



2018 PHARMACEUTICAL
and LIFE SCIENCES
TRENDS

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With next-generation technology molding the business landscape, generation Z entering the workforce, and global economic uncertainty, life sciences companies face another challenging year in 2018. Opportunities remain, however, for companies to drive differentiation and top-line growth by weaving a focus on the patient and patient experience into their strategy.

In the *2018 Pharmaceutical and Life Sciences Trends*, Clarkston Consulting evaluates four key themes and their impact on the pharmaceutical, biotech, and medical device industries. Artificial intelligence, personalization (most notably personalized medicine), digital transformation, and financial health will be motivating factors significantly impacting business decisions this year. For our key themes, we define the categories thus:

ARTIFICIAL INTELLIGENCE

Industry 4.0 and artificial intelligence are the hot buzz words this year that all companies are trying to get a better handle on. In our definition of AI as a theme impacting the life sciences industry, we include initiatives around analytics, big data, machine learning, blockchain, internet of things, and design thinking.

FINANCIAL HEALTH

Ever a focus for any business, industry margin and pricing pressures continue to make financial health of the utmost importance for life sciences companies. This will include efforts on operational or cost efficiencies, revenue generation and growth, M&A/consolidation, and tax optimization.

PERSONALIZATION

Accounting for both science and business, personalization includes both therapies, devices, and treatments created for a specific patient, and the increasing focus to personalizing the patient experience via advanced communication and engagement strategies and technologies.

DIGITAL

For life sciences companies, this will include initiatives around patient engagement via digital channels and more substantially, a greater focus to cloud/cloud-hybrid platforms and the importance of data management.

As you read through the *2018 Pharmaceutical and Life Sciences Trends*, consider where your organization has distinctive capabilities which can enable your business to take advantage of the opportunities 2018 will bring to the industry.

ARTIFICIAL INTELLIGENCE

REAL RETURNS ON ARTIFICIAL INTELLIGENCE

While uptake in artificial intelligence may seem slow in life sciences compared to other industries, the potential shift it represents will indelibly impact the way drugs and medical devices are discovered, designed, created, distributed, and used. AI will drive more combination products, higher quality, and more personalization across the industry.

At its core, the power of AI for pharma lies in its ability to mine and analyze enormous sets of raw data, such as those generated through R&D – an area in life sciences with the most to gain in these nascent stages of AI adoption. AI stands to bring a stronger degree of certainty in the clinical stage by enabling a more thorough understanding of biological and disease complexities that would in turn enable a more targeted approach at the onset, thus increasing the likelihood of clinical success and decreasing the associated risks.

As the volume of data collected increases, so too does the potential of AI to have a transformative impact on the industry. Like many technological innovations, AI success will depend on strong data management principles and the organizational ability to work cross-functionally as the tech will inevitably impact every side of the business.

EXAMPLES TO FOLLOW IN 2018

What does AI look like for your business? Takeda Pharmaceutical's foray into AI provides a perfect example of how the technology can be leveraged to address the most challenging industry obstacles:

Takeda Pharmaceuticals achieved a 67% increase in drug concentration levels and a 90% mean cumulative adherence through cross-functional alignment and a partnership with an AI start-up. Through the project they:

- used AI-enabled technology to confirm patients took the medication,
- collected data on the most common lapse points in adherence, and
- created real-time response team for incidents tracked by AI.

BEYOND THE HYPE OF BLOCKCHAIN

The hype around the potential use cases for cryptocurrency took multiple industries by storm in 2017. As 2018 unfolds, strategy and planning around the blockchain technology underpinning cryptocurrency will continue to evolve in life sciences, particularly in the clinical and supply chain aspects of the business. As a decentralized ledger of information, the blockchain could allow for:

- better clinical trial participation and overall patient safety
- ease and efficiency of smart contracts
- improved supply chain integrity
- more timely and efficient compliance with regulatory requirements

These are just a few of the well-documented potential uses for blockchain technology, which will continue to grow in number as the technology is explored further. We'll also begin to see how blockchain will intersect with other emerging innovations, such as personalized medicine, to drive value in areas such as scheduling, administering, and reporting. Life sciences companies should focus their time and resources to developing blockchain proofs of concept in order to understand the potential uses and impacts to their business and operations.

2018 BLOCKCHAIN RESOURCES

Whether you're a cryptocurrency expert or new to the technology, these resources will help you better understand and communicate blockchain and its potential effect to your business.

- ***"Blockchain Explained: How It Works, Who Cares and What Its Future May Hold"*** [Article]
- ***"Unchained"*** [Podcast]
- ***"The Blockchain Explained"*** [Video]

GETTING READY FOR AN IOT WORLD

With increasing frequency, the internet of things (IoT) has been touted as a cure-all through the use of live data for real-time decision-making. In 2018, more life sciences companies will start to explore these capabilities in earnest. First and foremost, the benefits to the supply chain and manufacturing side of the business will drive IoT investments to maintain product quality via live temperature and stability monitoring, increase operational efficiency through improved inventory management, better manage supply and demand through real-time tracking and oversight, and improve traceability of the supply chain to meet regulatory requirements around serialization.

But these are just a few of the dozens, if not hundreds, of applications of IoT to drive true business value. As the success of IoT largely depends on a business's ability to manage and act on their data, life sciences companies should invest in strong data governance and data management initiatives to ultimately realize the vast returns that IoT can offer.

IoT PLATFORMS TO EXPLORE IN 2018

As with any new technology, there are multiple players vying for market share while the industry is still in the early stages. Keep an eye on these platforms in 2018 as they continue to evolve as some of the most promising platforms in the space:

Aeris IoT Platform, SAP HANA IoT Foundation, PTC ThingWorx, relay Cloud, Teezle TMatrics IoT Platform

PREPARING FOR A NEW WAVE OF DISRUPTION

In 2017, it was reported that [Amazon had applied for and received pharmacy-wholesaler licenses](#) in several states, leading to a rapid drop in stock value for some of the industry's largest wholesalers. As the line between health and technology continues to blur, technology juggernauts such as Apple, Microsoft, Google, and Facebook have also begun dipping their toes in the life sciences water with more to come in 2018. No matter which industry outsider causes it, disruption in the space is cause for concern for any life sciences leader.

Vertical integration, such as the [CVS-Aetna](#) deal in 2017 or the recently announced [generics company comprised of 450 U.S.-based hospitals](#), will also bring significant strategic challenges to the industry. As stakeholders in the healthcare value chain consolidate, align, and integrate for increased leverage and purchasing power, the life sciences industry will be further pressured to demonstrate the differentiated value they offer to patients, caregivers, and other partners in the healthcare landscape.

KEY HEADLINES FOR 2018

As we progress into 2018, be on the lookout for more headlines like these as new entrants join the industry:

["Apple announces effortless solution bringing health records to iPhone"](#)

["How Big Tech Is Going After Your Health Care"](#)

["Novartis and Apple to scale up clinical trial collaboration"](#)

SPENDING WISELY WITH TAX REPATRIATION

With potentially hundreds of billions of dollars at their disposal thanks to historic tax overhaul in the United States, US-based life sciences companies will have new resources to fuel growth, pay down debt, and increase shareholder value. Repatriation dollars withstanding, medical device manufacturers received another early gift in 2018 with the two-year extension of the hiatus of the 2.3% medical device sales tax of 2015.

Also, with tax reform came the reduction of the orphan drug tax credit – once a 50% credit now reduced to 25%, potentially disincentivizing investment in the area. Backed by increased spending power in the industry, 2018 will likely see a rise in M&A – already evidenced by the acquisitions of Bioverativ and Juno Therapeutics by Sanofi and Celgene respectively, bringing M&A dollars to \$20 billion shortly into 2018.

2018 COMPANIES TO WATCH

As 2018 progresses, watch these companies carefully for M&A activity:

Amgen, Pfizer, Biogen, Gilead, Merck, Eli Lilly, and Johnson & Johnson

FINANCIAL HEALTH

MAKING SURE THE PRICE IS RIGHT

Only a few years ago, achieving regulatory approval was the most critical milestone in a drug's journey from discovery to commercialization. Today, regulatory approval is clearly still a crucial step but it's the negotiation and execution of a successful pricing and reimbursement arrangement for each product that has become the real barometer for success - not only for the specific product but for the business as a whole.

With a total of **176 drug pricing bills in 36 states in 2017**, legislators are maintaining a watchful eye that could very well be escalated to the federal level in 2018. Particularly as the advent of personalized medicine ushers in the "era of cures," pricing for one-time use drugs will be under the microscope. As it emerges more and more as industry norm, it's critical that organizations begin to consider the mechanics for a pay-for-performance pricing structure and the potential impacts to operations and long-term strategy.

2018 VOICE IN THE CROWD

[Acorda Therapeutics CEO, Ron Cohen, has been vocal on the need for understanding and collaboration as the industry navigates new science, and with it, new pricing structures:](#)

"We have been reaching out to other parties in the ecosystem to talk about – not finger-pointing – but how can we present reasonable proposals that will benefit everybody and also, frankly, keep the prime directive in mind, which is in addition to the fact that we are all or most of us are companies that need to show a profit eventually,"

PERSONALIZED MEDICINE

MAKING PERSONALIZED MEDICINE A REALITY

As personalized medicine increasingly moves from the theoretical to the practical, life sciences companies are now focusing on operationalizing the associated processes to manufacture, distribute, and administer treatments. The vein-to-vein nature of personalized medicine will force supply chain leaders to reconceptualize almost every aspect of the traditional operational model to account for more stringent temperature and stability controls, crunched production and delivery times, impacts to capacity planning, and more.

Life sciences leaders should start by assessing current manufacturing locations against their targeted patient populations to understand where investment is needed. Consider advocacy organizations, hospitals, and health systems that could serve as partners to enable proper and timely administration of the treatment. As this new personalized landscape evolves, collaboration within the healthcare ecosystem will be essential so manufacturers should also be considering the portals by which they'll connect with both patients and providers to drive effective and sustainable engagement.

WHO TO FOLLOW IN 2018

While it's a topic covered by multiple journalists, Statnews.com correspondent Meghana Keshavan provides unique and timely insights on the practical side of personalized medicine.

Statnews.com, Meghana Keshavan
"Personalized cancer therapies show great promise. The hitch? Manufacturing them efficiently"

PERSONALIZING THE PATIENT EXPERIENCE

The very nature of personalized medicine affords pharmaceutical companies nigh-impenetrable patent exclusivity which represents some of the appeal for big pharma in spending big on these capabilities now. Generics makers, on the other hand, may view this shift with a bit more reticence, and with good reason.

That said, the market for the generics business remains ample. In June 2017, the FDA began publishing a list of off-patent, off-exclusivity drugs that currently lack an approved generic. This list, updated every 6 months, further signifies the FDA encouraging development in generics.

Although the impact to generics won't be immediate, the shift to personalized medicine will permanently alter their future landscape. While personalized medicine may not be included in their portfolio, the personalization of patient engagement through beyond-the-pill offerings will allow generics makers to differentiate their market position and therapeutic value. Investing now in both technological and organizational abilities that enable greater patient-centricity will pay off as the well of potential products shrinks.

KEY STRATEGY IN 2018

*Generics maker **Cycle Pharmaceuticals** is collaborating with drug delivery company **Aprexia** to deliver treatments utilizing **Aprexia's** differentiated technology to create a more valuable patient experience.*

"Aprexia Pharmaceuticals and Cycle Pharmaceuticals Partner to Develop 3D-Printed Orphan Drugs"

TESTING THE TESTING AND DIAGNOSTICS MARKET

Biological science is just one area of personalized medicine generating tremendous innovation and discovery. The surrounding technology, such as genomic sequencing and diagnostics, will continue to evolve to support this pioneering science.

As it's apparent that the cost of personalized medicine will be high compared to traditional treatments, early diagnoses and risk assessments will be an increasing focal point for patients, payers, and regulators as a means for intervening earlier with more cost-effective therapies to prevent or mitigate the disease or condition. As we evolve out of an era where multiple therapies are used to address symptoms and drug interactions and move to confronting the root-cause disease head-on, leaders in the life sciences industry should invest now in diagnostics tools, services, and capabilities to meet the needs of tomorrow's patient.

KEY STATISTIC IN 2018

As personalized medicine continues to evolve, the market for ancillary technologies and services will experience steady growth.

According to **MD+DI**, Needham & Company expects the diagnostic market to grow 4.7% over 2018 with 7% growth in the molecular diagnostic market.

GETTING AHEAD IN THE CLOUD

The globalization of the pharmaceutical value chain means the ability to easily and efficiently integrate with multiple partners simultaneously is paramount to business success and cost/operational efficiency. To that end, life sciences businesses should continue investing in cloud platforms in every functional area. Where the privacy and security of both patient information and intellectual property may have been a concern in the past, hybrid cloud solutions ensure that information is protected while also enabling the key capabilities of the cloud.

Adoption of cloud technologies is exceptionally advantageous as it makes post-merger integration easier and more-cost effective for most companies. Furthermore, cloud solutions will make the adoption of next generation technologies easier and more efficient, including machine learning, artificial intelligence, IoT, etc. Life sciences organizations must execute a comprehensive cloud strategy or work quickly in 2018 to establish one.

KEY USE CASE FOR 2018

As your business begins exploring the adoption and use of cloud-enabled technologies, look forward to the future and consider the possibilities of a technological landscape in the cloud, such as:

The internet of labs – a super lab that taps into technologies such as 3D printing, robotics, advanced computer simulations, and more to drive transformative improvements in collaboration, logistics, and capacity planning.

MANAGING DATA BEFORE IT MANAGES YOU

The ability to record, manage, and utilize data effectively has quickly become the strongest indicator of success for businesses in the life sciences industry. Data volumes continue to swell and we're entering an age where a person's most private data – their genetic makeup – will be transported up and down the supply chain, making data management even more important.

Life sciences organizations have taken great leaps forward in the past few years by establishing core data and analytics capabilities within their organization. Moving forward, understanding the cross-functional impacts of data use and ownership will allow life sciences companies to make evidence-based decisions with confidence and speed.

KEY 2018 REGULATION

With data privacy and security taking an ever-increasing role in all aspects of business, this regulation will have long-term effects on any business in the EU or operating with an EU-based company.

As of May 15, 2018, the **General Data Protection Regulation** (GDPR) goes into effect in the European Union, creating more stringent requirements around how data is accessed, recorded, used, stored, and more. Any life sciences organization operating in the EU will be impacted.

DIGITAL

TELEHEALTH AND DIGITAL ENGAGEMENT WITH PATIENT 2.0

In today's age, patient expectations are being defined by the convenience of nearly every other aspect of their lives. With the ability to feed, clothe, and transport themselves via a few finger taps, the modern patient is now asking for the same from their health resources. Life sciences investment in digital capabilities continues to rise as the benefits to the business are twofold – first, patients are more engaged with their care and more likely to achieve better outcomes, and second, the interaction allows businesses to collect more behavioral data and adjust their offerings and outreach accordingly. Understanding that digital isn't a one-size-fits-all solution will enable life sciences executives to focus on the core challenges they'd like to solve for their patients and create a digital strategy with truly valuable returns.

KEY 2018 RESOURCE

As your business explores connecting and sharing information with your patient populations, the following resource will provide you with insight into how these digital channels will be regulated.

The Center for Connected Health Policy provides both **a federal and state-by-state breakdown of existing and pending telehealth laws and reimbursement policies** – critical for any manufacturer looking to collect more data from their core constituents.

PLANNING FOR THE FUTURE

A strategic plan for 2018 likely includes elements of each of the areas covered here. Depending on your business objectives, some will carry more weight than others. Regardless, there are certainly trends that any life sciences organization must be prepared to address in 2018, including consolidation, personalized medicine investments, taxes, cloud infrastructure, telehealth, and data management.

Some or all aspects of each of these trends will undeniably impact your strategy, operations, and/or people. The above trends are imperative to creating a business and operational environment that's prepared to successfully utilize advancements in patient engagement, IoT, machine learning, diagnostics, and more.

Finding and addressing where you can demonstrate differentiation will drive future growth. Failure to act on these trends will leave your business lagging behind your industry peers. How is your business navigating 2018?

ABOUT CLARKSTON CONSULTING

Businesses across the life sciences industry partner with Clarkston Consulting to address industry specific challenges stemming from mergers and acquisitions, margin pressures, evolving technological and data capabilities, new regulations, shifting patient expectations, complex compliance technology, and quality operations. Our people combine industry and functional expertise to deliver solutions that fit your business, your goals, and your future. At Clarkston, your purpose is our purpose.

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