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2019 Health Technology Driving Forces

Navigating the Talent Crisis

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Driving forces in the health technology industry create both risks and opportunities. This report examines the significant forces impacting health technology companies in the U.S. with a focus on the talent acquisition challenge and strategies to achieve success. Trends and data have been aggregated from a variety of industry sources as well as from our professional experience.

Driving Forces

The global health technology industry is accelerating at a projected compound annual growth rate (CAGR) of 5.6%[1] in medical device sales, 6.4%[2] in pharmaceutical sales and 9.5%[3] for smart health care products between now and 2024. Further, projections for overall national health care spending are estimated to increase at an average rate of 5.5% annually between 2017 and 2026.[4]

Global medical technology sales are forecast to reach nearly $600B by 2024 with research and development spending increasing 4.5% annually.[5]

By 2024 world-wide prescription drug sales are expected to be $1.2T, primarily due to novel therapies and increased global access to drugs. The growth expected between 2018 and 2024 is 600% more than between 2011 and 2017. Growth will be tempered due to payer scrutiny and sales losses from genericization and biosimilar competition.[6]

The health IT market is projected to hit $66.7B by 2024, a CAGR of 9.5%.[7]

Significant driving forces in the growing medical device, pharmaceutical, and health IT industries also impact the need for talent. Many of these talent-related forces are further examined in this report.

The Medical Device Excise Tax suspension is in effect through January 2020. The 2.3% levy on medical technology sales, part of the Affordable Care Act, has been deeply unpopular in the industry.

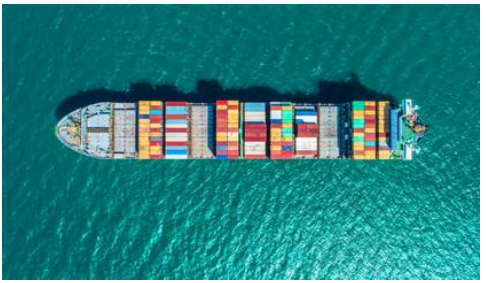
Since the excise is a tax on sales, even companies that were not profitable, had to pay it. The tax disproportionately harms start up companies that are building medical technologies of the future.

Advamed, the medical device industry's lobbying group, has argued the tax prevents companies from investing in research and development and takes away money that could be used to develop new technologies and add jobs. According to AdvaMed, the U.S. medical device industry lost nearly 29,000 jobs while the tax was in effect from 2012 to 2015.[8]

Repeal efforts have received broad bipartisan support. The U.S. House of Representatives has voted to repeal the tax. The Senate has yet to vote on this issue.

U.S. health technology investments rose substantially in 2018. Venture-backed investment in U.S. medical device, biopharma and diagnostic tools exceeded 2017 by over 60%. Biopharma investments led

the activity with $13.5B, a 110% increase over the prior year. Medical device investment rose nearly 50% while diagnostic tools remained relatively flat. According to Silicone Valley Bank's *Trends in Healthcare Investments and Exits 2019 report*, they observed a slowing in the fourth quarter of 2018 and anticipate venture financing to decelerate slightly in 2019 as the U.S. moderates Chinese investments.[9]



Trade policy. Tariffs on steel, aluminum and other products imported from China are impacting health technology companies. Since mid 2018, the U.S. has enacted 10% to 25% tariffs on $250 billion of goods imported from China. In return, China responded with tariffs on $110 billion of U.S. goods. President Trump is pursuing alleged Chinese theft of intellectual property, forced technology transfers, ownership of U.S. companies in China, and tariff and nontariff barriers, among other issues. If progress is stalled with China, on March 2, 2019 U.S. tariffs will increase up to 25% on all goods currently subject to the mostly 10% tariffs. The original tariff list included components for products such as pacemakers, needles, ultrasound equipment and catheters. The number of listed products has since been reduced. Pharmaceutical companies are most impacted by the tariffs placed on chemicals used in the production of drugs.[10]

The U.S., Mexico and Canada have signed a trade agreement (USMCA) that must be approved by their respective legislatures - anticipated in 2019. Under this agreement, sales of biologic drugs garnered stronger protection, including that from cheaper generic competition for at least 10 years versus the current eight year protection in Canada and five in Mexico. U.S. protection is currently set at 12 years.[11]

As pricing on imports and exports impacts the industry, companies will be investing in supply chain and marketing talent to protect gross margin erosion.

Device connectivity. The health IT sector is expected to increase at an unprecedented CAGR of 9.5% between now and 2024.[12] Companies are progressively investing in connected technologies. A key challenge is the integration of data from new technologies. According to a recent Deloitte survey, "many companies also find it a challenge to address the critical funding and skill gaps, as software constitutes an increasing proportion of product innovation."[13] Health technology companies should focus on developing digital competencies and skills in research and development and beyond.

Increasing cyber security regulations. Recent cyber security breaches of connected medical devices, such as Stryker medical beds and Becton, Dickinson FACSLyric Cytometry Solutions, underscore the need for more security around these devices.[14]

In April, 2018, the FDA released the latest version of its *Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health*. In addition to zeroing in on improving patient safety and medical device cybersecurity, the FDA shared plans including *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices* and *Postmarket Management of Cybersecurity in Medical Devices*.[15] In October 2018, the FDA released revised draft guidance on premarket considerations and requirements for medical device cybersecurity controls.[16]

The FDA has established a Software Precertification Pilot Program to provide guidance on the development of a regulatory model to assess the safety and effectiveness of software technologies without inhibiting patient access to these technologies. The pilot is expected to launch in

2019 with the objective to streamline regulatory oversight of software related medical devices developed by companies who have demonstrated a strong culture of quality and organization excellence, and who are committed to monitoring performance of their products in the U.S. market.[17]

Other countries are also focused on improving medical device cyber security. The Chinese government has enacted a number of laws, regulations and standards to increase cybersecurity, some went into effect in 2018. The European Union's (EU) *General Data Protection Regulation* (GDPR) is a rigorous regulation related to data protection and privacy. Recently, the GDPR introduced a much broader definition of personal data.[18]

Medical device companies should prepare for securing their connected medical devices throughout their life cycle and reduce risk to patients and data security.

Modernization of the regulatory landscape throughout the world is receiving significant attention from health technology companies. Two significant impacts on the regulatory landscape are the European Medical Device Regulations (MDR) and In Vitro Diagnostic Regulations (IVDR) which went into effect in May 2017 with an implementation deadline of May 2020 for the MDR and May 2022 for the IVDR. These regulations may result in longer commercialization times, higher costs, challenges in working with Notified Bodies and elimination of older products no longer justified from a cost/benefit perspective.[19]

The FDA's Office of Combination Products was established in 2002. Since then, there has been an increase in the number of combination products along with a more complex regulatory landscape. Combination products combine devices, drugs and/or biological products - transforming the patient experience. In 2016 the FDA released the *Postmarketing Safety Reporting Final Rule* with the start of enforcement expected in July 2019. The European Medicines Agency recently passed a provision to recognize drug-device combination products and regulate them under the EU Medical Device Regulation Compliance rule by May 2020.

The FDA proposed modernizing the 510(k) clearance pathway which would impact almost 80% of medical devices reviewed by the FDA. Under consideration is a requirement for applications to compare devices with products that have been on the market for less than 10 years. The FDA is also working on a *Safety and Performance Based Pathway* for categorically well-understood devices that would rely on objective criteria in the absence of a predicate device.[20]

In the pharmaceutical industry, there are a number of elements impacting a strong regulatory focus on the pricing of drugs:

- 340B Drug Pricing Program is pending Final Rule
- Many states have already or will be passing new regulations to limit pharmaceutical costs
- Value-based purchasing agreements[21]

These elements will lead to pricing pressures, greater transparency and the need for more reporting.

Ensuring market access to lifesaving drugs has the attention of legislators and regulators. They are concerned that specialty pharmacies might not be well controlled and some activities might put patients at risk or interfere with the practice of medicine. Companies face significant challenges in managing risks related to specialty pharmacy relationships. Appropriate governance and controls must be in place to reduce those risks.

We have scratched the surface of the modernization of the regulatory landscape and highlighted a few of the more significant driving forces. Health technology companies must achieve ongoing regulatory compliance. Gain a commitment from management to excel at compliance, establish a clear road map, and ensure available resources to effectively implement those strategies.

Other notable trends include a 28% increase in the number of first-time device approvals (PMAs, HDEs and PDPs) in 2017. 510(k) clearances rose 9% in the same year.[22]

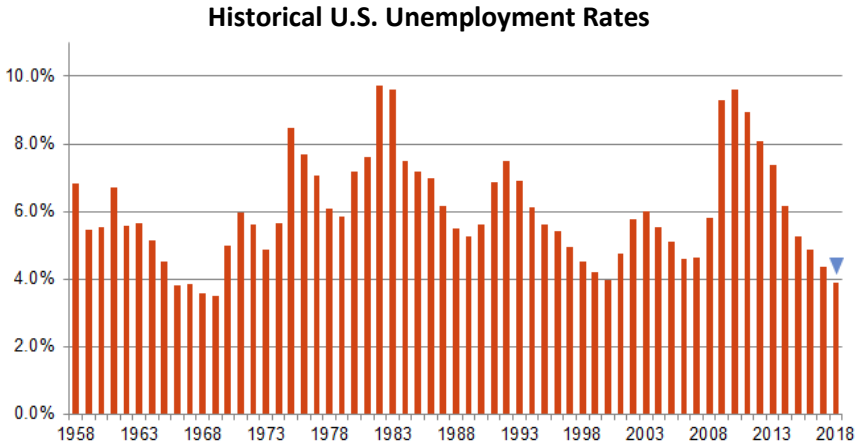
In 2018, FDA's Center for Drug Evaluation and Research (CDER) approved 95% of its novel drug approvals on the first cycle and 71% were approved in the U.S. before receiving approval in any other country.[23]

Health technology sector driving forces propel the need for experienced talent. In the following sections of this report, we explore the drivers of talent scarcity and provide strategies to ensure you, and your company, are equipped for success.

Talent Scarcity

Historically low unemployment rates. At the end of 2018, U.S. unemployment was 3.9% - the lowest rate in 50 years. Couple this with bullish industry growth projections, and it points to accelerating talent scarcity for medical device, pharmaceutical, and health IT companies for many years to come. In addition, many of the states with the highest levels of investment in medical device, pharmaceutical and health IT technologies are experiencing low unemployment rates and will be challenged to secure the type of talent required for future growth.

States like Minnesota, with a strong concentration of health technology companies, have even lower unemployment rates than the national average. At the end of 2018, Minnesota's rate was 2.8%.



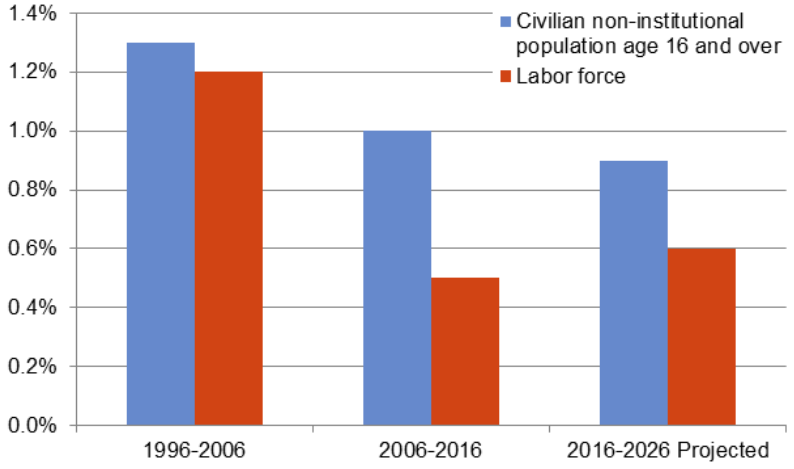
Bureau of Labor Statistics

Talent scarcity, along with longer time frames to fill roles, will continue to be an issue facing health technology companies in 2019 and beyond. Historically, jobs in this sector have grown in number and share of the

U.S. labor force year over year. Healthcare industries and their related occupations are expected to account for a large share of new jobs projected through 2026, as the aging population increases the demand for healthcare services.[24] Additionally, technological and regulatory changes in the health technology sector are driving demand for more and new kinds of talent.

Labor force growth is slowing. According to the Bureau of Labor Statistics' projections, labor growth is projected to increase at an annual rate of 0.6%. This rate is only slightly faster than that experienced in the 2006-16 decade - 0.5%. However, it is slower than the several decades prior to that.[25] With a health technology industry growing at over 5% annually, there will be a shortage of talent to meet the demand.

Annual Rate of Change – Population and Labor Force

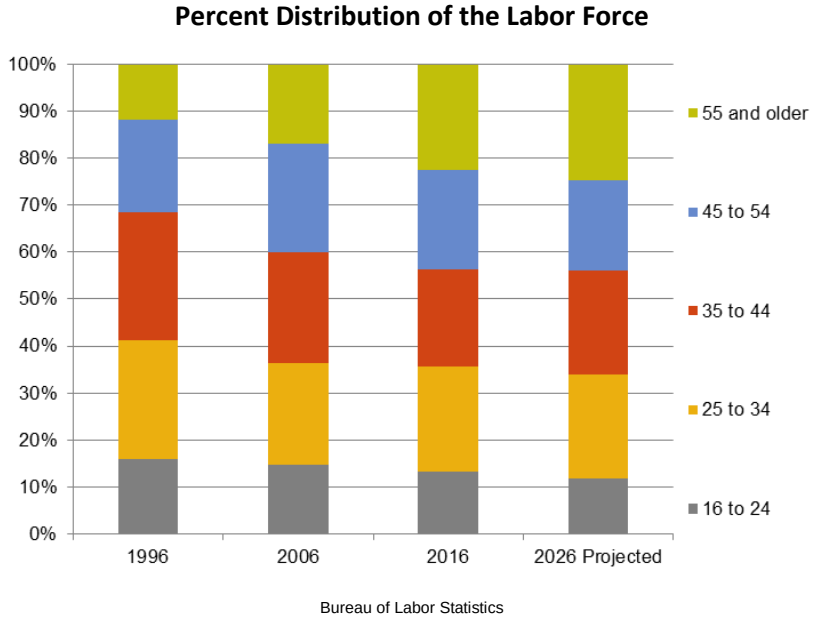


Bureau of Labor Statistics

Participation rates in the labor force have declined from 2007 to 2018 by 5%. Baby Boomers are exiting the workforce with fewer new workers to take their place. This generational gap increasingly presents a problem for the expanding health technology industry. Many leaders throughout

the industry come from a generation of Baby Boomers now at retirement age, spurring demand in companies to replace knowledge and experience. Further, Millennials are overtaking Baby Boomers in pure numbers in the workforce.

During this retirement trend there is an opportunity to utilize the wealth of knowledge held by Boomers who still want to participate in the workforce. For more information regarding this trend, read our blog found at www.talencio.com called, "The Knowledge Train is Leaving! Mind the Gap."



Bureau of Labor Statistics

Lack of new, skilled graduates to the field. U.S. universities are not producing enough skilled graduates, including scientists and engineers to fuel demand. In manufacturing alone, the U.S. will need to fill about 3.5 million jobs by 2025 and as many as 2 million of those jobs may go unfilled, due to difficulty finding people with the skills in demand.[26]

Navigating the Talent Shortage

The challenge for 2019 and beyond continues to be how you and your company can be in a position to reap the benefits of a growing health technology market and to also mitigate talent shortages. What measures will most effectively ensure the supply of talent needed to meet industry growth projections and achieve your individual and corporate goals?

Tackling talent shortages is a daunting task for any company, especially in a U.S. economy with an unemployment rate at a 50 year low. As the health technology industry continues to grow and new opportunities for innovation emerge, you will need to be deliberate in taking measures to successfully find the talent that your company needs. Get ready to take advantage of the changing landscape and create and implement strategies to ensure you have great talent when you need it.

Keep the talent you already have. Now that you have attracted great people how do you keep them highly engaged? A recent study by O.C. Tanner Institute of 10,000 employees around the world on workplace culture; "Talent Magnets: 6 Essential Aspects of Workplace Culture" came to some stunning conclusions. For more information regarding this trend, read our blog at www.talencio.com called, "The Power of Purpose".

Companies that focused and achieved even marginal improvements in the 6 most important aspects of culture; purpose, opportunity, success,

appreciation, wellbeing and leadership; saw some staggering improvements. These companies were:

- 53% more likely to have highly engaged employees
- 29% more likely to have employees innovating and performing great work
- 27% more likely to have increased revenue last year
- 25% more likely to have teams growing in size instead of stagnating or decreasing in the last year
- 22% less likely to have experienced layoffs in the last year[27]

Other ways to keep your employees engaged are:

- Flexible work such as remote work, flex work schedules and even short sabbaticals to allow employees to pursue other interests
- More generous PTO and volunteer days off
- Continuing education and quality in-house training
- Benefits like an onsite gym or gym membership
- Onsite daycare or daycare discounts

While mostly only larger companies can pull off the onsite daycare, these are all things that can help ease the burden many employees encounter.

Provide referral bonuses and work your network. Ask your employees to identify quality candidates and provide a referral bonus to those finding new hires. Make the incentive for your employees significant so that it actually drives talent to your organization.

Share your need for specific talent with friends, family and your professional network. Post the position on relevant social sites. Within the health technology industry, LinkedIn is the leader in this area.

Leverage contract staffing. Contract and fractional staffing allow you to

maintain a nimble and flexible workforce. Contract staffing continues to be a popular alternative for growing and innovative industries across the country. Be open to tapping into contract staff for the specific experience you need. As the market continues to evolve, this strategy will help you to fill talent voids and remain competitive. For more information regarding this trend, read our blog at www.talencio.com called, "Have Your Cake and Eat It Too."

Employ foreign talent. Consider utilizing the H-1B visa system to fill the need for additional STEM workers for positions requiring specialized knowledge. The H-1B program has a cap of 85,000 visas per year, including 20,000 specifically for recipients of advanced degrees.[28] Most H-1B employees have at least a bachelor's degree, and the majority hold master's degrees. 64% of the visas were for jobs in science, technology, engineering and math.[29]

Immigration laws allow some attractive options to the health technology sector. For example, hiring foreign students graduating with STEM degrees can allow 29 months of protected employment to companies rather than the standard 12. The immigration system also allows additional temporary and permanent visas to workers who exhibit "extraordinary ability" in their field. National interest waivers are also available, especially for foreigners with research experience in innovative and progressing fields like health technology.

Demand for H-1B workers has rapidly risen in recent years. In the past five years, the visa cap was reached within a week of the application

period opening. Conversely, between 2000 and 2013, the visa cap was reached twice. The employer application cost ranges from $1,710 to $6,460 for each visa.[30] This is a challenging strategy but once mastered, can be fruitful.

Increase compensation. With the tight labor market, many employers are reevaluating their compensation budgets. According to Mercer's *2018/19 US Compensation Planning Survey Update*, employers are estimating their budgets for average total pay increases, including merit and promotional budgets, to be 3.4%, slightly up from 3.2% last summer. The base salary increase is estimated at 3%. The survey also indicates that of the 30% of employers projecting higher total pay increase budgets, changes were mainly focused on promotional increases while merit increases remained flat.[31] Top performers often receive two times the median salary increases of other employees. Many employers help fund the increases for high performers by limiting awards for standard or substandard performance.[32]

Surprisingly, the overall U.S. talent shortage has not significantly impacted overall increases in compensation to the extent one would think. However, our experience indicates that in certain health technology fields, such as regulatory affairs and software engineering, increases are occurring at a rate above average.

Ensure your wages are competitive, keep critical talent and broaden your pool of new professional resources.

Reward employees. Employers are relying more on short and long-term incentive plans and pay-for-performance programs. These programs can provide meaningful pay and differentiation to top performers. However, it is important to ensure there is a return on the investment and the incentive is individually meaningful.

Build brand awareness. Ensure your corporate brand not only attracts clients, leverage it to attract talent. To start, ensure your employees have fulfilling experiences. Explore Glassdoor where anonymous reviews can be found on your company and address any issues. Talk with your employees and survey them. Create and implement strategies to make needed changes. It starts from the top and a strong, positive brand will help drive talent to you.

Market your company's positive brand. Many companies are using video and several leverage "day in the life" features to talk about their jobs. Online tools to leverage are: Facebook, LinkedIn, Instagram, Snapchat and YouTube.

Incentivize education. While not an immediate solution, the surest avenue to make certain that future talent exists is to create that talent. Government and educational institutions have made providing students with both research and workplace experience in health technology a priority. Most public and private universities offer master's programs in biomedical engineering, with many providing stipends for internships that provide job experience to students. In some cases, local governments step in to partner with companies to pay portions of intern salaries to relieve some of the financial burden. The Technology Councils of North America (TECNA) sponsors about 50 company and university partnerships throughout the continent with the intention of fostering collaborative technological innovation. By entering a partnership and offering paid internships, you could provide a student with experience in your company along with incentive to remain in the industry.

Collaborate with a reputable partner. If you lack the expertise or time to focus on talent acquisition, partner with a reputable recruiting or staffing firm to get the talent you need, when you need it. When conducting a search for a direct hire and choosing a partner to assist with the search, know the difference between engaging with a contingent versus retained search firm and the impact your decision will have on your success in filling the role, especially in a time of historically low unemployment.

In our recent blogs at www.talencio.com, "Search Strategies in a Tight Labor Market" and "Mitigate Talent Risk", we further discuss ways to stay ahead of the talent acquisition curve.

2019 is upon us with significant opportunities for growth in health technology. Being proactive in understanding market forces and mitigating the risks of the talent shortage is crucial to realizing your objectives. Consider taking some or all of the steps we have outlined to ensure your competitive advantage and growth.

Talencio helps the health technology community by putting the right people in the right place to solve problems and identify opportunities to move healthcare forward. To learn how other companies have partnered with Talencio to mitigate talent risk, visit us at www.talencio.com, call us at 612.703.4236 or email pnorbom@talencio.com. Talencio has been the preferred provider of vetted, accomplished professionals to the health technology community for over 11 years.

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