing costs, time, and improving the success rate of bringing new therapies to market.

"There is application of AI and ML already within some areas of the industry, but the setup of the technologies requires significant capital expenditure, and the models are dependent on the amount and quality of data that are available for them to draw on. We are potentially some distance away from seeing universal adoption, but we are seeing major players in the industry harnessing the potential of existing technology, and building systems to grow as the amount of data that can be accessed increases. While there is no substitute for human interaction and experience, technology must be leveraged where possible to make the design and manufacture of drugs safer and more efficient."

Celebrating the Modular Approach – with Jerry Keybl, Senior Vice President, Biopharma Products and Strategy, Avantor

"Regardless of the manufacturing path, one transformative improvement that could dramatically elevate the biopharmaceutical industry is the adoption of modular manufacturing defined by product attributes rather than the manufacturing process. This not only optimizes existing therapies, but paves the way for rapid production of new, emerging therapies.

"This approach focuses on critical quality attributes and process parameters that define the product's efficacy, safety, and quality. This method ensures that the final product meets its intended quality and efficacy standards, allowing for more dynamic and adaptable manufacturing processes.

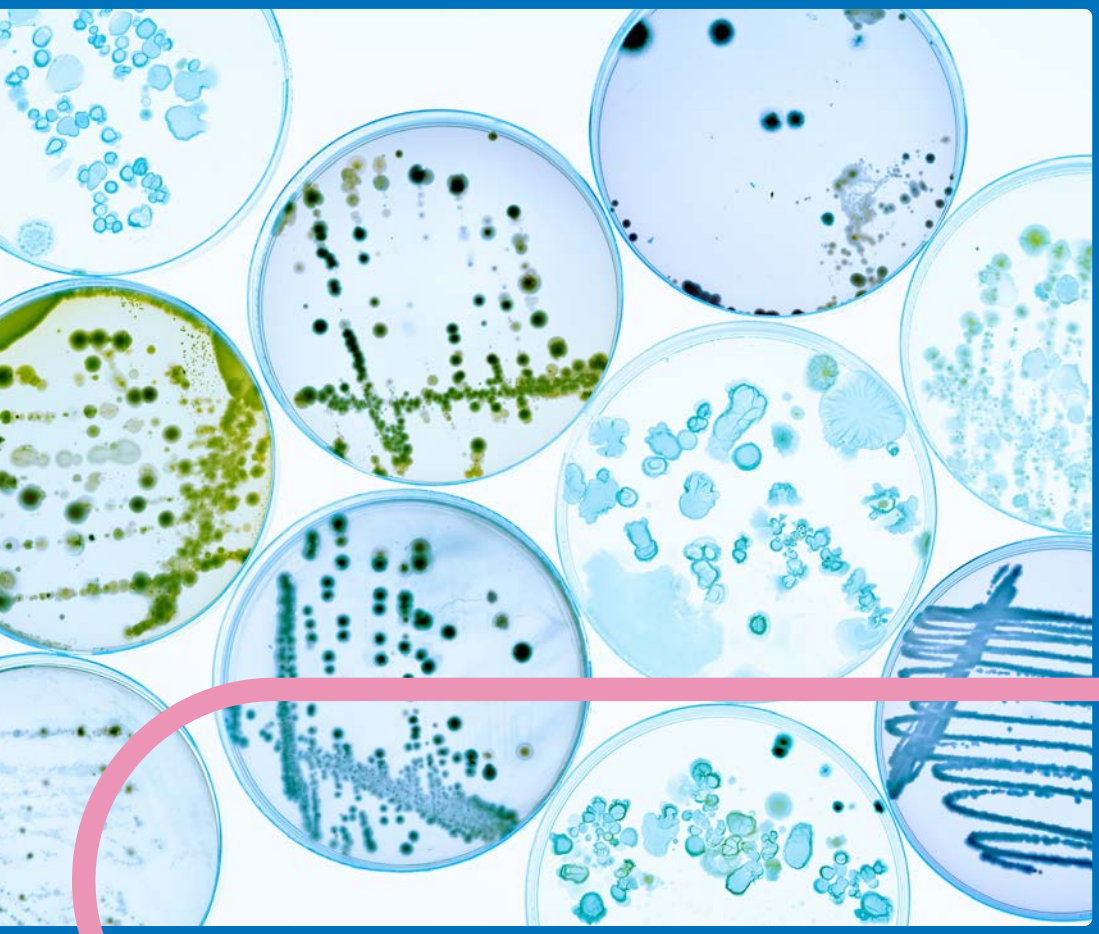
"In addition, the manufacturing process can be broken into modular units that can each be validated for specific attributes. These manufacturing modules can be reconfigured or replaced if needed, providing greater flexibility and efficiency. Modular manufacturing allows for rapid adaptation to new therapies and changes in production needs, which is particularly beneficial for personalized medicines and rapidly evolving treatment modalities. This method provides a holistic and integrated approach to validation, with process and product data flows as the foundation.

"Transitioning to attribute-based validation and modular manufacturing represents a paradigm shift for the pharmaceutical industry. We can unlock significant manufacturing productivity, enhance flexibility, and drive down costs – making these new treatment options accessible to more patients.

"In addition, something else I would like to see in drug development and manufacturing is as much standardization as possible around novel therapies. Wherever possible, platform processes and standardized raw materials and consumables should be employed to reduce complexity, accelerate manufacturing timelines and reduce costs. In addition, I would like to see clear and consistent regulatory standards for new modalities, balancing safety and the unique aspects of these therapies, such as production processes and efficacy definitions.

"Together, these changes would improve patient outcomes and advance the industry as a whole."

Want to read more views on the future of pharma? Check out: themedicinemaker.com/the-multifaceted-future-of-pharma



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"I feel as if I have to do better, run faster, and improve every day to get more medicines to patients."

Building Culture, Driving Growth

Sitting Down With… Lars Petersen, President and CEO, FUJIFILM Diosynth Biotechnologies

What inspires you to get up every day?
Patients, and the potential impact you can have on their lives. I spent eight years working for Genentech. When you make medicines for cancer, you often receive letters from patients and their families thanking you because you saved the life of their friend, their wife, their child, etc. This is such rewarding and purposeful feedback.

Now that I work at FUJIFILM Diosynth Biotechnologies, the exciting and passionate thing that makes me get up every day is having such a big platform to make a difference for patients. We work with innovators, big pharma, and biotech companies across the world. We see their pipelines and the impact to patients, and we hear stories on a much broader scale, which is very rewarding.

The more influential I am in my career, the more I can impact the agenda and direction of the entire life science industry. I feel as if I have to do better, run faster, and improve every day to get more medicines to patients. I think we all feel like this when working in this industry.

Did you find the switch from biopharma to CDMO challenging?
I certainly had to give it some thought. Specifically, I considered how I could apply my mindset to the CDMO business.

I had never seen the CDMO business as a purposeful part of the industry before; it was more an organization that merely churned products out whilst trying to make as much money as possible! To some extent, you still see that in the parts of the industry, but I'm trying to drive a different agenda to make sure that everything we do at this company has the same purpose and focus that innovators have. At our company, our aim is to be partners for life. What we mean by that is we are doing much more than just developing and manufacturing biopharmaceuticals; we partner with and work alongside our clients every step of the way to bring life-changing therapies to patients around the world.

What is overwhelming is seeing the impact and the opportunities we have with so many companies in what we do. Multiple opportunities mean multiple products and multiple launches, so the speed and pressure are immense – more so than what you would see in an innovator company with fewer products. The work is never done. There are always new products coming and it takes some getting used to.

What's your academic background and how has it helped your career?
I'm an engineer trained at the Technical University of Denmark, which – at the time – was the only place you could really get a master's degree in engineering in Denmark. I went straight out of school directly into the life sciences. My background is in automation and engineering in a manufacturing facility for life sciences. That's how I found my way into the industry, starting very early at Novo Nordisk. My training in engineering has helped me a lot to understand how pharma manufacturing works. My tenure with Novo Nordisk gave me a deep understanding of what the big pharma companies need from their CDMOs. As President and CEO for FUJIFILM Diosynth Biotechnologies I can merge these two.

How has the culture in Denmark helped play a role in your career?
Denmark is a small country, but there are a handful of life science companies, including Novo Nordisk, which were very big at the time I was studying (though not as big as they are today of course!). Life sciences is a popular career, particularly for those in the Copenhagen area where most of the universities are situated. The popularity of life sciences and my passion for helping people destined me for this industry. Jutland is home to the more traditional, mechanical industries with companies such as Danfoss, Grundfos, Lego, and Bang & Olufsen.

What are the key attributes of a successful CEO?
CEOs have changed a lot. You need to be mindful of the shifts and transformations in the world, and you have to understand how people are shifting. You must understand how business is changing and how to navigate between those shifts, as well as what is important to stakeholders and investors.

For me, it's all about people and stakeholders – and making sure you understand where the industry is going must be foundational to the strategy. Our three strategic pillars are: people first, transform the industry, and unprecedented delivery.

What are you doing when you're not being a CEO?
I have a wife and three kids, as well as a dog and a house, so I'm extremely busy making sure I have enough time for all that! I like to travel. I enjoy history, and what we can learn from it. The more you dig back into history, the more you learn to look at the future. I also like music and going to concerts too. Every single day is wonderful. I would love to have 24 hours more every day, but I think I'm in a wonderful position being in a job with so many good people around me. The people behind what we do are the most important thing. If we can find the real purpose of who we are, we create a psychologically safe space to be in and get on with doing what we think is best for the world.

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