2020 INDUSTRY TRENDS

A Q1 Productions Report on Life Science Industry Trends for 2020

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Explore upcoming programs to learn about addressing these top concerns and more.

TABLE OF CONTENTS

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Introduction:

Curious how your life science organization will be impacted in 2020? This report provides professionals with a better understanding of trends and developments expected over the course of the year. Changing dynamics across the globe will affect companies at multiple target areas, impacting the way organizations will have to work to remain agile and innovative. From evolving technology and government policies to international regulations and their implementation, companies will need to adapt to embrace changes to pricing structures, landscapes within healthcare entities and consolidation. Read on to hear how organizations are preparing for continued growth and development, so companies can remain competitive, maximize revenue and deliver the best and most advanced therapy for patients.

ABOUT Q1 PRODUCTIONS

Q1 PRODUCTIONS TAKES PRIDE IN THE THREE CORE PILLARS OF EDUCATIONAL EXCELLENCE:

PEER-LED CASE STUDIES AND MASTER CLASSES

Industry leaders from organizations such as Medtronic, Johnson & Johnson and Stryker lead solution driven, in-depth discussions on key industry challenges and new research in the field.

KNOWLEDGE SHARE AND PROFESSIONAL DEVELOPMENT

In addition to case study presentations, programs provide a mix of panel discussions, group breakout sessions and interactive workshops to expand shared learning among the audience.

STRUCTURED NETWORKING

Each program is designed to provide multiple opportunities to network and benchmark not only with peers but also payers, regulators, ACOs, patient groups, notified bodies, legal teams and more.

Survey Findings:

Q1 Productions surveyed over 100 professionals and related stakeholders in late 2019, with a goal of obtaining insight into the greatest challenges the life science industry expects to face in 2020. Survey respondents include senior industry professionals within the medical device and pharmaceutical industries, working in roles from product development and innovation to regulatory affairs, pricing and reimbursement. Dive into the forecasted challenges below.

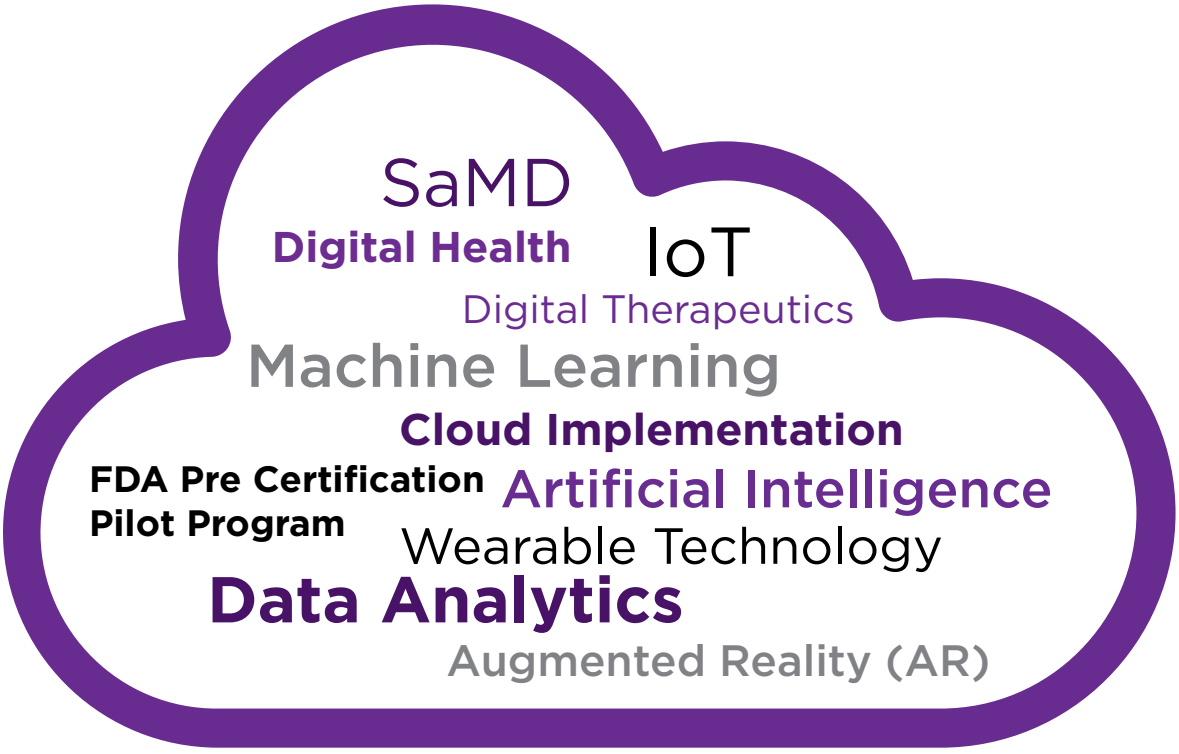
Evolving Technological Capabilities in Life Sciences: Digital Innovation Unleashed

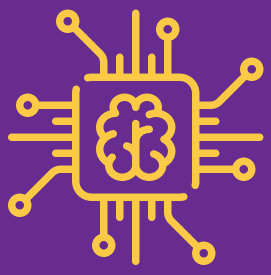
Throughout 2020, technological updates, as well as changes to the methodology and use of tech tools across life science organizations, will continue to take place increasing the knowledge and adoption of digital health opportunities. Digitalization will continue to impact all areas of the lifecycle including research and development, manufacturing, company organization, commercial endeavors and quality and regulatory efforts.

Technological Innovation

The role of Artificial Intelligence (AI), Machine Learning (ML) and Data Analytics (DA) is evolving and advancing to improve implementation while becoming further embedded in the development of next generation products. Through iterative development, AI, ML and DA push the boundaries of adaptive learning in the healthcare industry and support patient engagement. The use of smart devices in clinical trials, as well as the development of applications for mobile use, demonstrate ways in which the expansion of technology enhances innovation while also improving automation and further personalizing medicine for all patients.

Primary examples of industry technological innovation to watch in 2020:





Primary examples of industry technological innovation to watch in 2020 (Cont.)

Process Automation

Beyond the innovation of external tools, many life science organizations' internal processes are continuously updating to enhance overall efficiency, evolve team structures and improve company ROI. Use of a leaner, quicker approach through agile methods support greater data management and team organization, while facilitating cost savings and adding value to the organization by transforming company practices and culture.

Updated Regulations & Requirements

With the swift and consistent changes taking place to transform the digital landscape of life science industries, there is a need for updates and improvements to cybersecurity and related regulatory requirements to occur just as quickly and frequently. Led by regulatory, quality and compliance leaders, the level of regulation must match the level of knowledge and technological invention and progress with the innovation and challenges that arise.

Next steps

Though digital transformation is embedded into a multitude of components across life science industries, it is highlighted in the innovation currently taking place throughout product portfolios, as well as automation, to improve efficiencies and regulatory management of cutting edge updates. As new facets of the business model evolve and undergo digital transformation, organizations must focus on best practices for hiring and retaining talent specific to the digital needs and approach of the company, as well as providing ample support and change management procedures as the company culture and workforce evolves.

Explore upcoming programs to learn about addressing these top concerns and more.

Looking Ahead to the Next Phase of EU Regulation: Full Implementation of MDR & IVDR

The market for medical device and diagnostic products is experiencing a monumental shift as the implementation of the EU Medical Device Regulation (MDR) and the EU In Vitro Diagnostic Regulation (IVDR) is right around the corner. With the three-year transition period for devices elapsing in May 2020 and May 2022 for IVDs, much uncertainty remains for manufacturers regarding the new standards for performance, evidence and quality system management that must be met by all products being sold in the EU.

Under the new regulatory framework, manufacturers are facing significant added administrative costs due to the need for increased focus on clinical evidence collection to verify product safety and efficacy. Companies must move forward despite the relative ambiguity surrounding submission requirements and make difficult decisions regarding how to best comply with the rules or risk removal from the EU market. As an added challenge, interpretation of the regulations is expected to differ between notified bodies, so clarity is needed regarding practice standards.

Enhancement of clinical evidence is the most prominent task incumbent upon the industry as a result of the MDR and IVDR. Regulators' increased focus on post-market follow-up data, along with the stipulation of additional notified body reviews, has heightened the need for companies to develop and fully adopt a streamlined regulatory strategy. Along with the increased demand for clinical evidence, companies are eager for insight into optimizing compliance with the new regulations for labeling. For diagnostic companies, this is particularly true as they navigate the inclusion of UDI into product labels.

Looking Ahead to the Next Phase of EU Regulation: Full Implementation of MDR & IVDR (Cont.)

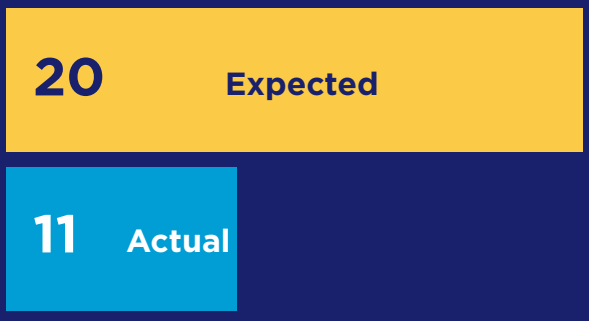
Among the changes put into place by the MDR and IVDR, more stringent requirements are placed on notified bodies opting to become designated under the new regulation. Delays in regaining this designation, along with the fact that some notified bodies have decided to discontinue certification of medical devices and diagnostics, has resulted in concern that the impending deadline will arrive without the necessary professionals in place to handle the volume of submissions.

Harmonization of processes and systems, both in interpreting the regulations and in ensuring regulatory compliance, has been critical to the evolution of the medical device and diagnostic industries over the past year, and this trend is expected to continue. In order to effectively strategize for the implementation of the MDR and IVDR across organizations with international presence, for example, experts recommend translating regulatory content into all languages at the beginning of the process to avoid discrepancies in expectations between internal stakeholders. Additionally, evolving regulatory environments in other major markets, such as China and the US, continue to press regulatory teams to develop comprehensive strategies for remaining compliant around the world.

Both the EU MDR and IVDR will have substantial and lasting effects on manufacturers, providers and end-users, propelling advancement in everything from clinical evidence expectations to quality systems management. It is, therefore, imperative that industry leaders seek to better understand how competitors are impacted by the new regulations, gaining insight into the overall state of the market.

Notified Bodies designated for EU-MDR certification*

***(as of February 20, 2020)**



Navigating a Wide World of Device Regulations

To map an increasingly globalized device market, both manufacturers and regulatory bodies are striving to bring the production and monitoring of medical devices closer to a central standard, in pursuit of safe and effective devices for users around the globe. For industry members, the pressure to keep pace with frequent and far-reaching regulatory shifts continues to influence device development, with such changes taking form in new requirements or revisions to existing guidelines. Because each market introduces a novel suite of relevant guidelines, the harmonization of regulatory activities is critical for companies working across geographical boundaries.

EU

As deadlines loom for both the EU MDR and the EU IVDR, manufacturers are facing shrinking timelines to bring both new and legacy devices into alignment. Nevertheless, after conducting thorough gap analyses and maintaining implementation timelines to ensure compliance, medical device companies are encountering roadblocks as a result of the relative shortage of notified bodies (NBs) approved to grant MDR and IVDR certification. This bottleneck has increased already-lengthy device approval and recertification wait times as approved NBs struggle to keep up with a high volume of applications.

One of the recently-implemented strategies to alleviate this congestion is a four-year extension of the deadline for manufacturers of some Class I devices, effectively centering compliance efforts on devices with increased risk. This extension dovetails with global efforts to reduce the complexity of regulatory approval for low-risk devices, including the launch of a streamlined notification pathway launched this year by Brazil's ANVISA (RDC 270/2019).

Uncertainty continues to surround Brexit as UK regulatory bodies and device manufacturers seek to forecast the current implications of the act on regulatory operations. The presence of a hard border has the potential to interrupt the supply chain of device components and finished devices, and medical device companies with CE Marks issued by UK NBs are considering the switch to EU NBs to maintain certification.

Global

2019 marked the deadline for Canadian device companies to transition to the Medical Device Single Audit Program (MDSAP), signifying another step toward a globally standardized method of monitoring medical device manufacturers by connecting five major global markets under a single audit. Despite this steady movement toward a global standard, device manufacturers continue to cite worldwide regulatory changes as a pressing challenges.

Central to this issue are the ambiguous rates of device innovation, regulatory change and ability of regulatory inspectors to examine devices based on the most up-to-date information. Medical device companies are conducting clinical research and designing devices based on new standards, while inspector activity often aligns with outdated regulations, resulting in approval delays. The reverse also occurs, with companies in the midst of research and development suddenly being faced with new guidances and requirements that were not present at device inception. As the volume and rigor of worldwide device regulations increases and shifts, manufacturers operating in multiple markets are turning to centralized systems to enhance collaboration and harmonization between distinct global regions while staying abreast of current regulatory activity.

The volume of guidances issued has resulted in an incredibly complex development and approval landscape for US companies. Even as the Agency seeks to draft regulations that align with international standards, direct communication and relationships between device manufacturers and the FDA remains a crucial step in interpreting FDA literature.

Companies ranging deeper into the frontier of digital health face difficulties in developing Software as Medical Device (SaMD), as the fast-and-loose nature of innovation in the tech world collides with the strictly regulated arena of medical devices. The use of SaMD has proliferated over the last decade, but a shortage in quality and regulatory personnel equipped to fully understand and evaluate AI-based devices threatens to stifle continued and agile development.

Number of Medical Device/Radiation-Emitting Product Guidance Issued by the FDA in 2019*

Source: FDA.Gov
*as of December 16th, 2019

Evolving Health Policy & Payment Models Impacting Pricing & Reimbursement Structures

Pharmaceutical, biotech, medical device and diagnostic organizations face considerable uncertainty related to pricing and reimbursement of health products, driven by a range of factors including evolving government policy focused on value-based care, changing payment structures at the private and public level, payer consolidation and consumer pressure focused on product fees and the total cost of care.

Of greatest concern to industry executives is the forthcoming election cycle in the United States and potential changes implemented by a new administration. Coupled with this uncertainty is the ongoing debate surrounding the viability and continuation of the Affordable Care Act (ACA), which has provided insurance to many previously un-or-under-insured individuals. While insecurity must be considered in forecasting and planning for the short and long term, the focus on high quality care, improved outcomes and lowering of the total cost of care will certainly be at the forefront of importance, regardless of the administration.

At both the public and private payer level, life science manufacturers continue to face difficulty in obtaining positive and comprehensive coverage for products, particularly new and innovative therapies that lack long-term evidence and data to support the positive impact on health outcomes. The generation, collection and analysis of data has never been more important in obtaining coverage, particularly in a consolidated marketplace where large organizations dominate, creating pressure and increased scrutiny on prices. Utilization of data to exhibit and define the value, particularly through real-world evidence, is crucial in an increasingly data-driven decision making framework focused on better outcomes and reduced costs.

Changes to payment models which focus on total cost of care driven through innovative contracting are also of concern to manufacturers, as price erosion continues to impact relations between payers, health systems and manufacturers. Ensuring data-driven decisions are taken into account is of essential importance in ultimately ensuring patient access to life altering products is maintained.

Consumer pressure placed on health systems and policy makers, as well as industry, will also continue to be of concern in 2020 as high-cost products remain in the spotlight, with regulators responding through legislation aimed at restricting prescription drug costs. Of particular uncertainty is the long-term impact price restriction will have on overall industry innovation, and the ability to develop and bring to market new products amid rising barriers to entry from both regulatory process, as well as reimbursement and market access channels.

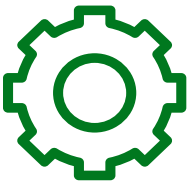
On an international level, life science manufacturers face increasing competition from market entrants producing lower-cost products, while leveraging reduced production costs to provide lower-cost alternative to existing products. Ambiguous trade deals with international partners, China in particular, and an ongoing unpredictability surrounding the European market and the outcome of Brexit will also continue to weigh on pharmaceutical and medical device executives looking to integrate new and existing products into global markets.

Growth and Consolidation within US Hospitals and Health System Entities

Mergers and acquisitions within US hospitals and health care entities, such as ambulatory facilities, group purchasing organizations (GPO) and managed care networks, have been widespread over the past decade and are forecasted to continue into 2020 and beyond. Factors contributing to hospital consolidations, in particular, include the migration to value-based care and payment systems, economic and financial pressures and the rapid pace of technological change and digital innovation. Facing declining reimbursement rates, recent industry research has also found that some hospital systems have utilized mergers and acquisitions as a means to leverage negotiations with payers.

Ambulatory surgery centers (ASC) have also experienced a substantial rise in growth by focusing on routine, low risk procedures outside of a traditional hospital setting, and are forecasted for continued success and development in 2020 and beyond as more patients and surgeons alike utilize their services. ASCs are reshaping the way in which healthcare is delivered, and life science companies will likely cater to and prioritize these working relationships to maximize product success.

Strategic partnerships with group purchasing organizations (GPO) are another critical area of interest for life science corporations planning for the future, particularly for those focused on market access strategy and commercial excellence. In recent years, many GPOs have been acquired by larger organizations, which has ultimately narrowed the playing field and reduced the overall number of available GPOs for manufacturers to negotiate and contract with.



Life science manufacturers are intertwined with, and dependent on, a variety of hospital and health system entities and, therefore, must work together in order to provide patients and end users with the most efficient and effective products. Managing and evaluating these ongoing relationships while monitoring their growth and development is critical for continued market access and commercial success.

Conclusion:

In 2020 we can expect innovations in technology to remain at the forefront of the industry, regulations to develop and implementations to initiate as the push for global regulatory harmonization continues. We will see landscape shifts take place in healthcare at points of pricing, reimbursement and consolidation. Waves of impact will take place across device, diagnostic and pharmaceutical organizations globally. These combined factors make up the changing environment for the life science industry and demonstrate opportunities for organizations to increase revenue and remain competitive to deliver high quality, innovative devices and drugs.

Who We Are:

At Q1 Productions our mission is to propel highly regulated industries forward through a platform of curated executive education, driven by research and grounded in collaborative knowledge share. We strive to make a difference in people's lives. We do this by helping our clients bring new, safe and innovative products to market in order to make a positive impact on the lives of those facing health challenges. Explore upcoming programs to learn about addressing these top concerns and more.

Contributors:

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Division Manager in Life Science Programs

Brooke Akins is a Division Manager in Life Science Programs at Q1 Productions in the Chicago office. Brooke currently resides in Uptown and is originally from the Northwest suburbs of Chicago. After studying Journalism, she graduated with a degree in Communications from DePaul University and continues to have a passion for research and writing. She's been with Q1 Productions for over 9 years in a variety of conference production roles and enjoys collaborating with industry thought leaders throughout the production process.

Nina Dunn
Conference Program Manager

Nina Dunn is a Conference Program Manager at Q1 Productions in the Chicago office. Nina graduated from the University of Illinois at Chicago with a degree in psychology, and she pursues her passion for contributing to the advancement of educational opportunities through her work and volunteer pursuits. She enjoys working with industry leaders to produce focused educational meetings. Nina currently resides in the Andersonville neighborhood and enjoys reading and travel.

Kate Jeter
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Kate Jeter is Vice President of Conference Production and President of the Healthcare Forums Division at Q1 Productions. She has over 13 years of experience with the company, serving as an expert product development and management executive.

Madelyn Maxbauer
Conference Program Manager

Madelyn Maxbauer is a Conference Program Manager at Q1 Productions. She primarily focuses on collaborating with executives and leaders from the life science industries on a variety of areas ranging from medical device labeling, strategic sourcing and patient advocacy. Madelyn also has experience developing new conferences in the pharmaceutical and biotech industries, including gross-to-net and digital transformation.

Alli McIlvain
Content Marketing Associate

Alli McIlvain is a Content Marketing Associate and creates and delivers life science, pharmaceutical, food and dietary and healthcare event campaigns for delegates and sponsors. She develops content across all our platforms: email, social, advertising, web and more. She is our SEO lead, helps maintain the Q1 and Healthcare Forums websites and blogs and manages media partnerships.

Austin Sisson
Conference Program Manager

Austin Sisson is a Conference Program Manager at Q1 Productions. Austin moved to the Midwest from North Carolina and worked in Chicago's non-profit sector for several years before joining Q1 in 2019. He has a deep love of writing, both creatively and professionally, and brings that passion to his work at Q1 through session writing and correspondence with industry leaders. In his free time, Austin may be found experimenting in the kitchen, seeking out Chicago's haunted locations on his bike, or reading a good book on the back porch.

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Natalie Zunker is a Content Marketing Associate and writes and delivers content for EU and US medical device and diagnostic delegate, sponsorship and webinar campaigns. She develops content across all our platforms: email, social, advertising, the website, and more. She produces photos and videos for individual campaigns and the Q1 Productions brand.