MEDTECHSTART

A PrimePath Publication

FEATURE:

From Burnout to Balance: A Guide for Overcoming Job Stress

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CEO'S MESSAGE

Hey there!

Welcome to the first issue of our brand-new magazine! I'm beyond excited to introduce you to a publication that's been in the making for quite some time. This is a special moment for all of us, and I couldn't be prouder to share it with you.

So, what's this magazine all about, you ask? Well, let me give you the lowdown. Our goal is simple: to provide medical device and biotechnology entrepreneurs and professionals with a blend of content that will educate, inform, entertain, and inspire to help you move your journey forward.

When we started Prime Path Medtech, it felt like every day I was confronted with unexpected challenges that weren't directly related to Medical Devices, but were related to company formation, the aspects of running and managing a business, and, frankly, the life events that can get in the way. A resource like MedTechStart would have gone a long way to help me understand relevant information, topics, as well as finding great partners to support our journey.

You see, our team believes that life is too short to spend hours searching for information when all this content can be delivered to your door in an easy-to-use format. Making your journey a bit easier is precisely why we embarked on this adventure of starting our magazine.

In these pages, you'll find a wide array of topics that cater to all elements of business. From thought-provoking features on cutting-edge technology to heartwarming profiles of extraordinary individuals and companies to inspire you, we've got you covered. We'll explore the realms of product development, business formation, medical device regulations, innovation, lifestyle, team development and everything in between.

We're here to help you create businesses that make products that create an impact.

But hey, this magazine isn't just a one-way street. We want to hear from you, too! Your voice matters to us, and we want to create a community where ideas flow freely. We encourage you to reach out, share your thoughts, and engage in lively discussions with fellow readers. Together, we can create something truly remarkable.

So, my friends, buckle up and get ready for an incredible journey. We're thrilled to have you on board, and we can't wait to embark on this adventure together. Let's dive into the first issue and let the magic unfold.

Enjoy the ride!

Warm regards,

Bill Jacqmein

CEO, Prime Path Medtech

Science-Backed Strategies for Boosting Productivity in a Remote Workforce

A Guide to the Future of Productivity Online

By Daniel Lehewych

According to a publication in the journal Technology in Society, the worldwide public reaction to the COVID-19 pandemic has led to remote work becoming as commonplace as traditional in-person work for employees. The availability of various work modalities has emerged as a significant aspect in this shift. In particular, according to *Gallup*, upwards of 70+ million Americans can now do their job remotely, and only 20% of "remote-capable employees" are working full-time in-person.

From a scientific perspective, the effects of such trends are promising, with the condition that remote work environments are appropriately managed by employees and managers alike.

As stated by professor of organizational behavior at William & Mary, Jeanne Wilson, Ph.D., to the *American Psychological Association*,

"Often, managers use busyness, working late, or other [traditional] proxies to infer that an employee is effective; in a remote work situation, managers must rely more heavily on results. That's a hard transition for a lot of people to make."

As the *Harvard Business Review* reported, managers are more likely to view remote work as harmful to productivity. In contrast, employees are more likely to view it as a vital source of improving productivity.

Remote work is here to stay. According to the Bureau of Labor Statistics, the number of employees doing remote work is only slated to increase over the next ten years.

Managers and employees must learn to cooperate in a way that cultivates a symbiotic relationship, enabling them to adapt to different work arrangements and derive optimal advantages. Without such collaboration, the full potential of remote work will not be fully realized and its benefits may be limited. Here are some science-backed strategies for boosting productivity in a remote workforce:

FOCUS ON *WHAT* EMPLOYEES GET DONE, NOT *WHEN* THEY GET IT DONE

Remote workers must discipline themselves to figure out a routine or schedule that permits them to meet work deadlines. This will vary from worker to worker.

Additionally, the nature of such deadlines should be negotiated in advance so that workers can adjust their routines accordingly.

As stated in the journal, *Organizational Dynamics*, employees find remote work palatable because it gives them a strong sense of flexibility and control over their lives.

Therefore, attempts from employers to determine how employees spend their time remotely are "ill-advised."

For example, remote work provides parents with the opportunity to balance work and childcare responsibilities more effectively. However, this flexibility can

"Often, managers use busyness, working late, or other [traditional] proxies to infer that an employee is effective; in a remote work situation, managers must rely more heavily on results. That's a hard transition for a lot of people to make."

only be fully realized if management does not require employees to be constantly available or "on-call." Imposing such a high level of control on employees who are constantly on call not only adversely affects their well-being but also diminishes their productivity. Trust That Workers *Will Work*.

The pathway to this requires establishing trust between employees and managers – which, in practice, means allowing workers the space and time to complete work projects without interruption.

One obstacle to achieving this goal is the common misconception among managers regarding the urgency of tasks. They often perceive most tasks, including emails and unnecessarily lengthy meetings, as highly time-sensitive and crucial. As Georgetown computer science professor Cal Newport, Ph.D., states in his landmark book on human productivity, *Deep Work*, managers tend to give too much credence to "non-cognitively demanding, logistical-style tasks, often performed while distracted. As a result, these efforts tend not to create much new value in the world and are easy to replicate."

Instead, Newport recommends that managers give more weight to "deep work" or "professional activities performed in a distraction-free concentration that pushes your cognitive capabilities to their limit. These efforts create new value, improve your skill, and are hard to replicate."

Deep work occurs within the realm of what psychologists refer to as "flow states," characterized by focused concentration and high productivity. The value of these flow states lies in the production of high-quality work that directly contributes to the success of projects and overall organizational performance. However, the benefits of such flow states are undermined when they are disrupted by irrelevant distractions, like emails. Unfortunately, employers often artificially inflate the urgency of emails through mismanagement practices, impeding the potential for deep work and its positive impact on bottom. In other words, much of employers' mistrust of remote work results from misperceptions because of flawed priorities regarding work tasks.

HELP WORKERS ESTABLISH BOUNDARIES

As further suggested by *Organizational Dynamics*, employers have a duty to their employees to ensure that they feel accommodated – that they have the flexibility to create the most amount of value while conducting deep work on projects that concern company bottom lines:

"This could include providing funds to set up a proper home office, computing equipment, and separate communications devices for work and personal lives. Boundaries between work and home are critical. Our results suggest that while increased productivity is associated with greater intensity of work, productivity, meaning, stress, and health are all enhanced by a separation between work and activities that constitute life outside of work."

Establishing open communication channels to accommodate individual workers' needs through diverse work flexibility options is a crucial step in the right direction. Employers should wholeheartedly embrace and support boundaries that allow workers to attend to personal responsibilities, such as picking up their children or completing college coursework, as long as the core projects they deliver maintain a high standard of quality. Recognizing the positive impact of these boundaries on worker well-being and productivity, employers should actively assist workers in establishing and maintaining such boundaries. In doing so, employers can foster a work environment that prioritizes work-life balance and empowers employees to achieve their best while fulfilling their personal obligations.

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EU New Updated Amendment!

A new amendment to EU 2017/745 (EU MDR) has been published in the Official Journal of the European Union. The release of Regulation 2023/607 on March 15, 2023 amended the validity deadlines for certificates issued in accordance with the EU MDD (90/385/EEC or 93/42/EEC). Certificates issued under MDD will remain valid until:

- December 31, 2027 for class III devices and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws wedges, plates, wires, pins, clips and connectors
- December 31, 2028 for class IIb other than those covered by the previous point
- December 31, 2028 for class I devices placed on the market in sterile condition or having a measuring function.
- December 31, 2028 devices for which the conformity assessment procedure did not require the involvement of a notified body and where the declaration of conformity was drawn up prior to MSay 26, 2021.

Devices which fall into the categories above may be placed on the market or put into service until those dates as long as the following conditions are met:

- The devices must continue to comply with the applicable directives
- There must be no significant changes to the design or intended purpose
- The devices must not present unacceptable risks to health or safety.
- The manufacturer must have a quality system which meets the requirements in EU MDR in place by May 26, 2024
- The manufacturer or authorized representative must submit a formal application with a notified body for a conformity assessment of the device by May 26, 2024 and a written agreement with a notified body for the conformity assessment of the device must be in place by September 26, 2024.

Additionally, class III custom-made implantable devices may be placed on the market until May 26, 2026 without a certificate issued by a notified body provided that the manufacturer or authorized representative has submitted a formal application with a notified body for a conformity assessment of the device by May 26, 2024 and a written agreement with a notified body for the conformity assessment of the device is in place by September 26, 2024.

Manufacturers and authorized representatives should also keep in mind that the MDR requirements for post-market surveillance, vigilance, and registration of economic operators apply even to the devices marketed under the MDD conformity assessment during this transition time.

Although this extension provides additional time for manufacturers and notified bodies to update legacy devices to meet EU MDR requirements, it's important to note that notified bodies may be overwhelmed as the deadline approaches, potentially leading to delays in processing certifications. Therefore, it's highly recommended that manufacturers prioritize obtaining EU MDR certification as quickly as possible to avoid potential delays or non-compliance. It's unlikely that the EU Parliament will grant any further extensions.

What comes to mind when you think of Utah? Skiing on the greatest snow on earth? Breathtaking vistas at national parks like Arches, Zions or Capitol Reef? A quality of life that is among the most desired in the country? What about one of the fastest growing life sciences industries in America?

Utah's Current Life-Science Landscape

By Datra Quin

Since 2012, Utah has become home to one of the fastest growing life sciences industries in the nation. Over 1,000 life sciences companies contribute $13 Billion to the state's GDP, while providing employment for over 50,000 employees. Utah is a great place to do business, especially for startups. Lower taxes, supportive regulatory environment, a skilled workforce and a welcoming innovation hub are increasingly attracting companies to the state, especially those in life sciences.

As a result of this rapid growth and ideal landscape, BioUtah was created in 2012 to elevate the stature and influence of Utah's life science community on the national and global stage. As the state's only trade association dedicated solely to the life sciences industry, the organization serves Utah's medical device, biopharma and healthcare industries through networking, advocacy and education programs. BioUtah creates value for its 200 + members through events, legislative initiatives, and communication outreach. They foster relationships within and between industry, government and education to provide growth opportunities through funding, talent acquisition and development, as well as strategic partnerships.

Utah's governor, Spencer J. Cox, credits BioUtah with playing a critical role in expanding life sciences presence and innovation across the state. According to Governor Cox, "Life sciences have become a strategic pillar of Utah's economy. The industry embodies entrepreneurship and innovation in its work to improve and save lives through advanced testing, novel technologies, and groundbreaking cures."

THE GOAL OF BIOUTAH

BioUtah is an independent, 501 (c) (6) trade organization comprised of manufacturers and developers of medical devices, pharmaceutical, diagnostics, and biotechnology. Together they form an ecosystem that fosters collaboration, promotes innovation, and delivers the technologies that save lives and improve quality of life. National trade associations and key service providers that provide industry support also make up BioUtah's membership. 90% of its members are businesses which have operations, or are headquartered in the state of Utah, but members also include national and international groups who want to be involved and stay privy to activity in the local market.

The Association's President & CEO, Kelvyn Cullimore, has three decades of experience as a medtech CEO and over a decade on the board of the Medical Device Manufacturers Association. He brings a unique understanding of industry and policy issues to advance BioUtah's objectives and help its member companies. Cullimore has been the CEO of BioUtah since October 2018 and says, "We think of ourselves as all things life science in the state of Utah."

In addition to connecting businesses to investors, Cullimore believes that the group's advocacy is another benefit of membership in BioUtah, "We are the voice of the industry here. So, when it comes to policy at either the state or federal level, by joining with us, industry

leaders strengthen their voice on advocacy issues. If there is a bad policy being considered, we can try and stop it. If there's a good policy being considered, we can advance it."

Cullimore also stresses that the association provides group purchasing opportunities. Members can save more than the cost of their membership by taking advantage of BioUtah's existing contracts with vendors such as Chubb Insurance, UPS and Office Depot.

Utah's life sciences industry is a key driver of the state's economy, and BioUtah is committed to growing the industry into a global leader by advocating for legislative initiatives focused on the cause of healthcare in Utah at both the state and federal levels. "BioUtah works closely with our economic development partners here in the state of Utah, including EDC, Utah, whose job it is to recruit companies to come to the state. We're a resource for them." Cullimore said. "We work with any life science companies in the state, or those that have an interest in coming here."

BioUtah helps both the public and private sectors to better appreciate the economic contributions made by the life sciences industry by providing educational forums in order to bring current topics of discussion to the forefront and by encouraging collaboration and innovation amongst members.

BIOUTAH EVENTS

In addition to educational forums, BioUtah hosts two events each year to foster growth and education between the industry and its partners. In the spring, The Entrepreneur & Investor Life Sciences Summit is held, and in the fall, they host the Utah Life Sciences Summit (formerly known as BioHive).

The Entrepreneur & Investor Life Sciences Summit was established to bring together investors and companies seeking funding. The Summit also highlights the life sciences companies in Utah to showcase exciting investable technologies being developed in the state. The E&I summit also features programming designed to help foster the entrepreneurial spirit, educate on practical applications of business development, and provide content to assist early-stage companies by promoting networking between various segments of the life sciences community.

This year's summit held at the University of Utah, with just over 400 registrants, placed particular emphasis on companies seeking funding. According to the summit recap on the association's website, "Six companies participated in the popular Pitch Competition, each deserving recognition for their vision and novel technologies. The judges faced a difficult decision in choosing just two winners. nView Medical took first place and Birch OS was a close second, as runner up."

"Attendees heard from distinguished speakers, including keynote speaker Monica DiCenso, with J.P. Morgan, who addressed market conditions and a timely analysis of the Silicon Valley Bank failure. Panels featured an impressive lineup of CEOs who have successfully taken life sciences companies from concept to commercialization, as well as national and local investors that highlighted opportunities for startups and helped innovators understand the state of financing in the industry."

A popular perk of this summit for these young companies was the ability to meet with an expert that could guide them on applying for, and winning, NIH grants. NIH grants were created to spur innovation and assist in product development costs, but the submission process is daunting to those without experience. Providing life science entrepreneurs with actionable guidance by an industry expert is one of the main pillars of BioUtah's mission.

"This year's record attendance reflects an excitement about the innovation and growth potential of Utah's life sciences industry," said Cullimore. "In fact, new data released by the University of Utah's Kem C. Gardner Policy Institute confirmed that Utah has been home to the fastest growing life sciences community in the nation from 2012-2021."

"This year's record attendance reflects an excitement about the innovation and growth potential of Utah's life sciences industry..."

Following the pitch competition, several successful Utah life science companies gave presentations on their company's journey from startup to successful business. One of these companies, Owlet, which was born from a new parent's desire to keep his children safe and decrease caretaker anxiety, has grown into a very successful Utah-based company. Owlet is focused on bringing new products to market that will keep babies safe and parents more informed regarding their child's health.

The summit wrapped up with a ski day at Deer Valley. Ski enthusiasts shredded the mountain while others enjoyed a slope side lunch, engaging in conversations started at the conference.

This fall, BioUtah will host the Utah Life Science Summit. Formerly known as BioHive, the convention's dedication to innovation and collaboration to help improve healthcare for millions of patients remains the same. This year's summit will showcase a thriving collective of more than 1,100 companies representing the life science and healthcare innovation ecosystem of Utah's economy. This includes researchers, developers, and manufacturers of therapeutics, devices, and diagnostics, as well as laboratory facilities, healthcare delivery systems, digital health, health IT, and supply chain businesses that support these industries.

The Life Science Summit's purpose is to tell the story of the nation's fastest growing life science hub to the people of Utah, the nation and the world. By supporting each other and strengthening the collective expertise and resources, the summit aims to bring unique solutions to impact patients faster while helping to make our healthcare system more efficient.

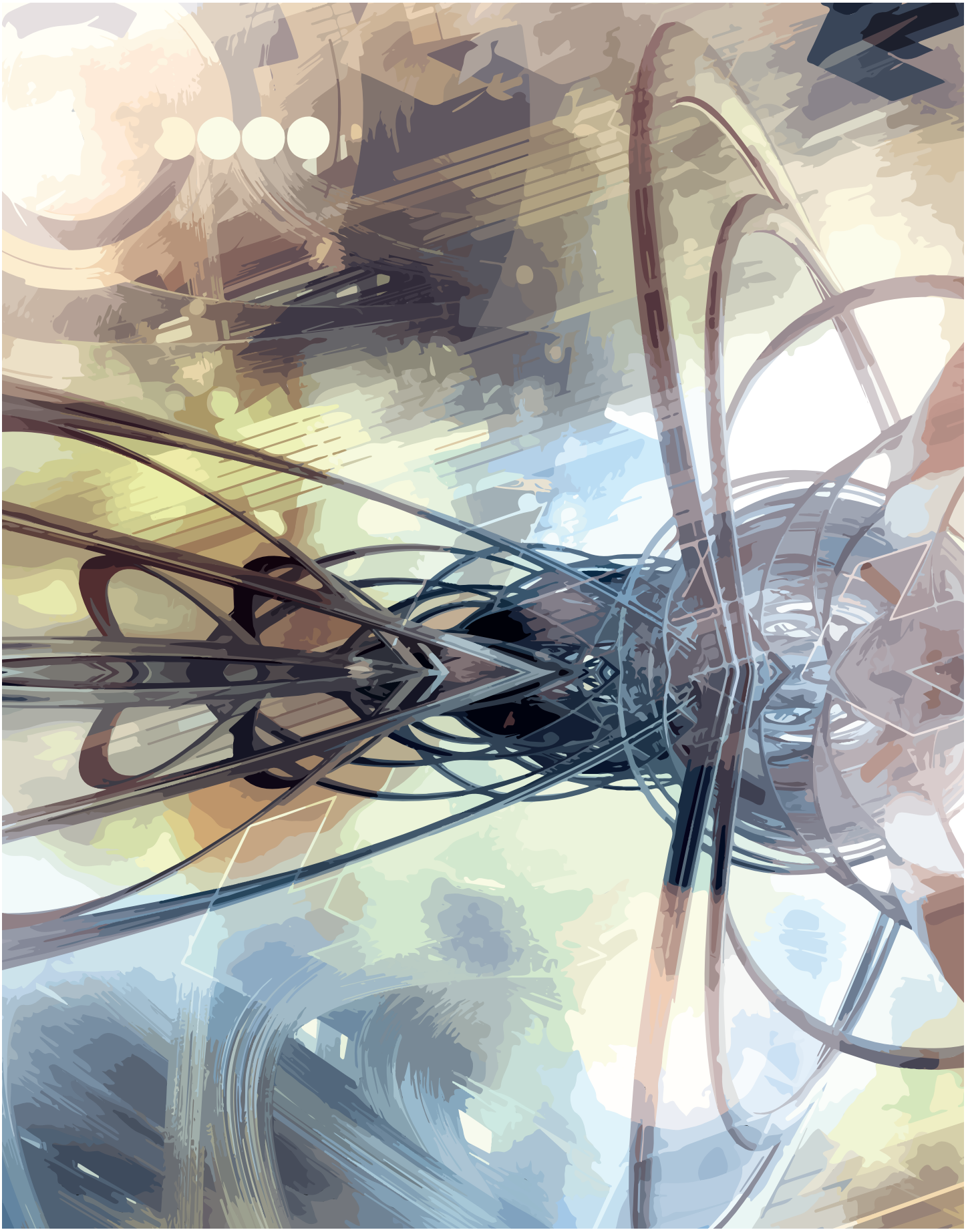
BIOUTAH FOCUS

As one of the nation's fastest growing life science communities, BioUtah believes the state's unity has always been their strategic advantage. BioUtah aims to enhance the standing and impact of Utah's life sciences community by capitalizing on the state's capacity to attract top talent from local universities and out-of-state professionals drawn to the region's expertise in life sciences and the exceptional quality of life it offers. Additionally, BioUtah seeks to leverage these advantages to attract venture capital and foster a diverse community.

BioUtah's extensive network of key influencers on the state, national and global levels, educational networking opportunities, and significant discounts on products and services is open to anyone since there is no cost to be a part of the collective and membership to BioUtah is not required.

For more information visit: bioutah.org

BIOUTAH



Six Reasons Why Viedoc is the Right Fit for Clinical Research

By Viedoc

Viedoc has been accelerating clinical trials since 2003. Today, it's one of the fastest-growing eClinical platforms for modern data collection in clinical studies, having been used in over 5,000 trials, across 30,000 sites, and with over 1 million patients. Their state-of-the-art applications include EDC, ePRO/eCOA, eCRF, Televisits, eTMF, and more.

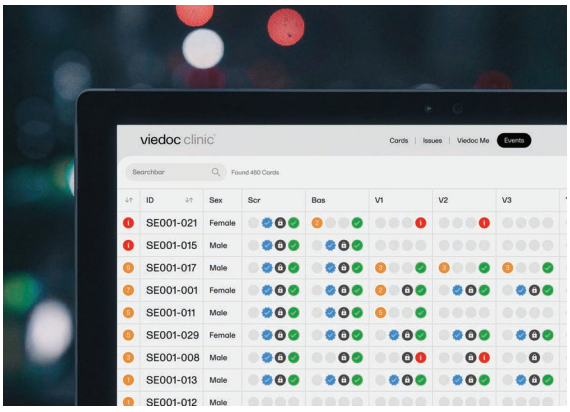
Viedoc's commitment to making clinical trial data more accessible, adaptable, and secure has made them a trusted provider among leading sponsors, institutions, CROs, and medical device companies. With their powerful tools and streamlined interface, Viedoc provides reliable access to user-relevant information, enabling users to manage all aspects of their clinical study in one engaging solution. Whether it's a traditional multi-site study or a decentralized trial, Viedoc's flexible, future-proof, and secure eClinical solution offers the speed, reliability, and ease of use needed to drive life-changing research forward.

Viedoc scales for any phase in any trial–the system provides a modern, intuitive interface, is secure, and compliant. Your CROs and trial sites can get up and running with Viedoc in less than half the time it takes with other EDCs.

Here are six reasons why Viedoc is the right fit for sponsors.

IMPROVED DATA QUALITY

Viedoc Clinic can be configured to enforce data validation rules and checks, so you can ensure that the data entered into the system is accurate and complete. You can also set different permissions so that only certain roles have access to certain types of data and patient information.



INCREASED EFFICIENCY

The Viedoc system can streamline many tedious and time-consuming tasks associated with data management, such as data entry and report generation. With Viedoc Reports, you can download and generate detailed reports from the patient to site to the country level, saving you time and effort.

BETTER DATA ORGANIZATION

Viedoc TMF is used to organize and store data in a structured and easily searchable format, which can make it easier to find and analyze the data you need. The software sources the essential files in your studies, so you can more easily satisfy regulators and audits.

Viedoc TMF supports the global standard, DIAs Reference Model, that provides a standardized way to organize the documents under zones, sections, and artifacts. That way, you can find articles faster.

ENHANCED COLLABORATION

Viedoc is cloud based. This means you can access it online anywhere at any time. Since users have access whenever, wherever, and can share data with team members and collaborators, regardless of their location, they can strengthen and improve collaboration and communication.

GREATER DATA SECURITY

Viedoc can be configured to protect data with security measures such as two-factor authentication and user access controls, which can help prevent unauthorized access to the data. As well, it is compliant with GDPR, HIPPA, APPI, and GB/T

35273-2020. Viedoc as a company also implements an ISMS and is certified according to ISO 27001.

FACILITATION OF REGULATORY COMPLIANCE

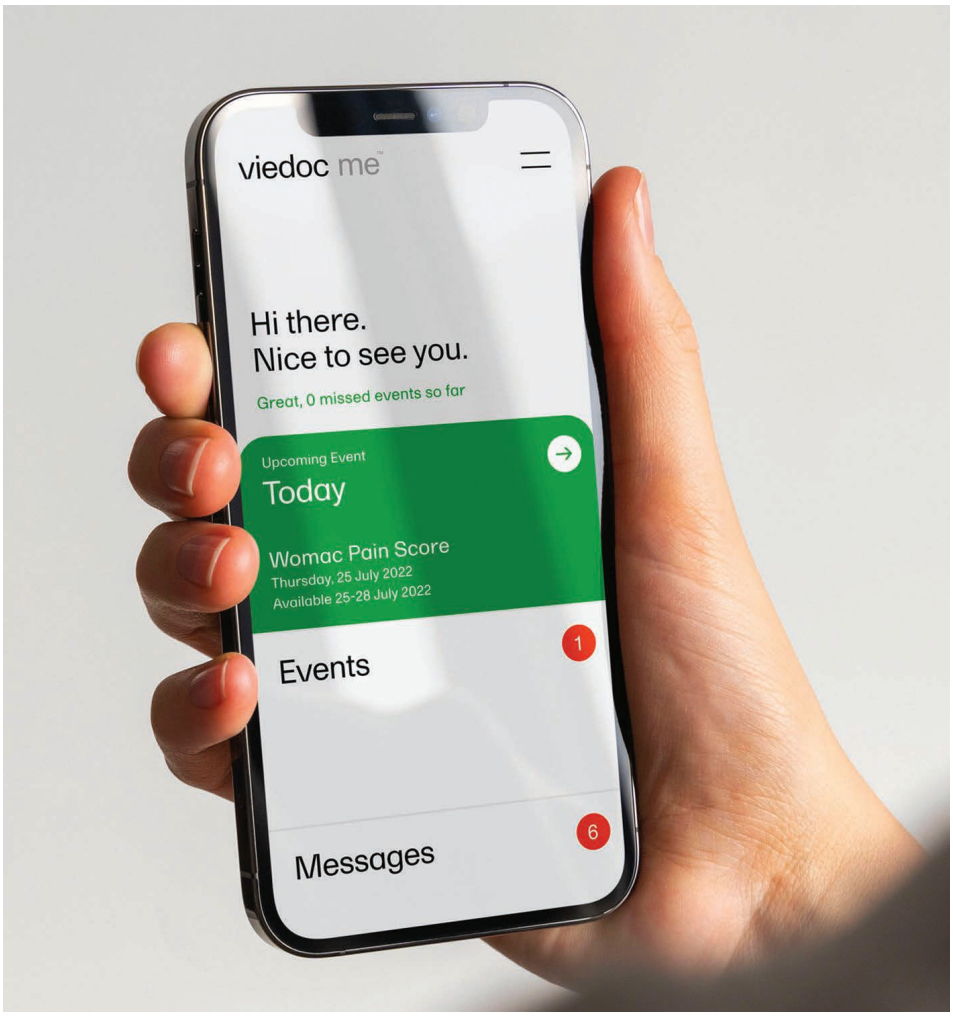
The Viedoc solution meets the requirements of regulatory bodies, such as the FDA, and helps organizations stay compliant with relevant regulations. With Viedoc your files are always a few clicks away, saving you time when it comes to inspections.

CONCLUSION

Viedoc offers world-class professional services that will help you with any questions or concerns at every step of the way.

If you want to save time, effort, and costs, while boosting your security while centralizing your workflow, you can book a demo with the Viedoc team at www.viedoc.com.

viedoc™



SOLUTIONS OVERVIEW

Viedoc is a state-of-the-art cloud-based software solution that offers a comprehensive suite of tools designed to streamline clinical trials. Viedoc provides a unified platform that includes EDC, ePRO/ECOA, eCRF, eTMF, and more, all accessible through a single sign-on (SSO). With Viedoc, organizations can simplify their clinical trial management process and improve their data quality while also enhancing collaboration and data security. This unique solution provides a centralized platform that can be accessed from anywhere, making it the perfect choice for sponsors looking to optimize their clinical trial workflow.

THE ESSENTIALS

VIEDOC CLINIC™
FOR THE INVESTIGATOR
Manage all your trial data in one engaging solution

VIEDOC ADMIN™
FOR THE STUDY MANAGER
Get your study started – and keep it running smoothly

VIEDOC DESIGNER™
FOR THE STUDY BUILDER
Create your own professional study – no advanced design or coding skills needed

THE ADDONS

VIEDOC ME™
FOR THE SUBJECT
Reliable data collection, directly from the source

VIEDOC REPORTS™
FOR THE DATA MANAGER
Tailorable reporting for quicker, deeper insights

VIEDOC CONNECT™
FOR THE DECENTRALIZED TRIAL
Fully integrated support for Televisits and eConsent

VIEDOC LOGISTICS™
FOR THE SUPPLY MANAGER
Smooth, secure and seamless inventory tracking and randomization

VIEDOC TMF™
FOR THE SPONSOR
Powerful documentation management on investigator and sponsor level

VIEDOC PMS™
FOR JAPANESE PMS STUDIES
Flexible data collection for the Japanese market

ABOUT VIEDOC

Viedoc designs engaging software for the life science industry. By accelerating clinical trials on all levels, Viedoc's solutions support major pharmaceutical, biotech, and medical device companies, as well as renowned research institutions worldwide. Headquartered in Uppsala, Sweden, Viedoc also has offices in America, France, Japan, Vietnam, and China. Since Viedoc's inception in 2003, over 1 million patients in more than 75 countries have participated in studies powered by Viedoc. Discover more at www.viedoc.com

W.F.H. - otherwise known as Work From Home

By Logan Simmons

Since the beginning of the Covid-19 Pandemic in early 2020, the majority of us have been made aware of remote working; an employment arrangement in which employees perform their job duties from any location, most often within the comfort of their own homes, rather than the office, warehouse, and store.

Chances are if you haven't had the opportunity to work remotely already, you've at least given it a thought a time or two. Maybe you've come across an ad or job board, and see Company X is hiring for your exact position for the same salary if not more. You begin to ask yourself, is it too good to be true? What are the perks of working from home? What are the downsides? Would remote work be ideal for me? Can I still be efficient in completing my tasks? These are all common questions to ask yourself when deciding to jump into a WFH position. As an engineering professional that has experienced both traditional and remote work styles, I am here to provide insight on these questions and more.

Let's start a few years back to get a real understanding on just how much remote work has impacted the job industry. Data obtained from the American Community Survey, the demographics survey program conducted by the U.S. Census Bureau, revealed that in 2019, fewer than 6% of Americans were working from home[1]. Upon the initial impact of Covid-19 in May 2020, around 35% of the American workforce reported working from home, an increase from 9 million people in 2019 to 48.7 million[2]. Upon the decline of initial worry and the introduction of vaccines in 2021, people began slowly returning to the office. Even still, the U.S. Census Bureau determined roughly 17.9%, approximately 27.6 million people, were still working remotely in 2021[3]. This makes you ask, what prevented people from returning to the office? And for those who returned, what were their reasons?

Following the WFH boom of 2020, many companies and industries realized the duties of many jobs could be completed at home. According to a study by Jonathan Dingel and Brent Neiman, in association with the University of Chicago Booth School of Business, 37% of jobs in the United States are capable of being performed entirely at home[4]. The top 9 occupational groups likely to have remote positions include[5]:

- Legal
- Computer and Mathematical
- Business and Financial Operations
- Management
- Architecture and Engineering
- Arts, Design, Entertainment, Sports, and Media
- Life, Physical, and Social Science
- Community and Social Service
- Sales and Related

Understandably, the 9 occupations with minimal chance of remote availability are:

- Building and Grounds Cleaning and Maintenance
- Construction and Extraction
- Educational Instruction and Library
- Healthcare Practitioners and Technical
- Healthcare Support
- Installation, Maintenance, and Repair
- Office and Administrative Support
- Production
- Personal Care and Service

Besides falling into one of the popular remote industries above, and the convenience working remotely provides, what other reasons should consider working from home?

MONEY

Let's talk C.R.E.A.M.. Popularized by the 1990s hip-hop group the Wu-Tang

Clan, this acronym stands for "Cash Rules Everything Around Me", and they weren't wrong. In a 2017 study conducted by LinkedIn, in which the site surveyed more than 14,000 professionals from 28 countries, two key discoveries were made[6]. Not only do 70% of professionals seek to hear about salary in the first message from a recruiter, but 59% of candidates also claim salary is the leading factor contributed to feeling fulfilled in their career[6]. If salary is an important factor to you, there's good news. A study by Payscale in 2021 found that when data was not controlled for factors such as job title and location, employees who worked remotely earned 23.7% more than their non-remote counterparts[7]. Even when those compensable factors were included for analysis, fully-remote employees still earned 1.9% more than their non-remote counterparts[7]. Moreover, Fortune claimed that in 2022, remote employees could find themselves earning an average of $3,000 more than those working in-person roles[8].

HAPPINESS

They say money can't buy happiness, so is it possible to be happy in a remote role regardless of compensation? Well don't fret, several studies have determined remote work increases employee happiness by more than 20%. According to Forbes, a Tracking Happiness survey of almost 12,500 employees across 4 continents found that not only does employee happiness increase, but that there is a significant correlation between happiness at work and overall life happiness[9]. Regardless of age and gender, data from the respondents revealed 27% of overall life happiness is contributed to happiness at work[9]. The same study also evaluated the correlation between commute times with employee happiness. Not surprisingly, data from the survey revealed employee happiness decreases as commute times increase[9]. Maybe spending more time with your family or having a better work-life balance would improve your happiness. Well it keeps getting better. The American Community Survey revealed remote workers now spend 11.1% of their saved commute time on childcare, while also spending 15.5% on housework[10].

HEALTH

Your health is not just based on your level of activity and the foods you consume, but also the frequency at which you're sick, how much stress you feel, and how much sleep you get. Gallup, a global analytics company, conducted a survey that revealed that those with longer work commutes are more likely to have been diagnosed with high cholesterol and obese BMIs[11]. In addition, CoSo Cloud, the private-cloud solutions provider for Adobe Connect, released results from a study that reported up to 42% of remote workers reported eating healthier than they normally would in the office, with 45% of the remote workers surveyed reporting they get more sleep as wellll1. In terms of stress, a study by PGi, a global provider of collaboration software and services, revealed 82% of people in the study reported having less stress levels working remotely than in the officel1. If you're still not convinced, a survey conducted by Wakefield Research revealed an estimated 69% of working Americans don't take sick days, with approximately 62% of employees going to the office even when sick[11]. All the more reason to work from your own home!

PRODUCTIVITY:

You may be thinking, how can I be productive working at home? Maybe your dog is barking at the neighbor's cat or construction is blaring through your open window. Turns out, it may not matter. According to a study of 16,000 workers conducted by Stanford, remote workers were found to be 13% more productive than those working in person[12]. Moreover, results from the Canada Life Survey showed that remote workers ranked their productivity at 7.7 out of 10 while office workers ranked their productivity at only 6. 5 out of 10[12]. In addition, members from both the Mexico Autonomous Institute of Technology and Chicago Booth School of Business launched a monthly survey of 30,000 American workers aged 20-64 beginning in May 2020. In March 2021, data from the survey revealed nearly six out of 10 workers reported being more productive from home than they expected

"...several studies have determined remote work increases employee happiness by more than 20%...not only does employee happiness increase, but that there is a significant correlation between happiness at work and overall life happiness."

they'd be[13]. Moreover, the average respondent's increase in productivity was valued around 7% higher than expected, with 40% of respondents reporting higher productivity at home during Covid-19 than when in the office prior to the pandemic[13].

TARGET POPULATION

So with all this evidence showing the positives of working remotely, why do some people still dislike it? Well, the answer may lie in demographics and personality types.

To begin, a study conducted by the job search site Joblist revealed that about 49% of the millennials surveyed would like to work virtually full-time. Only 27% of Generation Z respondents and even a smaller percentage of Generation X and baby boomers felt the same way[14]. Although not a direct correlation, it can be assumed that millennials are more likely to pursue remote roles as they are considered the more tech-savvy generation[15]. Millennials, those that were born between 1981 and 1997, were raised during the time of the modern-day technological evolution, making them more suitable to work with the technology required to work from home. In terms of education, Revelio Labs, a company that standardizes millions of publicly available employment records, revealed 55% of remote job postings require at least a Bachelor's degree[18]. For non-remote jobs in similar roles, only 40% of those positions required a Bachelor's degree[18].

Regarding personality, Recruiter.com has published a piece investigating "What Personality Type is Best Suited to Virtual Work?"[16]. In this article, it is suggested that extroverts are more suited to working remotely than introverts. This may come as a surprise for most, but there is actually a good reason behind it. They have found that "extroverted, curious, social types thrive more in virtual working situations because they are much more able to form the necessary connections to stave off isolation and collaborate effectively in virtual scenarios" [16]. Moreover, they report research has shown that disorganized individuals perform more efficiently within the office, because the office provides a structured, established environment. Workers that are more organized are better apt to work from their home because they can take the initiative to complete tasks without procedures or processes in place. In addition, if you struggle with communication or socialization, remote work may not be for you. Virtual work relies heavily on key skills that include well-written and easily comprehendible communication on a consistent basis. Next, Recruiter.com reports that the individuals that compose virtual teams are heavily interdependent on one another. Therefore, an employee looking to thrive in a remote environment must have collaborative skills on top of being self-motivated when working by themselves. Lastly, remote work is not suggested for individuals that prefer firm instruction and tight schedules. Instead, it suggests that employees that are comfortable with ambiguity, as it relies heavily "on personal initiative and independence of thought" will be successful in a WFH environment.

CONCERNS

With all the information and statistics presented in this article, it may be easy to assume you can't go wrong working from home. However, there are several key points to keep in mind.

Even with the surge of remote work the past few years, along with numerous studies revealing the positive aspects of remote work, a large quantity of companies are still not convinced. A study conducted by Microsoft that surveyed 20,000 people in 11 countries revealed 85% of leaders say "the shift to hybrid work has made it challenging to have confidence that employees are being productive"[17]. Moreover, the study revealed 49% of managers of remote workers "struggle to trust their employees to do their best work"[17]. In another study conducted by Citrix, in which 900 business leaders and 1,800 employees worldwide were surveyed, 50% of the business leaders believe when given the opportunity to work "out of sight" employees do not work as hard. Due to this belief, 48% of those leaders have had monitoring software installed on their employees computers. To no surprise, 49% of the 1,800 employees reported not trusting their employer, and understandably so.

Besides trust issues, companies are also looking to use remote work to their advantage in terms of paying employees. In a paper published by The National Bureau of Economic Research, 4 in 10 employers surveyed intend to allow more employees to work out of office, and hope to use that factor to "curb future wage increases"[19]. Ultimately, some companies are looking to pay remote workers less for the convenience of working from their own home. If you think working remotely can't be so great, that people would be willing to take a pay cut, just wait. In 2021, GoodHire surveyed 3,500 Americans, finding that 61% of the respondents would be willing to take a pay cut in order to work remotely full-time, with 70% of the respondents willing to forfeit benefits such as health insurance and paid time off to maintain a remote working status[20].

Lastly, although numerous studies have shown that productivity tends to increase with remote work, it does come at a cost. A study conducted by Ergotron found that 40% of employees report working longer hours at home than when in the office[21]. Maybe this is from less commute time or

more interruptions. Or maybe employees are more willing to work longer when they're comfortable, more satisfied with their environment, and less stressed. According to data obtained by the National Bureau of Economic Research, workdays for remote employees average 48.5 minutes longer[21].

Even with these concerns, remote jobs are more present than ever and here to stay. According to Upwork, a business networking site, it is estimated that around 22% of the U.S. workforce, approximately 36.2 million Americans, will be working remotely in 2025[22].

CONCLUSION

Maybe you took the time to read all the info, data and statistics above. Or maybe you skimmed right over it all. Either way, let's keep it simple. As an employee that has personally worked in-office and remote positions related to the engineering and medical device fields, I can agree with the positive aspects of remote work assessed above. However, I ask that you please be realistic with your expectations. As with any job you will still experience some level of stress or burnout in a remote position. It also may take some time for you to get accustomed to remote work and the level of communication and technology required to be successful at completing your duties. However, if you meet the criteria above, including, but not limited to, occupation, age, education, and personality, it may be worth looking into. You may just open up a brand-new world right from your very own home!

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Navigating Medical Device Registration in Mexico: A Pathway to Market Expansion and Life-Saving Impact

By Karla Hernandez

Mexico has a growing population of over 120 million people and a rapidly expanding healthcare system. Mexico's market for medical devices is also booming, with a projected revenue of US$6.38B in 2023. Entering Mexico's mercado de dispositivos médicos or medical device market can also translate to increased revenue, market growth and diversification for your medical device company. However, to market and sell medical devices in Mexico, registration seekers must navigate a complex regulatory system for medical device registration.

In Mexico, medical device registration and authorization is overseen by the Federal Commission for Protection against Health Risks (COFEPRIS), which is responsible for ensuring the safety and efficacy of medical devices sold in the country. The registration process beings with classifying your medical device.

COFEPRIS separates medical devices into six families based on purpose and function. The families of medical devices include:

- Medical equipment
- Prosthetics, orthotics and functional aids
- Diagnostic devices
- Dental devices
- Surgical materials
- Hygiene Devices

The medical devices are then classified based on risk, that is, any risk the medical device presents to the patient and/or user. Similar to the U.S. Food and Drug Administration (FDA), COFEPRIS has three classes, Class I, Class II and Class III, with Class I presenting the lowest risk. The following is a brief description of class:

- Class I: Low-risk devices that are not intended to enter the body, such as crutches or walking aids.
- Class II: Medium-risk devices that are intended to enter the body but do not penetrate the skin, such as thermometers or endoscopes.
- Class III: High-risk devices that are intended to penetrate the skin or come into contact with bodily fluids, such as implants or surgical instruments.

The classification of a medical device will determine the level of scrutiny it receives during the registration process. Class III devices will require a more rigorous review process than Class I or Class II devices.

Following the classification of your device comes the registration process. This process involves an evaluation of the medical device to determine if it is equivalent to devices that are already registered in Mexico and/or if it meets the applicable standards in Mexico. This process can be broken down into two main pathways: the Equivalency review process and the Standard review process.

The Equivalency review process is designed for medical devices that have already been cleared by a regulatory body in another country. The devices previously cleared by the U.S. FDA, Health Canada and Japan's Pharmaceuticals and Medical Device Agency (PMDA) are eligible for the Equivalency review process. The Equivalency review process can be beneficial to reducing the timeline of the review process and requires less documentation within the medical device's dossier.

The Standard review process is intended for medical devices that do not meet the Equivalency review process criteria and/or are new to the market. This process requires a more in-depth dossier of the medical device's technical information and involves a more comprehensive evaluation of the device's safety and efficacy.

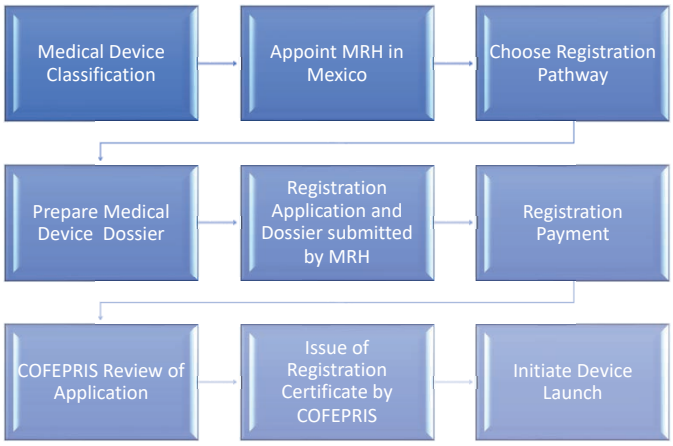
In both instances, Equivalency and Standard review process, COFEPRIS will evaluate the medical device's safety, effectiveness, and quality as well as any clinical data supporting the medical device's use. A third-party review is an optional step in the medical device registration process in Mexico. Companies may choose to have their medical devices reviewed by a third-party organization to expedite the review process. However, it is important to note that COFEPRIS will still conduct its own review of the medical device, and the third-party review does not guarantee approval.

There is an additional and required factor for registration seekers who are not Mexico residents, this involves appointing a Mexico Registration Holder (MRH). The MRH is a legal entity established in Mexico, that acts as a legal representative for the medical device company and facilitates the registration process with COFEPRIS. The MRH is responsible for submitting the registration application and serving as the point of contact for COFEPRIS. The MRH is also responsible for maintaining registration and compliance with COFEPRIS regulations.

Regardless of which review process is chosen, the registration process can take multiple months to complete. It is also important to be aware of reporting requirements and post market surveillance activities that will be essential to ensuring that the medical device remains in compliance with Mexican regulations.

An additional important aspect of medical device registration in Mexico, is the fee associated with registration. The fee for medical device registration with COFEPRIS varies depending on the type of device and the registration process. The fee structure is based on a set of guidelines issued by COFEPRIS, which outlines the fees for each type of medical device, the associated services and the level of risk associated with the device. For example, the fees for Class I devices are generally lower than those for Class II or III devices, as they pose a lower risk to patients. Overall, the cost of medical device registration with COFEPRIS can vary widely depending on the complexity of the device, the level of risk associated with it, and the services required for registration.

Overall, medical device registration in Mexico can be a rigorous and complex process however, the registration pathway can be successfully navigated with thorough planning and meticulous attention to detail. Achieving registration can bring your company market expansion and more importantly, bring life-saving medical technologies to patients who need them in Mexico.



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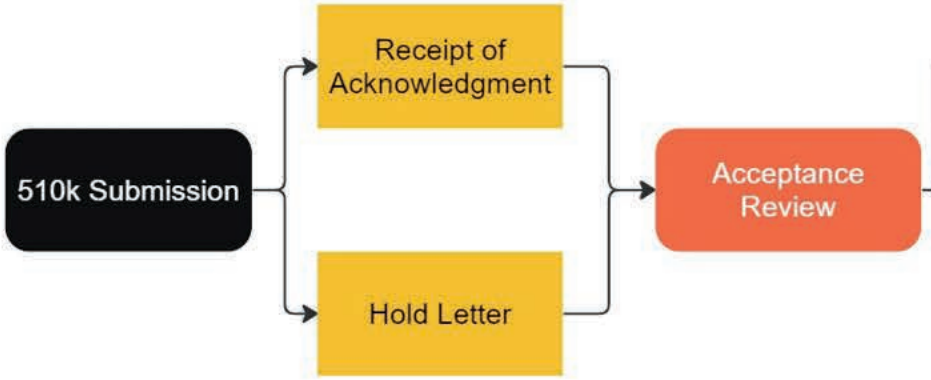
Submitting a 510K



By Elisabeth Miller

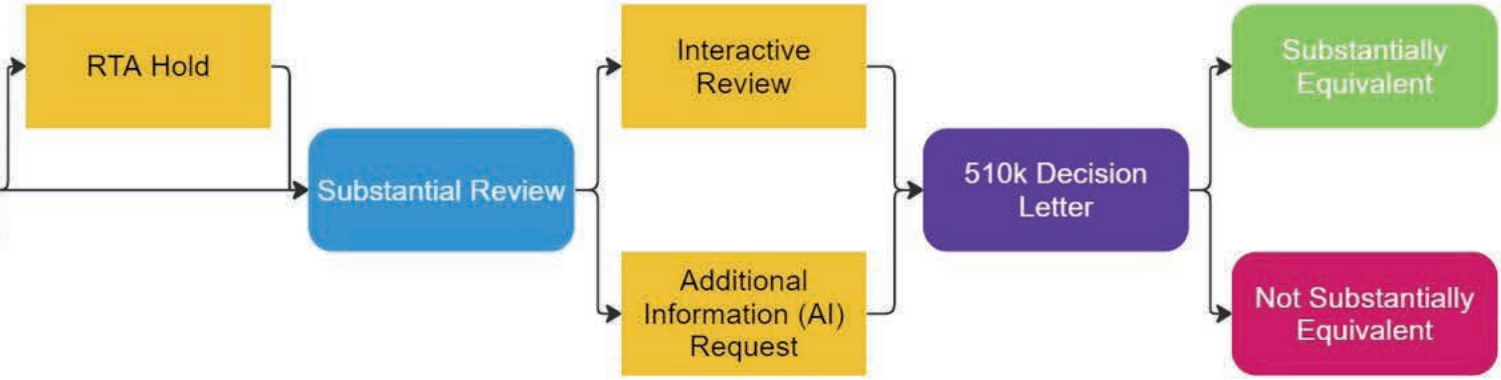
If you would like to market a medical device, chances are you've looked into submitting a 510k. A 510k is a submission to the Food and Drug Administration (FDA) for a device that does not require a Premarket Approval (PMA) application, but it is a Class I, II, or III device that is substantially equivalent to a device that is already marketed. A Class I device is a device with the least amount of risk to human health and safety, such as bandages. While Class III devices have the highest amount of risk to the patient, such as pacemakers. These devices have high amount of risk due to being implanted and in constant contact with the tissues of the patient, and they may be used to support human life. Typically, most 510k submissions are for Class II devices; there are very few Class I and Class III devices that follow the 510k pathway. A Class II device, as expected, falls in the middle of these two classes. These devices typically come in contact with the patient for longer periods of time than that of a Class I device but are not implanted like a Class III device may be. Examples of devices that may be in Class II are catheters, contact lenses, and dental retainers.

Your device will have a classification, product code, and designated review panel. The FDA has established classifications for around 1,700 generic devices which fit into 16 different medical panels for review. These 1,700 generic devices all have been assigned to one of the three regulatory classes.

To submit a 510k, there must be a device already on the market that is substantially equivalent to the device that you are trying to gain FDA clearance for. A substantially equivalent device is the device that is similar to your device in safety, efficacy, technological characteristics, and indications for use. You will use this device to prove to the FDA that your new device is as safe and effective as the already marketed device. The more similarities between the subject device and the predicate device, the stronger your argument will be for substantial equivalence. Proving substantial equivalence is the basis of your 510k submission. When referencing the already marketed device that you are trying to prove substantial equivalence to in your 510k, it will be called the "predicate device". The device you are trying to get clearance for will be considered the "subject" device throughout the 510k submission.

For the submission, there are many sections that revolve around proving the substantial equivalence of your device. Part of this submission will be forms that are provided by the FDA for use in your submission. There are also many other sections that are required in the final 510k submission for which the FDA provides guidance for. In total, your 510k submission will have 20 sections that cover a wide range of topics regarding your device such as the 510k summary, device description, and proposed labeling.

After following the FDA guidance and preparing for the submission, it is time to submit your 510k to the FDA. Currently, the FDA is transitioning from mailing the submission to submitting through an electronic portal. In the past, the 510k submission would have to be zipped and encrypted using the FDA's eCopy Software, downloaded on a flash drive, and mailed to the FDA Center for Devices and Radiological Health (CDRH) office in Maryland. Before the eCopy could be sent, payment for the 510k must have been received by the FDA and referenced in


RTA Hold
Substantial Review
Interactive Review
Additional Information (AI) Request
510k Decision Letter
Substantially Equivalent
Not Substantially Equivalent

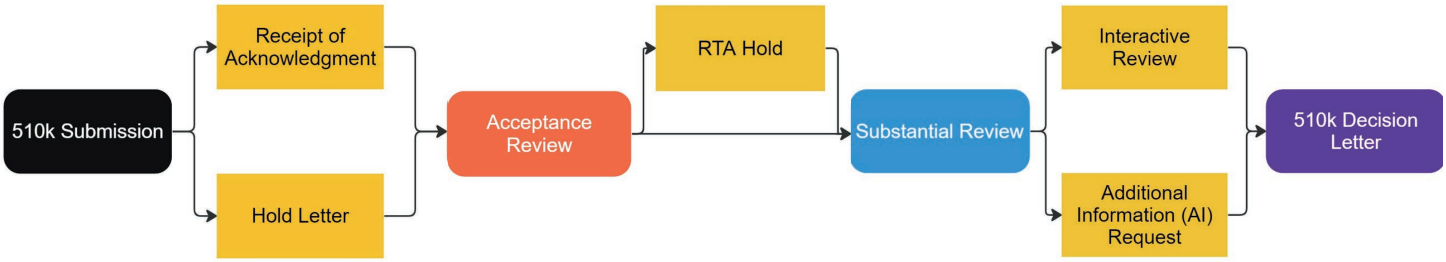
your submission to ensure the payment had been made. Over the next few months, the FDA is moving to an electronic format to submit all 510k files. The new online software is called the eSTAR program and will allow for 510k submissions to be completed electronically without the need for mailing in a physical 510k submission.

After the 510k has been submitted to the FDA, you will receive a Receipt of Acknowledgement. This document will provide you with your assigned 510k number. If your user fee for the 510k submission has not been paid, you will receive a Hold Letter from the FDA. This letter will inform you that a payment must be made in order to continue the 510k process. Once the payment is made, the 510k process will continue. If you do receive a hold letter, you have 180 days to respond and resolve the issue, otherwise the submission will be withdrawn from the FDA's system and a new submission must be created for the device.

The next step in the 510k process is the Acceptance Review. In this stage, the FDA will review your 510k submission to ensure that it holds the minimum necessary information that is required to enter into the next phase, which is Substantial Review. This decision must come from the FDA within 15 days of receiving your Receipt of Acknowledgement. If there is no decision received, your 510k will automatically move into Substantial Review. If the FDA does respond within the 15 days, and your 510k does not pass the Acceptance Review, it is placed into a Refuse to Accept (RTA) hold. If the FDA places an RTA hold on your submission, you will have 180 calendar days to respond to the hold.

An RTA hold could be placed for many reasons. The FDA uses the Acceptance Checklist, which is included in Appendix A of the "Refuse to Accept Policy for 510ks" document provided by the FDA, to review the 510k submissions. When the review begins, the assigned FDA reviewer will use this checklist as a guide to sort through your submission. There are 43 questions included in this checklist that requires "yes", "no", or "N/A" to each of the questions on this checklist. The list covers all sections of the 510k submission to ensure that all necessary information is included in your submission.

If you are to have an RTA hold placed on your 510k submission, you will receive the checklist that has been completed by the FDA reviewer. Each of the questions that caused the RTA hold to be placed on your 510k submission will be marked in yellow and there will be comments from your FDA reviewer regarding the questions they may have. There may be only one section that caused the RTA hold to be placed on the 510k, or there may be many sections that could require your response. There are many reasons why the FDA may ask questions, including missing information, or additional testing requirements to prove that your device is substantially equivalent. Before submitting your 510k, it may help to review and complete the same 510k checklist that the FDA uses to review your submission. This could help you catch simple mistakes and ensure all required information is present to ensure your submission is as complete as possible.



The RTA response must be sent back to the FDA using the eCopy mailing service, or in the future, the electronic service. Unless requested, the entire updated 510k submission does not have to be resent. Only the updated sections and the responses to their asked questions need to be sent back to the FDA. Once the FDA reviews your response, they will either issue another RTA hold is they have additional questions, otherwise you will receive acceptance into Substantial Review.

Once your 510k submission is in Substantial Review, the FDA has two options for communication with you, which are Interactive Review or an Additional Information (AI) request. If an Interactive Review is chosen, this means that your submission

will not be placed on hold and the communication will be through phone calls or emails. For an AI request, your submission will be placed on hold, and you will have 180 days to respond to this hold. An AI request is typically for longer, more substantial questions that may take more time to answer.

Once your submission passes this final phase of review, you will receive a 510k decision letter. This decision letter will state whether the FDA has determined your subject device to be substantially equivalent or not substantially equivalent, with the goal being for your device to be substantially equivalent to the already marketed device you have chosen to be your predicate. This means your device is now considered "cleared" and your work on your 510k submission is complete.

As explained above, a 510k FDA submission has many important steps to complete in order to gain clearance from the FDA.

Your device will fit into one of three medical device classes, but most 510k submissions are for Class II devices. The submission contains 20 sections that must be completed with the guidance of the FDA. Your submission will be based on the similarities of your subject device to the selected predicate device. Proving substantial equivalence is the key to your submission. Once your 510k has been submitted, it will be reviewed by the FDA to determine if your submission holds the minimum information required. From this phase, you may enter an RTA hold or move into Substantial Review. Once you are in Substantial Review, you may enter Interactive Review or have an Additional Information request. After this final stage, you will receive a 510k decision letter. This letter will detail if your device has been determined to be substantially equivalent or not. If your device is determined to be substantially equivalent, you will have received clearance from the FDA, and your 510k process is complete!

What is Mindfulness?

By Emily Cogburn

At first glance, mindfulness and work seem like they wouldn't go together. After all, mindfulness is the idea of enjoying and focusing on, or being present in, the very moment in which we are. But so much of working is about preparation—planning to attend a conference, preparing a presentation, organizing your workday or someone else's, even deciding who will work which shift—that it might seem the task of being in the present is impossible in the workplace. So what is mindfulness and how can it help us be better remote workers?

At its core, the idea of mindfulness is simply the practice of attending to the given moment rather than focusing our attention on the past or the future. "It's about paying attention in a systematic way," says Jon Kabat-Zinn in a series of lectures on his Mindfulness-Based Stress Reduction program. Launched in 1979 at the University of Massachusetts Medical School, its model has been used in schools, prisons, hospital, and veterans' centers. Most of the time, he says, we focus on the future (what we are going to do) and the past (what we have done wrong or what others have done to us). The practice of mindfulness is about avoiding focusing on anything outside of the present moment.

Most of us think this is necessary. How can we work without planning for the future? How can we move forward without dwelling on the past? When we are casting our mind into the future or in the past, it is seldom productive. Usually, we are not doing something as useful as planning a trip. Often, we are just worrying about a past we can't change or a future that might not even happen the way we think.

In fact, attending to the present moment has been shown to have benefits beyond just increased focus. First, it's actually good for our health. A study at the University of Wisconsin showed that a short program in mindfulness meditation gave participants improved immune and brain function. During another study in 2008, college students exhibited reduced stress levels after engaging in mindfulness practice. Mindfulness makes us more compassionate and thoughtful as well.

Perhaps even more directly work-relevant is the evidence that mindfulness can improve our focus and our ability to tune out distractions. Engaging in the practice also helps people be more creative, have confidence as leaders, and reduce multitasking, according to the University of California at Berkeley. It might even reduce obesity, improve sleep, and help us deal with negative feedback.

MINDFULNESS AT WORK

According to Forbes magazine, Google, Intel, and other companies have found that implementing mindfulness programs at their workplaces have led to decreased stress levels, better decision-making, and improved overall wellbeing in their employees. Better engagement at work and dedication to a job or company can also result from increased mindfulness.

More companies are seeing the benefits and offering mindfulness training. A survey of 163 companies in 2018 showed that more than half offered mindfulness programs to their employees. Research shows that even short sessions of yoga, meditation or mindfulness training can help employees be more productive.

Mirabai Bush, who introduced mindfulness to Google, told the Guardian that mindfulness doesn't stop conflict from arising in the workplace, but it makes employees better at dealing with issues so that "they are more likely to be skillfully acknowledged, held, and responded to by the group."

Part of the benefit is making people more aware of their own emotions, she says, giving them more choices on how to deal with them. Mindfulness practitioners are then able to reflect on where the emotions are coming from and react with compassion rather than just reacting quickly in the moment. Some people sum up these benefits as something called "emotional intelligence." The idea is that we become more aware of our own emotions but also attuned to the emotions of others.

Though emotion isn't something we like to associate with work, it is very important to developing work relationships with others. Almost any business is ultimately successful or unsuccessful because of interpersonal relationships—between workers, with workers and clients, and among management and employees. Being attuned to emotion, then, can be a skill with great value in the workplace.

In order to learn to improve our emotional intelligence, we have to slow down and make an effort. Reflection is key and this is something many of us don't take time to do. Mindfulness encourages us to take a step back and figure out what is causing us to lose focus, feel under stress, react badly to conflict, or simply lose the ability to cope in the workplace.

HOW TO INTEGRATE MINDFULNESS INTO YOUR WORK

What if you don't work at Google or another company that offers mindfulness training? What if you work remotely or from home?

The great thing about mindfulness is that you don't really need any special equipment or even training. A few simple steps practiced regularly can produce results.

First, schedule time out of your day to do it. If you're the sort of person who schedules your day anyway, it should be easy to find a couple of five or ten minute blocks to devote to practice. If not, choose places in your schedule (before breakfast, after lunch, during that down time in the late afternoon when you really just want to take a nap).

But what to do? How can we become more mindful and focus on the present moment? There isn't just one answer, which is good because it means that you can find something that works for you.

Whatever it is, your practice should be about breathing and focus. Bringing attention to your breath is a great way to get ourselves into the present moment, however, it's easier said than done. Here are just a few suggestions:

1. Try yoga. Going to classes is great, but if you don't have time or money to physically head to a studio or the gym, it's easy to do at home. A mat is helpful but not necessary. According to Yoga Journal, Bright + Salted Yoga, Yoga with Adriene, and Breathe and Flow are some of the best yoga channels on YouTube. My favorite yoga app is Nike Training Club, which is free. There are also other yoga apps to try including Daily Yoga, Pocket Yoga, and Down Dog.
2. Learn to meditate. Getting started with meditation can be intimidating. The idea of sitting still and focusing on only your own breath seems impossible at first. There are many YouTube videos and apps for this too, however, such as Headspace and Calm. Buddhist temples sometimes offer services that are essentially meditation lessons. Participants sometimes listen to a lecture and then sit in silence for up to ninety minutes.
3. Float. A float tank or sensory deprivation tank is a good way to nudge yourself into a calmer state of mind. Usually salt water, the tanks are located in dark rooms with soundproofing. As you float for 60 or 90 minutes, you focus on your breathing without distractions. At the same time, the water also helps you into a calmer state of mind.
4. Kabat-Zinn suggests incorporating mindfulness into everyday life by taking moments to focus intensely on something like a sight, sound, or smell. Doing this at moments of intense stress or anxiety can help temper those feelings, but you can also choose random times to do it, especially at first. He also says it can be helpful to focus your mind on how your body feels. Notice what the chair feels like under you or how the water feels hitting your skin in the shower. He calls these "micro-moments" of meditation.
5. Walking meditation, another exercise Kabat-Zinn suggests, involves taking a walk anywhere—in your house, your office, or outside—while paying attention to each step. Feel the sensation of your feet touching and leaving the ground and try not to focus on any thoughts that might intrude in your mind.
6. Body scan. This can be done seated or lying down. Draw your focus to one body part at a time. You can start with the feet and work your way up if you want. As you hone in on each part, try to relax it as much as possible. This is a great exercise to do before bed, to promote better sleep.
7. Just take some quiet time. If all of this seems too difficult, just schedule a few minutes away from the screen and the phone every day. Go outside or into a place where you don't normally work, and just sit quietly. Crafts can also be a good way to focus the mind away from work or conflict. Learning to knit or crochet is easy with YouTube videos or try cooking, sewing, or learning an instrument, anything that doesn't involve a screen or other people. The feeling of the yarn ins your hands or the scent of tomatoes cooking can be a little mini-meditation.

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Intellectual Property (IP) Explained

By Leela Madan, Your IP Attorney® and Owner of Madan Law PLLC

Running a business can be hard, especially when you don't know what parts of your business can be protected or how to protect them. The good news is, you probably already know your core product/service offering and probably also have picked out your company name, your product/service name(s), logos, and maybe even a slogan/tagline, all of which can be protected as intellectual property. These are assets you need to protect. Registering these assets using patent and trademark laws can help.

WHAT IS A PATENT?

A patent grants the owner of an invention the exclusive right to make, use, and sell the invention in the United States. A patented invention can be a product, a method of making the product, a method of doing something, an algorithm for software, and so on. A patent can only be obtained by submitting a patent application for the invention to the United States Patent & Trademark Office (USPTO). To be granted a patent, a patent application must meet certain criteria, i.e., the invention must be new, non-obvious, and useful.

WHAT IS A TRADEMARK?

A trademark can be a word, phrase, symbol, design, color, smell, sound, or a combination of these that represents a company's brand and tells a consumer where a good/service comes from. Trademarks are best protected by registering them with the USPTO. To obtain trademark registration, a trademark application for the mark must be submitted to and accepted by the USPTO and must show the trademark in-use-in-commerce in the United States. Examples of famous trademarks are the Nike Swoosh, the Netflix sound (bad-dum), the magenta color used by T-Mobile, and even the smell of Play-Doh.

WHAT IS A COPYRIGHT?

A copyright is a mechanism used to protect works of art, e.g., music sound recordings, song lyrics, books, paintings, poems, and even other works such as software source code, educational workbooks/curricula, and website content. To obtain copyright registration for a work of art, an application must be submitted to the United States Copyright Office (USCO) and certain criteria must be met, e.g., the work must have been made by a human rather than by AI.

WHY SHOULD YOU REGISTER YOUR IP?

1. Deters Infringement by Third Parties

By federally registering your IP, your IP will appear in public databases where other parties and potential competitors will look. For example, many people check the USPTO Trademark Electronic Search System (TESS) to see if a trademark is already in-use and, similarly, check Google Patents to see if an invention has already been patented. The mere presence of your IP in these databases is often enough to deter infringement by a competitor.

2. Deters the Import of Counterfeit Goods

By federally registering your IP, you have the option to have a copy of your registration sent to Customs & Border Protection (CBP) where they will search for counterfeit goods being imported into the country and seize them before they reach their destination, again deterring infringement before it happens.

3. Adds Value to your Business

As the name Intellectual Property (IP) suggests, patents, trademarks, copyrights, and trade secrets are all assets – property – that you own. As property, they can be listed on the company balance sheet and can even be used as collateral to secure financing. These assets can also increase

"…patents, trademarks, copyrights, and trade secrets are all assets – property – that you own."

the value of a company when it's sold. And, finally, any money you spend in obtaining and registering these assets can also be deducted as a business expense to reduce your tax liability.

4. Adds Credibility to your Brand

By federally registering your trademark, you can use the ® symbol in connection with your registered trademark. This not only signals to others that the mark is federally registered, but also adds to the reputation and credibility of your business because many consumers perceive this symbol to be an endorsement by the USPTO.

5. Strengthens an Infringement Lawsuit

In the event of an infringement lawsuit, having your IP federally registered prior to the infringement may allow you to sue in federal court to stop the infringement and also for damages such as your lost profits and/or the infringer's profits earned – maybe even with a 3x multiplier – and your attorneys' fees.

Also, by having your IP federally registered, you can bring suit against any infringer in any city or state in the U.S. because federal registrations give you protection in all 50 states.

6. Improves Chances of Registration in Foreign Countries

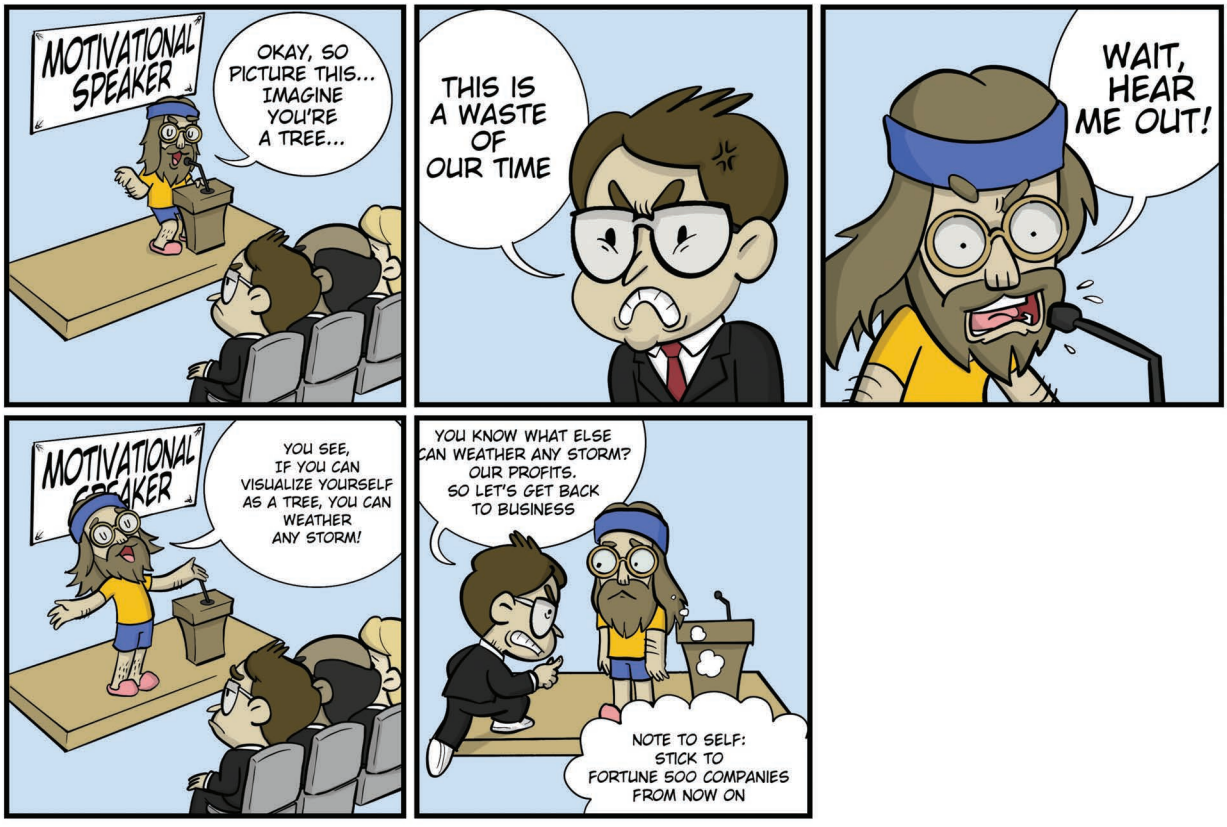
By federally registering your IP in the United States, you can use that registration to file foreign applications by claiming priority to the U.S. registrations, which speeds up registration in most foreign countries.

7. Allows for Instant Removal of Infringing Content on Social Media

By federally registering your IP, you can remove infringing content from most social media platforms without having to resort to costly litigation. Most social media platforms, such as Instagram, Facebook, Twitter, and TikTok, have infringement takedown forms you can submit to get content removed, but most require a USPTO or USCO registration certificate. So, for example, if a competitor opens an account or makes a post with a confusingly similar trademark to your registered trademark, you can fill out a form and get the account or post removed, and in some cases, you can even take that username from the infringer, all without having to file a lawsuit or send a cease and desist letter.

WHETHER YOU ARE A START-UP OR AN ESTABLISHED BUSINESS, YOU HAVE IP. TO LEARN MORE ABOUT HOW TO IDENTIFY AND PROTECT YOUR IP, PLEASE VISIT US AT WWW.MADAN-LAW.COM AND/OR ON SOCIAL MEDIA @MADANLAW AND @YOURIPATTORNEY OR REACH OUT TO US AT (713)364-4796 AND ONE OF OUR LICENSED PATENT ATTORNEYS WILL BE GLAD TO HELP YOU. MENTION THIS ARTICLE AND WE WILL WAIVE OUR PATENT CONSULTATION FEE.

Comic Relief



From Burnout to Balance: A Guide for Overcoming Job Stress

By Datra Quin

In our pursuit of delivering exceptional performance at work, we may frequently neglect the importance of our health and well-being. It is becoming increasingly prevalent for professionals, particularly those working in high-pressure and competitive industries, to experience work-related stress or burnout.

Burnout is a type of stress disorder that results from prolonged exposure to work-related stress, often caused by an overwhelming workload or unrealistic job expectations.

Med-Tech and medical device industry professionals take pride in their dedication and hard work, often including working long hours. However, this commitment to their work may also increase their vulnerability to burnout. Experiencing burnout can result in feeling overwhelmed, exhausted, and incapable of coping with the daily demands of life. These effects can have significant physical, mental, emotional, and professional consequences that can be catastrophic. A report published by the *American Psychological Association* in 2021 reported **more than three-quarters** of employees experienced work-related stress (2).

Additionally, every **3 out of 5** employees admitted to negative impacts of work-related stress, including lack of interest, motivation, energy (26%), and lack of effort at work (19%).

PREVALENCE OF JOB BURNOUT

Burnout can be more prevalent among females than males. Relatively young age groups i.e., < 25 years, may encounter less burnout than people aged 25 or older, where work stress/burnout appears to peak at ages 35 to 54[3].

MAJOR CAUSES OF JOB BURNOUT [4]

According to the Mayo Clinic, common factors that can contribute to burnout are:

Lack of control: Being unable to influence job-related decisions such as your workload, schedule, or assignments can lead to burnout. Similarly, not having access to necessary resources can also contribute to the issue.

Unclear job expectations: If you don't have a clear understanding of what is expected of you, it can be challenging to feel confident and comfortable at work.

Heavy workload and long hours: Having an excessive workload that requires working long hours can increase the risk of burnout

Dysfunctional workplace dynamics: Office bullying, micromanagement, or feeling undermined by colleagues can all cause stress and contribute to job burnout.

Extremes of activity: Jobs that are either monotonous or chaotic can lead to fatigue and burnout as it requires constant energy to remain focused.

Lack of social support: If you feel isolated both at work and in your personal life, it can lead to increased stress and the likelihood of burnout.

Work-life imbalance: Spending too much time and effort at work can leave you with insufficient energy to enjoy time with your family and friends, leading to burnout.

*"…every **3 out of 5** employees admitted negative impacts of work-related stress, including lack of interest, motivation, and energy (26%) and lack of effort at work (19%)."*

Working in a helping profession: People in helping professions, such as healthcare and social work, often face high demands, which can lead to burnout.

Lack of control: Feeling like you have little or no control over your job, including your workload or schedule, can contribute to burnout.

BURNOUT AND YOUR HEALTH

A cohort study published in BMJ (British Medical Journal) analyzed the effects of job overload on employees for a period of 25 years. It revealed that high job strain was associated with high serum cholesterol levels (hyperlipidemia), increased body mass index (BMI), and a consequent enhanced risk of cardiovascular mortality [6].

Another study published in the Journal of Local Regional Anaesthesia mentioned that burnout could have an association with musculoskeletal diseases (among females) and enhance the risk of Type II diabetes [1].

Is burnout a mental disorder or a medical diagnosis?

According to the *World Health Organization (WHO)*, burnout seems to be an occupational phenomenon NOT a medical condition [5].

From the perspective of clinical psychology and psychiatry, burnout is NOT a mental health disorder. Burnout is not included in the Diagnostic and Statistical Manual of Mental Disorders.[7]

CHECKLIST FOR JOB BURNOUT SYMPTOMS [8]

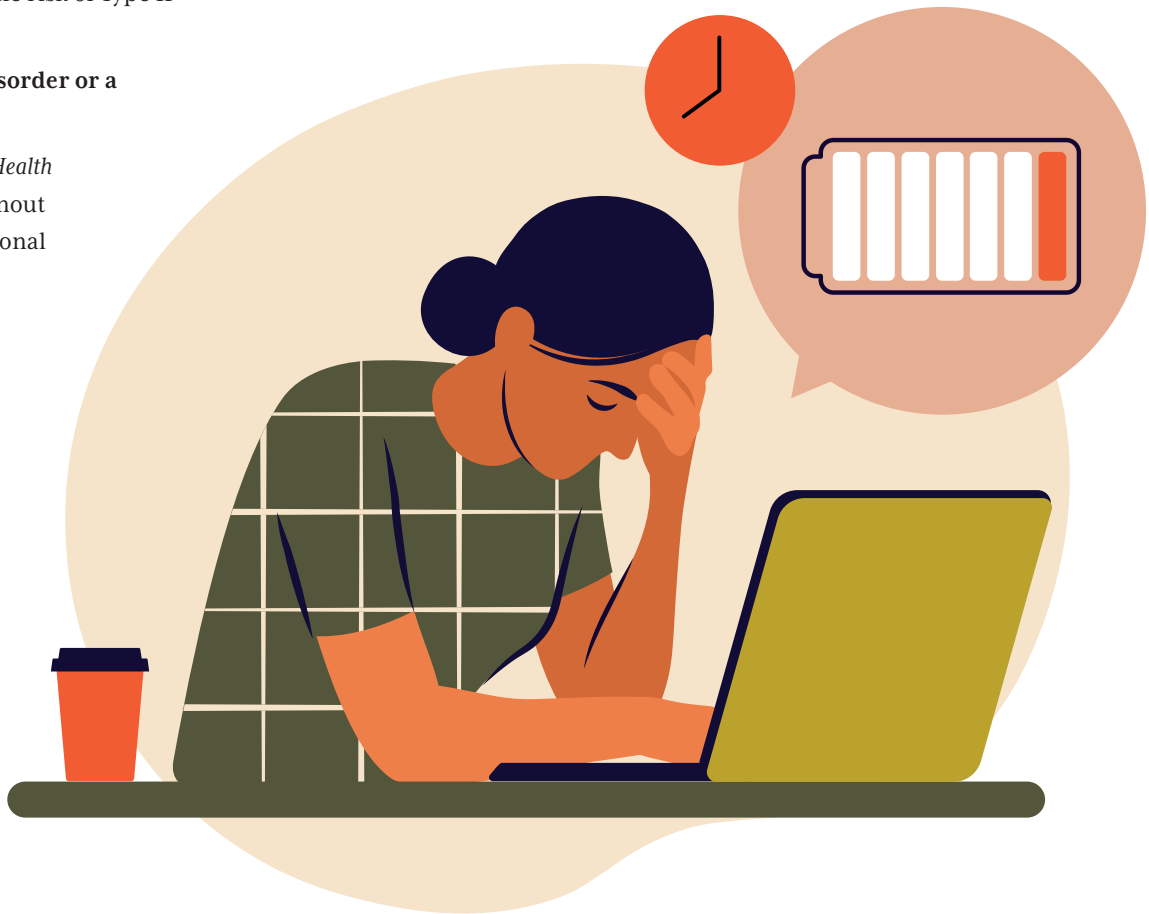
- ✓ Irritation or anger with customers, clients, and colleagues
- ✓ Dragging yourself to work and struggling to get started
- ✓ Feeling uncertain, nervous, or anxious
- ✓ Feeling helpless or powerless
- ✓ Lacking motivation
- ✓ Feeling tired or overwhelmed
- ✓ Feeling sad or depressed
- ✓ Experiencing disturbed sleep or altered sleeping habits
- ✓ Having trouble concentrating
- ✓ Experiencing physical symptoms that are difficult to explain such as, headaches, body pains, or changes in bowel habits

BURNOUT COPING STRATEGIES

Make Self-Care Your First Priority

You may have heard the saying, "No one can take better care of you than you." Research has shown that individuals experiencing burnout often neglect their own self-care practices, such as getting enough sleep, eating a healthy diet, exercising regularly, and maintaining social connections. These basic needs are essential for both physical and mental well-being.

- **Do not sabotage your sleep for work**— A sleep-deprived body never functions well and may also diminish your mental capabilities. Getting enough sleep is crucial for recharging and restoring both your body and mind. It allows your body to rest and repair, while also helping you to feel more alert and focused during the day. Lack of sleep can worsen the symptoms of burnout and contribute to other health



problems, so it's important to prioritize good sleep habits as part of your self-care routine.

- **Incorporate physical exercise into your daily routine**— Physical exercise can be an effective way to elevate mood and reduce feelings of fatigue and sluggishness. Exercise has been shown to increase levels of neurotransmitters, such as serotonin in the brain, which can help improve mood and reduce stress. Regular physical activity can also help improve overall physical health, reduce the risk of chronic diseases, and promote better sleep, all of which can be beneficial in managing burnout. A study published in the *Journal of Sports Medicine* found that physical exercise and mental stress are reciprocally related [(9)].

  In addition to exercise, exploring stress-management programs can be highly beneficial in relieving stress and managing burnout. Practices such as yoga, tai chi, and meditation have been found to effectively reduce stress levels and promote relaxation. These activities focus on mindfulness, deep breathing, and gentle movements, which can help calm the mind, improve mental well-being, and enhance resilience to stress. Incorporating these stress-management techniques into your routine can provide valuable tools for self-care and support in combating burnout.

- **Maintain healthy eating habits**— People who experience burnout may suffer from dysregulations or imbalances of certain neurochemicals in their brain [(10)]. Changes in mood and behavior can be influenced by unhealthy dietary habits. The food we consume not only provides fuel for our bodies, but also plays a role in regulating our mood and behavior. Certain nutrients, such as omega-3 fatty acids, vitamins, and minerals, have been linked to brain health which can impact our emotional well-being. On the other hand, a diet high in processed foods, added sugars, and unhealthy fats may contribute to inflammation and oxidative stress, potentially affecting brain function and mood negatively. Therefore, maintaining a balanced and nutritious diet is important not only for physical health, but also for promoting positive mood and behavior.

  Research has shown that our gut microbiota produces 95% of the serotonin in our body [(11)] and regulates our mind and behavior via the vagus nerve. Healthy food flourishes those bacteria, while unhealthy diets destroys them. Certain vitamin and mineral deficiencies can contribute to burnout symptoms. For example, low levels of vitamin D, vitamin B12, and iron have been associated with fatigue and low energy levels and a deficiency in magnesium, which is important for nerve and muscle function, can cause irritability and anxiety, which may contribute to burnout.

- **Engage in Activities you Enjoy** — Indulging in leisurely pursuits can provide a break from the stress of work and help to promote relaxation and a sense of well-being. This can include a wide range of activities, such as watching movies, playing sports or games, spending time with friends or family, pursuing hobbies, or simply taking a relaxing bath or enjoying a massage. Making time for these activities can help to reduce stress and promote a healthier work-life balance.
- **Spend quality time with your people** — Taking time to connect with your loved ones can help you relax and unwind. You can also use this time to discuss any unresolved thoughts or worries that are contributing to your burnout. Talking things out with someone you trust can help you feel lighter and less burdened. Additionally, your loved ones may be able to offer guidance and support to help you avoid or overcome burnout.

UNHEALTHY HABITS TO AVOID:

- **Numbing the Symptoms** - avoid relying on alcohol or drugs as a means of relieving burnout, as this can exacerbate the problem. While substances may provide temporary respite, they can have detrimental effects on both your physical and mental well-being in the long term.
- **Waiting to seek help** - It is important to seek medical or psychiatric help if you are experiencing severe burnout accompanied by suicidal thoughts, even if you feel afraid or hesitant to do so.
- **Feeling guilt or shame for being overwhelmed** - Being overwhelmed with work stress is common, but it's important to recognize that it's a signal from your body and mind that you are pushing yourself beyond your limits without adequate rest or breaks. It's crucial to listen to these warnings and prioritize self-care.

WORK-RELATED STRATEGIES

Set clear boundaries for your work hours and stick to them.

Avoid making a habit of working long hours or staying late in the office. Instead, strive to complete your work within your regular working hours as much as possible.

Establish boundaries and make it a habit to disconnect from work by turning off your mobile phone and laptop when you're at home.

If you find yourself with an overwhelming workload, take a moment to prioritize your tasks and identify what is urgent. It's important to not take on too much at once and to schedule less urgent tasks for a later time.

If you find yourself consistently working overtime, or beyond your capacity, it may be worth having a conversation with your manager or supervisor. They may be able to provide additional resources, such as outsourcing certain tasks or hiring additional staff, to help distribute your workload. It is important to communicate your concerns and workload to your supervisor to find a solution that works for both you and the organization.

Allow yourself time to rest and rejuvenate.

Continuously working without breaks or time off can decrease productivity and efficiency. If you're struggling with burnout, it's important to take some time off to recover, even if you choose to stay at home. A good approach to combat work-related fatigue is to take a break from work and focus on physical and mental restoration. This means setting aside all work-related affairs and dedicating quality time to yourself.

Hang Up and Hang Out

Even during time off, it's common for people to continue thinking about work or checking work-related messages, which can prevent them from fully disconnecting and relaxing. This can contribute to ongoing feelings of burnout and prevent recovery.

Engaging in non-work-related activities and hobbies during time off can help provide a break from work-related stress and promote relaxation. Research has shown that engaging in leisure activities can significantly reduce the risk of burnout.

Taking time away from work is important for preventing burnout and maintaining a healthy work-life balance. Here are some tips for getting the most out of your time away from the office:

1. **Set boundaries:** Set a clear distinction between work and personal time. Avoid checking emails or taking work calls during your time off.
2. **Plan ahead:** Schedule your time away in advance and create a list of activities you would like to do. This will help you make the most of your time and ensure that you are doing things you enjoy.
3. **Disconnect:** Consider disconnecting from technology during your time off. This can help you be more present in the moment and reduce stress.
4. **Engage in non-work related activities:** Recharge by rediscovering old hobbies, exercising, spending time with loved ones, or exploring new places.
5. **Relax:** Allow yourself to truly relax and unwind during your time off. Take naps, read books, or do anything else that helps you recharge your batteries.

By following these tips, you can get the most out of your time away from the office and return to work feeling refreshed and re-energized.

RETHINK YOUR DAILY ROUTINE

Repetitive routines, even if you are working efficiently, can increase the likelihood of burnout over time. While it may seem like you have little control over your daily activities, making small

changes to your routine can have a positive impact on your overall well-being. Start by introducing minor modifications to your routine and see how they affect your day. As you become more comfortable, gradually add changes that you feel will work well for you.

TAKE SHORT, BUT REGULAR BREAKS

Your body and mind require regular breaks to recharge, just as you recharge your gadgets. Waiting until burnout sets in to take a break is not advisable.

According to HSE (Britain's national regulator for workplace health and safety), short and frequent breaks of 5-10 minutes every hour are more effective to refresh and recharge than a long break of 20 minutes every 2 hours [12].

During these breaks, you can stretch, take a walk, socialize with colleagues, or spend time getting some fresh air - all of which can help you feel better.

REDUCE YOUR WORKING HOURS IF POSSIBLE

If you find that working long hours is taking a toll on your health and wellbeing, it may be worth exploring options for reducing your workload. This could include delegating tasks to others, prioritizing your most important projects, or seeking support from colleagues or a manager.

DEVELOP CONNECTIONS WITH COLLEAGUES

Connecting with colleagues can be helpful in many ways, including emotional support and the opportunity to reflect on the challenges of working your given field. Sharing experiences and insights, you can learn from others how to better cope with stress and burnout.

TAKE ADVANTAGES OF COMPANY RESOURCES:

Consider reaching out to your company's employee assistance program (EAP) if one is available. EAPs provide confidential counselling and other support services to employees, which can include mental health support, stress management, and work-life balance resources. EAPs can be a valuable resource for those experiencing burn-out or other work-related stressors.

CONCLUSION

Job burnout is a challenge that many professionals in the med-tech/medical device industry face, but with the right tools and mindset, it can be overcome. By setting boundaries, practicing self-care, and seeking help when needed, individuals can prevent burnout and thrive in their careers. Remembering the importance of mental health and well-being not only benefits individuals, but also contributes to a positive work culture and enhances overall performance. With these strategies in place, individuals can achieve a fulfilling and rewarding career in the med-tech/medical device industry.

"...short and frequent breaks of 5-10 minutes after every hour are better effective to refresh and recharge than a long break of 20 minutes after every 2 hours."

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Tips For Creating A Strong Brand Identity and Marketing Your Business

By Staff

In today's competitive marketplace, creating a strong brand identity is more important than ever. A strong brand identity can help differentiate your business from the competition and make it more memorable to potential customers. In this article, we will explore some tips for creating a strong brand identity and marketing your business effectively.

THE IMPORTANCE OF BRAND IDENTITY

Before we dive into the tips, it's important to understand the significance of brand identity. A brand identity is the way that a company presents itself to the world. It's the combination of visual elements, messaging, and tone that conveys the company's values, personality, and mission. A strong brand identity is essential for a successful marketing strategy because it helps to build trust and loyalty with customers.

A strong brand identity can benefit your business in many ways, including:

Increased recognition: A strong brand identity helps customers recognize and remember your business. When customers are familiar with your brand, they are more likely to choose it over competitors.

Competitive advantage: A unique and well-defined brand identity can set your business apart from competitors and give you a competitive advantage.

Brand loyalty: A strong brand identity can create an emotional connection with customers, leading to brand loyalty and repeat business.

Now that we understand the importance of brand identity, let's explore some tips for creating a strong one.

TIP #1: DEFINE YOUR BRAND PERSONALITY

Defining your brand personality is the first step in creating a strong brand identity. Your brand personality should reflect your company's values, mission, and target audience. It's essential to have a clear understanding of your brand personality before creating any visual elements or messaging.

To define your brand personality, ask yourself the following questions:

- What are the core values of my business?
- What is my company's mission?
- Who is my target audience?
- What personality traits would best represent my brand?

Once you have a clear understanding of your brand personality, you can begin to create visual elements and messaging that align with it.

TIP #2: CREATE A STRONG VISUAL IDENTITY

Creating a strong visual identity is one of the most important aspects of building a brand identity. Your visual identity includes your logo, color palette, typography, and imagery. These visual elements should be consistent across all of your marketing materials, including your website, social media, and print materials.

When creating your visual identity, consider the following:

Your logo: Your logo should be simple, memorable, and reflective of your brand personality.

Color palette: Your color palette should be consistent across all of your marketing materials and reflect your brand personality.

Typography: Choose typography that is easy to read and reflective of your brand personality.

Imagery: Choose imagery that aligns with your brand personality and target audience.

A strong visual identity can help customers recognize and remember your brand, so it's important to invest time and resources into creating one.

TIP #3: DEVELOP A CONSISTENT TONE OF VOICE

Your brand's tone of voice is how you communicate with customers through written and spoken words. Developing a consistent tone of voice is essential for building a strong brand identity. Your

tone of voice should be reflective of your brand personality and values and should be consistent across all marketing materials.

- When developing your tone of voice, consider the following:
- Who is your target audience?
- What emotions do you want to evoke in your customers?
- What language and vocabulary should you use?
- What messaging should you use to communicate your brand personality and values?

A consistent tone of voice can help customers recognize your brand and build trust

TIP #4: CREATE A STRONG BRAND MESSAGE

A strong brand message is essential for building a strong brand identity. Your brand message is the story you tell about your company, products or services. Your message should be simple, clear, and memorable. It should communicate your unique selling proposition and what makes your business stand out from the competition.

When creating your brand message, consider the following:

- What problem does your business solve?
- What makes your business unique?
- What benefits do your products or services offer?
- What values does your brand represent?

Your brand message should be consistent across all of your marketing materials, including your website, social media, and print materials. This is vital because it will ensure that your target audience knows who you are whenever they land on your website or your social media. If things look slightly different, they might feel as though you are not the same business or brand, forcing them to lose trust in you.

TIP #5: LEVERAGE SOCIAL MEDIA

Social media can be a powerful tool for building a strong brand identity and marketing your business. Social media platforms such as Facebook, Twitter, Instagram, and LinkedIn provide a way for businesses to connect with customers, build brand awareness, and promote their products or services.

To leverage social media effectively, consider the following:

Choose the right platforms: Choose social media platforms that align with your target audience and brand personality.

Consistency: Be consistent with your branding and messaging across all social media platforms.

Engage with your audience: Engage with your audience by responding to comments and messages, and by sharing user-generated content.

Use visuals: Use high-quality visuals, such as images and videos, to make your social media posts more engaging.

TIP #6: CREATE VALUABLE CONTENT

Creating valuable content can help build trust and authority with customers, and can help establish your brand as a thought leader in your industry. Valuable content can come in many forms, including blog posts, videos, infographics, and ebooks.

When creating content, consider the following:

- Choose topics that are relevant to your target audience.
- Use your brand personality and values to guide your content.
- Make your content easy to read and understand.
- Use visuals to make your content more engaging.

Creating valuable content can help attract new customers, and can help build loyalty with existing csustomers. It will enable you to engage with customers by providing useful content they can connect with. When you do this, you will enhance loyalty and customers will value the fact that you have given them something they can utilize.

TIP #7: BUILD RELATIONSHIPS WITH INFLUENCERS

Building relationships with influencers can be a great way to increase brand awareness and drive sales. Influencers are individuals who have a large following on social media, and who can help promote your brand to their followers. When working with influencers, it's important to choose influencers whose values and audience align with your brand. Here are a few tips for building relationships with influencers:

Research influencers in your industry: Look for influencers who have a large following and whose audience aligns with your target audience.

Engage with influencers: Follow influencers on social media and engage with their content by liking and commenting on their posts.

"A consistent tone of voice can help customers recognize your brand and build trust"

Reach out to influencers: Once you've built a relationship with an influencer, reach out to them to discuss potential partnership opportunities.

Offer incentives: Offer influencers incentives, such as free products or discounts, to promote your brand to their audience.

TIP #8: HOST EVENTS

Hosting events can be a great way to build brand awareness and connect with customers. Events can be anything from in-store events, to webinars, to product launches. When planning events, consider the following:

Choose a theme: Choose a theme that aligns with your brand personality and values.

Invite your target audience: Invite your target audience to your event to ensure that you're connecting with the right people.

Provide value: Provide value to your attendees, such as educational content or discounts on your products or services.

Promote your event: Use social media and other marketing channels to promote your event and encourage attendees to RSVP. Hosting events can be a great way to create buzz around your brand and attract new customers.

TIP #9: USE EMAIL MARKETING

Email marketing can be a powerful tool for building relationships with customers and driving sales. When using email marketing, consider the following:

Build a quality email list: Build a quality email list by collecting email addresses from customers who have opted-in to receive your marketing communications.

Segment your email list: Segment your email list by demographics, purcshase history, or other relevant factors to ensure that you're sending targeted and relevant messages.

Use personalization: Use personalization, such as including the recipient's name in the subject line or body of the email, to make your emails more engaging.

Provide value: Provide value to your email subscribers by sharing exclusive content, discounts, or promotions.

By using email marketing effectively, you can build relationships with customers, increase brand loyalty, and drive sales.

TIP #10: LEVERAGE USER-GENERATED CONTENT

User-generated content (UGC) is content created by your customers or followers. This can include social media posts, reviews, testimonials, and other content that showcases how your customers use and interact with your products or services. UGC is valuable because it provides social proof and authenticity for your brand, and can help increase brand awareness and engagement. Here are a few tips for leveraging UGC:

Encourage customers to share: Encourage your customers to share their experiences with your brand on social media and other channels.

Monitor UGC: Monitor UGC related to your brand, and engage with customers who share it by liking, commenting, or sharing their posts.

Share UGC: Share UGC on your own social media channels or website to showcase how customers are using your products or services.

Use UGC in your marketing: Use UGC in your marketing materials, such as ads or email campaigns, to provide social proof and authenticity for your brand.

By leveraging UGC, you can build a stronger relationship with your customers, increase brand awareness, and boost engagement.

CONCLUSION

Creating a strong brand identity is essential for building a successful business. A strong brand identity can help differentiate your business from the competition, build trust with customers, and create brand loyalty. By defining your brand personality, creating a strong visual identity, developing a consistent tone of voice, creating a strong brand message, leveraging social media, and creating valuable content, you can build a strong brand identity and effectively market your business. Remember, building a strong brand identity takes time and effort, but the results will be well worth it.

Promoting Diversity in Clinical Trials

By: Jennifer Day

Avastin is a medication approved by the FDA in 2004 for the treatment of colorectal cancer; it works by blocking the formation of new blood vessels which allow tumors to grow and metastasize. After four years on the market, in 2008, Avastin was granted accelerated approval by the FDA for the treatment of advanced breast cancer when used in combination with chemotherapy. However, shortly after market clearance there were concerns about the safety and effectiveness of Avastin's newfound use for breast cancer patients. In just 2010 the FDA's Oncologic Drugs Advisory Committee voted to recommend that the approval be revoked, and in 2011 the FDA began the process of revoking their approval for Avastin's use in the treatment of breast cancer. This was due to the results of a number of clinical studies on Avastin in treating breast cancer. The studies started to show that Avastin did not provide a significant benefit to patients with advanced breast cancer, in fact, it appeared to have serious adverse effects, including high blood pressure and bleeding. So, the question is, if the early studies on Avastin didn't identify these issues why were these later stage studies unearthing so many issues?

An earlier study, the AVADO trial, had subjects that did not reflect the actual demographics of the disease state. There was an underrepresentation of older women and women of color. While the AVADO trial showed that Avastin delayed the progression of breast cancer, it did not appear to improve overall survival significantly. Conversely, other trials, such as the RIBBON-1 trial, that had more diverse subject populations in terms of race, ethnicity, and geographic location did not show significant benefit from Avastin.

While the approval of Avastin was not explicitly revoked due to lack of diversity, if all of the clinical trials had been more diverse it is likely that the medication's effectiveness and side effects in the general population would have been better characterized and understood. Thus, more accurate and reliable data could have been collected and considered when assessing the medication's safety and effectiveness. It is undeniable that including diverse populations in clinical trials can lead to a better understanding of medications and medical devices, and ensure that medications are safe and effective for everyone who may use them.

In 2022, the FDA released a guidance document for the industry titled "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials." This intention of this new guidance is to not only encourage, but assist both the pharmaceutical and medical device industry in increasing diversity in clinical trials, particularly with regards to racial and ethnic representation. The document acknowledges that certain patient populations have been historically excluded from, and underrepresented in, clinical studies. This has led to disparities in healthcare and worsened health outcomes for these groups. The FDA also details and emphasizes how the importance of diversity in clinical trials to ensure that the benefits and risks of medical products are understood across different patient populations.

More specifically, the guidance document recommends that sponsors develop a Race and Ethnicity Diversity Plan for their product. A plan is recommended for products that require any of the following:

- IND
- IDE
- Clinical studies to support a marketing submission for a BLA, NDA, 510(k), PMA, De Novo or HDE

The plan should be submitted to the IND Application as soon as practicable, as part of the IDE, and/or as part of the marketing submission. Upon submission, the plan should be marked. "RACE AND ETHNICITY DIVERSITY PLAN" in large, bolded type in the cover letter.

Fortunately, the FDA has provided the four key components that should be included in the plan:

1. Overview Of The Disease/Condition

a. Describe available data on the pathophysiology of the disease or condition in underrepresented racial and ethnic populations. As appropriate, describe any differential application, or use of, currently available prevention, screening or diagnostic strategies and treatments, across racial and ethnic populations.

b. Discuss the current understanding of, and available evidence supporting, any similarities and/or differences in the disease or condition under study that are associated with the underrepresented racial and ethnic populations in the United States.

2. Scope Of Medical Product Development Program

Briefly describe the planned trials or studies that will support the medical product's safety, effectiveness and, if a drug, dosage in a future marketing submission. Outline the following:

a. Study design, study population (including study eligibility criteria), endpoints and, the expected geographic locations of the trials or studies and how these aspects of the trial or study may specifically address inclusion of underrepresented racial and ethnic populations.

b. As applicable, summarize any differential findings from clinical pharmacology studies (PK /PD data, pharmacogenomics) that may be associated with certain racial and ethnic populations and/or other relevant information.

3. Goals For Enrollment Of Underrepresented Racial And Ethnic Participants

Define and provide justification for the planned enrollment of participants from underrepresented racial and ethnic populations.

a. Specify underrepresented racial and ethnic populations based on assessment in Category #1.

b. Specify goals for enrollment of underrepresented racial and ethnic participants (e.g., based on the epidemiology of the disease and/or based on a priori information that may impact outcomes across racial and ethnic groups; and where appropriate, leverage pooled data sources or use demographic data in general population). In some cases, increased (i.e., greater than proportional) enrollment of certain populations may be needed to elucidate potential important differences.

4. Specific Plan Of Action To Enroll And Retain Diverse Participants

a. Describe, in detail, the operational measures that will be implemented to enroll and retain underrepresented racial and ethnic participants in the planned trial(s) or studies, and the planned use of data to characterize safety, efficacy, and optimal dosage in these participants, when applicable.

b. Describe specific trial enrollment and retention strategies, including but not limited to:

   i. site location and access (e.g., language assistance for persons with limited English proficiency, reasonable modifications for persons with disabilities, and other issues such as transportation);

   ii. sustained community engagement (e.g., community advisory boards and navigators, community health workers, patient advocacy groups, local healthcare providers, etc.);

   iii. reducing burdens due to trial/study design/conduct (e.g., number/frequency of study-related procedures, use of local laboratory/imaging, telehealth);

c. Describe metrics to ensure that diverse participant enrollment goals are achieved and specify actions to be implemented during the conduct of the trial(s) or studies if planned enrollment goals are not met.

5. Status Of Meeting Enrollment Goals (As Applicable)

a. As the diversity plan is updated, the status of meeting enrollment goals should be evaluated. If the enrollment goals sponsor is not able to achieve enrollment goals despite best efforts, discuss a plan and justification for collecting data in the post-market setting.

There are several steps that the industry can take to achieve better diversity in clinical trials:

1. Identifying and addressing potential barriers to enrollment: Companies should identify potential barriers to enrollment for underrepresented groups, such as language barriers, lack of transportation, or distrust of medical research. Once identified, companies should develop strategies to address them. These may include providing language interpretation services, offering transportation assistance, or working with community organizations to build trust.
2. Monitoring and Reporting demographic data: Companies should monitor and report demographic data for clinical trial subjects to assess in real time whether the trial population adequately represents the intended patient population. This data should also be considered when making decisions about the safety and efficacy of the medical product.
3. Diverse locations of clinical sites: Companies should establish clinical study sites in areas that vary in geographical location to enhance the opportunity for the recruitment and retention of diverse clinical study subjects.
4. Incentives for participation: Offering financial incentives or other benefits, such as transportation or childcare, can help to increase participation from underrepresented groups.
5. Diversify the research team: Having a research team that reflects the diversity of the target population can help to build trust and improve communication with study participants.
6. Collaborate with minority-serving institutions: Clinical trial sponsors can partner with minority-serving institutions such as Historically Black Colleges and Universities (HBCUs) and Hispanic-Serving Institutions (HSIs) to increase participation from underrepresented groups.

The lack of diversity in clinical trials has long been recognized as a serious issue, leading to unequal access to healthcare for underrepresented groups. While there has been progress in recent years towards increasing diversity, there is still much work to be done. This recent addition to the clinical pathway for medical products aims to address this issue. While this new addition to the clinical pathway for medical products may be viewed as an additional burden, it is achievable. Just as all similar previous situations were achieved, companies must and will learn to adapt to this new requirement. In the end, it is undeniable that it will be a net positive.

More diverse clinical trials are essential to ensure that medical products are safe and effective for all populations. Increasing diversity in clinical trials, is an essential step towards ensuring equitable access to healthcare and improving health outcomes for all populations. It is important for the industry to recognize the value of diversity in clinical trials and work towards implementing strategies to increase diversity and representation in clinical research.

Cracking the Code: A Comprehensive Guide to Achieving Medical Device Approval in the EU

By: Janice Farris

Do you want to market and sell your medical device in the EU? Well, let us take a detailed dive into the ins and outs of getting approval; do not worry, anyone is capable of tackling this beast. While I'm sure that you have heard the horror stories of EU MDR (European Union Medical Device Regulation 2017/745), I'm here to tell you that it's not something that should send you running and screaming! Like any regulatory beast, just adhere to the requirements and you'll get approval in due time.

The first step in tackling the beast is hunting it down. In EU MDR talk, you first need to classify your device. Like the FDA, the MDR has risk classes I to III increasing from a device that poses minimal risk to patient safety to a device that provides life sustaining care. The EU MDR 2017/745 has 22 rules to use in order to properly classify your device that you can find in Article 51.

Once you identify the rules, or the classification of your device, you can begin preparing for the battle. Europe requires medical device companies to have a QMS (Quality Management System) and technical documentation. A Quality Management System is a comprehensive, formalized system that documents processes, procedures, and responsibilities that the company follows to achieve quality policies and deliver consistently high-quality products. If your device is not Class I, your QMS will need to be ISO 13485 certified by a notified body. Like the FDA, the EU MDR requires medical device companies to have SOPs (Standard Operating Procedures), work instructions, supplier management, validated systems, internal audits, etc within their QMS.

Technical documentation is an EU MDR specific requirement and is a prerequisite for the conformity assessment. Specific requirements of the technical file can be found in Annex II of the MDR. These requirements include, but are not limited to, a UDI (Unique Device Identifier), intended use, labeling (package label, instructions for use, etc.), manufacturing information, verification and validation procedures and reports, risk management file, and post market surveillance. The idea of the technical file is similar to the FDA's Design History File, but the technical file must be presented as a single PDF document.

The technical file must include a Clinical Evaluation Report (CER) that contains clinical data related to the safety, performance, and usability of the medical device. The purpose of this document is to prove that the device will perform as it is intended to and is safe for users. The CER is a living document, as pre-clinical, pre-market and post-market data should all be included and analyzed. MDR requires a thorough analysis of current state-of-the-art, or treatments that are currently and generally accepted as good practice. This is essentially an extensive evaluation of alternative treatment methods or benchmark devices for the indications that your device claims. An in depth, detailed, and justified literature review can be performed to find all relevant data (favorable and unfavorable); EU MDR enacts strict obligations regarding literature reviews. Additionally, the CER must identify and discuss risks related to the device and provide an acceptable benefit-risk profile.

A clinical evaluation of equivalence may be conducted for the CER, in which the clinical data is pulled from a device that has such similar technical, biological, and clinical characteristics that there is no clinically significant difference in the safety or performance of the two devices. MDR has tightened the equivalence justification requirements; for example, for Class III and implantable devices to claim equivalence, the manufacturers of the two devices must have a contract that allows full access to technical documentation on a continuous basis.

EU MDR introduces a new requirement for the designation of a person responsible for regulatory compliance (PRRC) if the medical device manufacturer has more than 50 employees and 10 million Euros in global sales revenue. The qualifications and responsibilities for the PRRC are laid out in Article 15 of EU MDR 2017/745. The PRRC must have four years of professional experience within medical device regulatory affairs or quality management system roles or have a university degree in law, pharmacy, medicine, engineering, or a relevant scientific discipline and one year of the professional experience described prior. The PRRC is responsible for ensuring that the technical documentation, EU declaration of conformity, and quality management system is robust and current and post-market surveillance and reporting obligations are satisfied.

When faced with the beast of regulation, the best resource is someone who has faced the same challenges that you are approaching. An EU Authorized Representative will provide that knowledge and guidance in your pathway to EU

market clearance. An EU Authorized Representative is a legal entity located in the EU that represents and aids non-EU manufacturers in complying to EU regulations. The Authorized Representative acts as a liaison between manufacturers and EU National Authorities. The responsibilities of authorized representatives are listed in Article 11 of the EU MDR 2017/745 and include verification of technical files and EU declaration of conformities, registration of medical devices with the appropriate National Authorities, and notification of complaints from users or healthcare professionals to the manufacturer and Competent Authorities. Personally, I have used Obelis Group to gain EU market approval and they made the process very clear and straightforward for an EU newbie like me. They were extremely responsive and always willing to answer any questions I had. In my opinion, the Authorized Representative is the reason why it seems like the EU has a clearer and easier pathway to market for medical devices than the US. Authorized Representatives pride themselves on consistently offering a hand to those working toward marketing their product.

Touching on the EU Declaration of Conformity (DoC), this is the document where the manufacturer accepts all responsibility for compliance of the device. It must declare that the product fulfills the necessary requirements of the CE marking directives and EU regulations and contain the contact details of the manufacturer and authorized representative. Devices can be covered under multiple CE marking directives and each has their own requirements for the DoC, so be sure to check out which one(s) your device falls under!

The final obstacle in tackling your beast is achieving approval from a Notified Body. Under EU MDR, you are required to choose a notified body (which is an independent organization that has been accredited by an EU Member State) to assess and approve the conformity, safety, and efficacy of your product. As the FDA is to the United States, Notified Bodies are to the EU. They are the ones who issue CE certificates, which is the golden ticket that you need to market your medical device in the EU. A list of Notified Bodies that are authorized for CE mark certification can be found on the NANDO (New Approach Notified and Designated Organization) website. Class I medical devices that are non-sterile, do not have a measuring function, and are not reusable surgical instruments are exempted from going through a Notified Body.

Along with EU MDR 2017/745 came an update to EUDAMED. This is the official database where data is stored on all medical devices registered in the EU. This database will be publicly accessible in order to encourage transparency, high performance, and safety of products. EUDAMED has six modules: actor registration, UDI and device registration, notified bodies and certificates, clinical and performance studies, vigilance, and market surveillance. It is necessary for all medical device companies to register manufacturers and devices on EUDAMED.

After your medical device has been approved by a notified body and you are selling in the EU, the regulatory battle is still not over. Similar to the FDA requirements, the MDR necessitates that medical device companies conduct post-market surveillance on their devices. This entails keeping tabs on the devices once they are in the user's hands and conducting trend analysis. Medical device companies should use information and experience gathered from their devices on the market to establish corrective and preventative actions (CAPAs) that improve their processes and eliminate causes of non-conformities.

With your medical device on the market and constantly being used by customers, you must practice vigilance. In the case of our beast, vigilance is spreading awareness if it is ever uncontrollable or poses a threat to society. Similarly, the EU MDR defines vigilance as "the identification, reporting and trending of serious incidents and the conduct of safety related corrective actions." Every "serious incident" or corrective action related to the safety of the device must be officially reported to the EUDAMED database. The EU MDR demands a 2-day reporting deadline for serious public health threats, a 10-day reporting deadline for a death or serious health deterioration, and a 15-day reporting deadline for all other serious incidents. Because of these reporting deadlines, the EU MDR encourages the safety and efficacy of products and allows medical device companies to build trusting and transparent relationships with patients.

The European Medical Device Regulations are designed to improve the safety, performance, and quality of medical devices. A high level of clinical evidence, post-market surveillance, technical documentation, and quality management is required in order to market a medical device in the EU, but just remember that the ultimate goal is to ensure patient safety! The process to market might seem long and tedious, but the EU MDR does a good job of clearly defining requirements and paving the path for a successful medical device company. With patience and diligence, you can tackle the beast and get your medical device approved for market in the EU!