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WHITE PAPER

DON'T WAIT!
KEEPING UP WITH MEDICAL DEVICE COMPLIANCE

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HIGHLIGHTS

For Companies with Medical Device Products

- The cost of reactive regulatory compliance is daunting, erodes credibility with customers and employees, reduces time to market and limits future strategic options.
- The risks of regultory scrutiny and non-compliance increase with the number of products and facilities in a company's portfolio. Compounding this, regulatory authorities are now willing to send far-reaching warnings based on the review of only a few sites.
- The demarcation line of what is a regulated device is shifting. Organizations that have historically not had products regulated as medical devices are now increasingly required to comply.
- There is no sustainable strategic plan without compliance expertise to help form and guide that strategy.

OVERVIEW: TURNING COMPLIANCE INTO A STRATEGIC ADVANTAGE (DOES YOUR PRODUCT SHARE PERSONAL HEALTH INFORMATION?)

Every business faces risk. Broadly speaking, the primary categories of business risk are Market, Financial, Execution, and Regulatory. Successful companies have developed a core competency in managing these risks, and turning risk management into a sustainable competitive advantage. For companies producing medical devices, recent trends have underscored the importance of managing Regulatory risk to remain a viable business.

As a medical device manufacturer or marketer, key performance indicators ("KPIs") likely include speed to market and time in market. To achieve this, a company must have an effective, data-driven product development platform interwoven with exceptional compliance policies and procedures.

Increased Data = Increased Risk

Reacting to issues as they arise and creating ad hoc fixes for those issues will only serve to 'gunk up the system', increasing procedural complexities and forcing you to kiss your speed to market and time in market goals goodbye.

As a compliance professional or someone responsible for products in your organization, you are likely familiar with Data Integrity ("DI"). You are also likely quite aware of trends called 'Big Data' or the 'Internet of Things' ("IoT"). Variability in how consumers use devices (intended or not) and the enormous volume of data being shared in the development and use of these devices put your KPIs at risk.

As more data is produced, shared, analyzed, and used in the consumption of your devices, the greater the strain on your compliance capabilities. Device companies MUST develop policies PROACTIVELY to manage the increased regulatory compliance risk that comes with the growth in data collection and sharing and the changes in how consumers use their products. Reacting to issues as they arise and creating ad hoc fixes for those issues will only serve to 'gunk up the system', increasing procedural complexities and forcing you to kiss your speed to market and time in market goals goodbye.

IT'S NOT YOUR FATHER'S FDA ANYMORE

The FDA is currently undergoing what is called 'program alignment'. Prior to this, a company in Chicago could expect FDA visits to be conducted by a familiar face responsible for that geography, regardless of expertise. The FDA is switching to a programmatic approach, where the facility will be inspected by an investigator with deep, specific experience in that product or compliance area, regardless of geography.

Furthermore, entire companies are increasingly held responsible for compliance issues, as opposed to an individual facility. No matter the location or sub-entity that may own that facility, the corporate owner is being held responsible. A single, adverse inspection may trigger directed inspections across all corporately held entities. This of course has significant implications for operations, supply chain, compliance, and mergers and acquisitions prospects.

To support these changes, the proposed 2017 FDA budget is 8% greater than 2016, primarily to increase staffing. Along with the programmatic approach to investigation, there is significantly less chance that the FDA is understaffed in any one region.

WHAT'S DRIVING COMPLIANCE RISK?

There are several trends that medical device companies must respond to stay aligned with regulatory bodies around the globe. The expectation and challenge has always been in the "C" of cGMP. Current trends in technology drive the need for new, innovative and current compliance practices. Failure to upgrade your monitoring and control processes or to keep up with the global expectations for internationally marketed products can mean failure in the face of a regulatory evaluation.

TREND 1: INTERNET OF THINGS

The scope of what constitutes a medical device has erupted, primarily due to the convergence of factors often called the Internet of Things (IoT).[1] IoT is essentially the ability for any sensor-laden object to measure, analyze, and send data to remote servers and receive data in return.

> ***By 2018, 50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications.[3]***

IoT is pushing consumer products towards a regulatory threshold, enabling the convergence of consumer devices and healthcare. IoT means data is available to drive decisions. A key value proposition for an increasing number of consumer devices is the ability to collect data that can be shared with a medical professional. **By regulatory definition, any data that is produced by a product that can be reasonably expected to be shared with a medical professional for the purposes of detecting, curing, treating or mitigating disease, means that product is a medical device and subject to regulatory scrutiny[2].**

According to industry estimates, "by 2018, 50 percent of the more than 3.4 billion smartphone and tablet users will have downloaded mobile health applications."[3] That parallels what one research firm estimates to be a healthcare IoT market size of **$410 billion by 2022, up from**

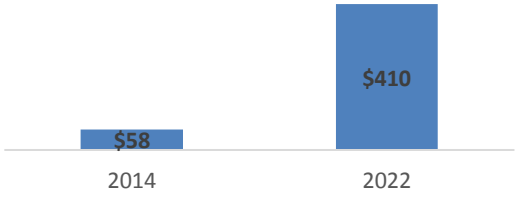


Figure 1: Healthcare IoT Market Size, 2014-2022

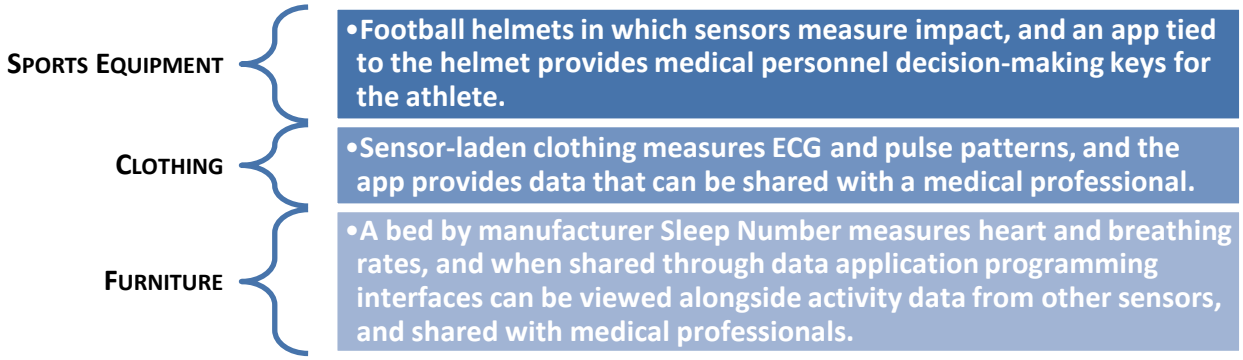
[1] To learn more about IoT and its impacts on compliance, see Lachman Consultants' whitepaper "Navigating Through the Cloud(s) in Life Sciences," a copy of which may be requested at www.lachmanconsultants.com

[2] U.S. Food Drug and Cosmetic Act, (FD&C Act), Section 321(h) (21 U.S.C. 321(h))

[3] FDA Website, Mobile Medical Applications, http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/default.htm, Web Accessed February 7, 2017.

$58 billion in 2014 – an astounding compounded annual growth rate of over 28%[4] (Figure 1**).**

A glance at the exhibitor list of the 2016 Consumer Electronics Show (CES) provides a litany of examples.



Of course, no data can be shared without the use of software. The software stack that supports the sharing of data, whether on-device, in the cloud, or elsewhere, is also subject to regulatory compliance. Specifically, any database that houses protected health information ("PHI") or application that interfaces with such a database and is shared with a healthcare provider must adhere to regulatory compliance rules.

Case studies from two large healthcare entities provide examples of IoT strategies and the entities facing regulatory scrutiny under these models.

Table 1: IoT Case Studies

Company & Strategy	What is Regulated (& Who's Responsible)
Royal Philips (NASDAQ: PHG) Combined its Health Tech and Consumer Lifestyle divisions Created JV with Salesforce.com to create a cloud-based platform to store clinical data from medical scanners, hospital IT systems, and remote monitoring apps. The platform allows systems integrators and software product developers to create apps. For example, diabetes patients can self-monitor and communicate with their physicians, while allowing the physician to connect this data to activity trackers and medical records.	• The platform (Royal Philips, Salesforce.com) • The devices (Royal Philips, other device manufacturers) • The hospital IT system (hospitals) • The apps (integrators, app developer)
GE Health Cloud (NYSE: GE) Created its own platform as a service model in response to Royal Philip's strategy. Stated goal is to connect 2 million health machines to the cloud, with GE analytics software for health IT professionals. A key part of the proposed value will be apps developed by independent software companies that will utilize and interact with platform data sources.	• The platform (GE) • The devices (GE, other device manufacturers) • The apps (integrators, app developer)

TREND 2: CYBERSECURITY

With the explosion of data being created and shared, cybersecurity has become an enormous risk to be

[4] Grand View Research, Internet of Things (IoT) in Healthcare Market Report, 2022, http://www.grandviewresearch.com/industry-analysis/internet-of-things-iot-healthcare-market, May 2016.

managed. The Center for Devices and Radiological Health (CDRH) has released its 10 priorities for 2017[5]. Leveraging 'big data' is one, and strengthening cybersecurity is another. It should be instructive that those two priorities are unchanged from 2016.

In the medical device manufacturing world, the risk of cybersecurity increases not only with each additional device, but more importantly with each additional employee and communication step at every node of the supply chain.

> ***The security of the medical device or object is only as secure as the network it communicates with. The network includes not only technologies, but also the people, procedures, and controls involved in the development, testing, and distribution of the device.***

As supply chains grow and become more complex, risk managers are scrambling to get ahead of cybersecurity risks. Just ask your colleagues in IT. Major medical device manufacturers may have over 1,000 suppliers for a given portfolio of products. Each interface and data hand-off increases the risk of data theft, data integrity, or other cybersecurity issues. The risk is of such concern that the HHS Office of the Inspector General has identified medical device cyber security as a principle area of focus in their 2017 work plan.

Who is ultimately responsible for cybersecurity risks in the development of the product? In case you haven't guessed, the manufacturer. A recent case in point is the market removal of a leading device manufacturer's infusion pumps due to an August 2015 FDA alert in response to potential cybersecurity flaws.

- **In 2013, several brands of the company's infusion pumps are discontinued due to quality issues (costing over $300m, according to the company).**
- **In August 2015, cybersecurity flaws are discovered, and the FDA issued a alert to have all pumps removed from use.**
- **The cybersecurity vulnerabilities in those pump systems included physical design, access verification in hospital systems, insufficient controls to verify data authenticity, improper password and information storage, and vulnerable 3rd party software.**
- **Despite many of the issues being at the downstream user level, it was the company's brand and the parent company's stock price that took a hit (nearly 20% drop in the 6 months following the FDA's actions.**

Figure 2: FDA Alert for Device Manufacturer's pumps due to Cybersecurity Flaws

TREND 3: MARGIN PRESSURES

In the United States, the Affordable Health Care Act (ACA) is pushing the healthcare system away from fee-based care towards value based care. The near-term ramifications of this change in reimbursement model is that providers must contain costs, through belt-tightening or through consolidation to find economies of scale and greater purchasing power.

[5] http://www.fda.gov/MedicalDevices/ScienceandResearch/ucm467550.htm

Medical device manufacturer margins are feeling this squeeze. Less frequent purchases and pushback against previously high-margin minor product upgrades, combined with the 2.3% excise tax introduced by the ACA have reduced public medical device company EBITDA from 15.65% in Q2 2015 to 8.18% in Q2 2016.[6]

As in any industry, margin pressures drive the need for greater efficiencies for medical device manufacturers. Particularly for smaller companies, efficiency gains in the absence of revenue growth lead to cutting corners on R&D and design while chopping supplier, material, and personnel costs. All of these steps increase regulatory risk.

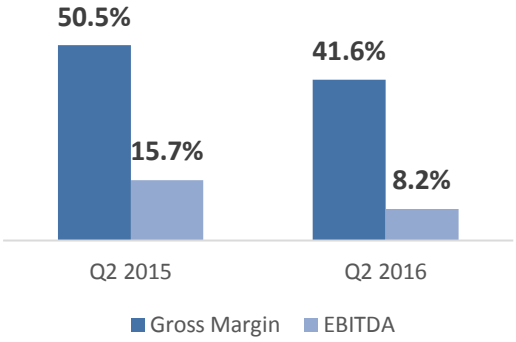


Figure 3: Medical Device Industry Margins

Reduced margins also mean companies must get new products to market faster. Ironically, improving regulatory compliance is the BEST way to maximize speed to market in an era of increased regulatory scrutiny.

TREND 4: SUPPLY CHAIN/OUTSOURCING

In this increasingly competitive and margin sensitive environment, companies often choose to focus on core competencies and double-down on compliance risk by outsourcing non-core functions. Contract manufacturing and outsourcing marketing and other functions do not reduce a company's regulatory burden for these functions.

In fact, extending the supply chain may increase regulatory risk, including these common causes:

- Cybersecurity risks from increased sharing of data (as elucidated above)
- Unclear delineation of responsibilities
- Lack of strong contractual language dictating regulatory compliance activities
- Inability to conduct supplier quality and procedure audits
- Limited understanding of foreign regulatory and importation requirements

TREND 5: MERGERS & ACQUISITIONS

In response to several of the previous trends, companies have been active in seeking strategic joint ventures, mergers, and outright acquisitions. The result has been a bifurcation of the medical device industry, into large conglomerate firms that are geographically or product focused and many small niche companies.

In 2015, Google, under its new parent, Alphabet, created Google Life Sciences. Already, GLS is partnering with other med tech giants and has partnered with another major life science company on a contact lens for diabetic patients to monitor blood glucose levels. Additional partnerships with GLS include, DexCom, Sanofi and Johnson & Johnson. Google is not alone in the race. Traditional biopharma firms such as Novartis, Abbott, and Teva, have been aggressively making deals to purchase and promote new technologies[7].

Mergers, partnerships, and acquisitions increase regulatory risk exposure. Partners and purchasers have their

[6] Compiled from public company data: http://csimarket.com/Industry/industry_Profitability_Ratios.php?ind=804

[7] Lawrence, S., FierceMedicalDevices' 2015 Fierce 15, http://www.fiercebiotech.com/special-report/fiercemedicaldevices-2015-fierce-15, FierceBiotech, Web Accessed February 7, 2017

own people, quality systems, management culture, and designs whose problems and risks are inherited. More importantly, partners and purchases have supplier networks that require deep scrutiny in assessing the level of regulatory risk a company just 'married' into.

As mentioned above, supplier networks are a particular area of regulatory agency focus, and it is imperative to understand what is being inherited in an acquisition to fully understand the risk of remediation issues and costs.

Small firms are not to be outdone. It is estimated that 80% of the medical device manufacturers in the US employ less than 50 people each[8]. The competitive advantage is development of high-tech specialization and innovation. These niche market firms are dependent upon research and development as well as success in bringing new products to the market quickly. Challenges to small firms include adequate staffing to support the many compliance and regulatory functions that are necessary in the development and marketing of devices. As many of these smaller firms thrive in innovation, they become targets for acquisition. In addition to the cutting-edge technology, the acquiring firm must use caution not to inherit compliance and regulatory challenges as well.

Key Areas of Regulatory Scrutiny

In today's highly competitive environment, medical device companies must drive efficiencies to achieve the margins desired by their board or investors. Pricing pressures are increasing as value-based healthcare models replace fee-for-service models. Providers are far less likely to accept high margin incremental product upgrades, forcing device companies to create new forms of value, either in the form of new products or product and service bundles. In such an environment, strategic review and investments in compliance can create a sustainable competitive advantage. The following are the areas regulatory agencies are scrutinizing heavily.

Why the definition of a medical device is important

Medical Device: An instrument, apparatus…or other article which is used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

- *FD&C Act, Section 321(h) (21 U.S.C. 321(h))*

Many instruments are obvious medical devices, but **consumer behavior and technology is driving the demarcation line well, well past what it was just a couple of years ago.**

[8] Collins, S., Analyzing the Competitive Landscape of the Medical Device Industry, http://marketrealist.com/2015/11/analyzing-competitive-landscape-medical-device-industry/, Market Realist, November 19, 2015

Product Design	As product uses change in the hands of consumers, the medical device industry is not well adapted to considering the design risks of what are effectively consumer products. This understanding gap creates significant risk that regulatory bodies like the FDA are anxious to proactively get under control.
Supply Chain & Controls	The FDA is focused on ensuring supplier compliance by putting pressure on the manufacturer. The complexity of modern supplier relationships strains control processes and increases risk. Increasingly, controls against unique device identification ("UDI") problems, counterfeiting, theft, and data integrity issues become more difficult as the supply chain lengthens.
Product Shortages	Also of concern for the FDA are product shortages. The FDA translates product shortages as both a) inability to manage the supply chain and b) evidence that quality system management practices are not being followed. As market use changes, the medical device manufacturer must also adapt its distribution, stocking, and warehousing strategies.
Marketing	As consumer and medical device products converge, marketing issues arise. Most medical device companies do not market to a fast-changing consumer marketplace, while to consumer products companies, regulated messaging is similarly unfamiliar. The FCC and FDA have increased scrutiny of companies promoting off-label use as marketers fight to maintain differentiation in a competitive, consumer-centric marketplace.
User Behavior	The FDA expects that manufacturers understand the various ways that consumers will use and interact with their products. If the FDA feels a reasonable person would come to the conclusion that data should be shared with a clinician, then it is a medical device. As user behavior is constantly evolving, this puts the pressure on the consumer product manufacturer to comply with regulatory stipulations if uses of their product abut regulatory thresholds.

There is always a great deal of fear and misunderstanding surrounding regulatory compliance with new technologies. The reality is that it becomes difficult for a company to understand whether it is in compliance or not without proper planning with compliance experts.

Impacts of Reactive Regulatory Compliance

There are numerous impacts from poor regulatory compliance – poor brand image, lost opportunities, slow market entry, and less time in market, to name just a few. But the number one impact of poor regulatory compliance is on profitability. Regulatory compliance discipline inevitably leads to long term quality (a sustainable competitive advantage), while the lack of discipline leads to quality issues and poor company performance. So, what does that mean, qualitatively?

According to a study by McKinsey Consulting, for the decade from 2001 to 2010, at least 1 publicly traded medical device company lost over 10% market capitalization each year due to quality issues. As a part of that same study, an analysis of medical device companies with average quality found that 3-4% of revenues are lost by not having top-quartile level quality.

To put that into perspective, for every $100 million in revenue, an additional $3-4 million goes to EBITDA in a top-quartile quality company[9]. Taking 2016 industry averages of EBITDA margins, that means an increase from the average of 8.2% to as high as 12.2%

Financial impact of going from average to good quality:
50% increase in EBITDA

[9] Fuhr, T., et al.,The Business Case for Medical Device Quality, McKinsey Center for Government, October 2013

EBITDA. That's a nearly 50% increase in EBITDA.

That same research also determined that the average cost of FDA actions are as follows:

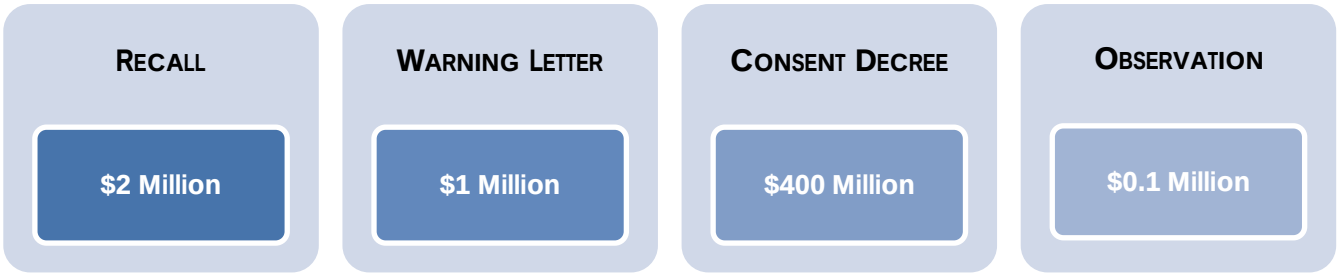


Figure 4: Costs of FDA Actions

Regulatory agency activity has shown no signs of slowing down. The number of US FDA inspections has remained consistent from FY'13-FY'15 at approximately 3,200. The average rate of Official Action Indicated findings is 6.2% for CDRH; whereas it is approximately 3.1% in the Center for Drugs. On average, there are 1,200 medical device recalls annually, representing over 2,500 marketed products. In FY'15, four Consent Decrees of Injunction were issued. Under programmatic changes in FDA, new work planning tools will focus inspection on the highest risk, most difficult to manufacture devices, creating opportunity for serious regulatory action in the absence of a robust quality system. The impact is not limited to domestic products. FDA continues to inspect foreign medical device manufacturers where the cost of non-compliance goes beyond a Warning Letter to an Import Alert, resulting in a loss of the US market. Regulatory scrutiny is also not limited to US FDA oversight. There has been 22.3% leap in revocation of EU certificates in 2015[10].

In case the economics of poor compliance discipline are not compelling enough, regulatory deficiency notices and warnings have significant time repercussions as well (see Figure 6).

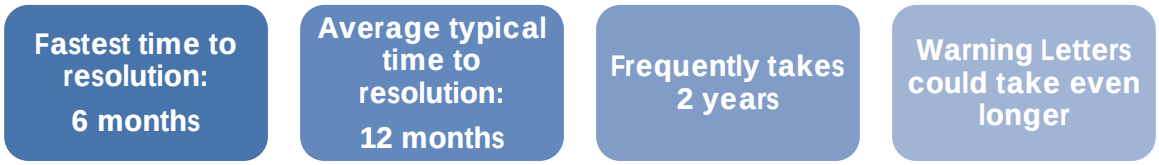


Figure 5: Lachman Consultants estimates of timelines to resolve regulatory deficiency notices (FDA Form 483)

With the change of payment structures in the US, the rapid convergence of consumer and medical device products, and growth in data sharing, economic and regulatory pressures in the medical device world are increasing. In this environment, time to market has become even more critical to shareholder value creation and sustainable profitability than ever before. However, speed without precision leads to compliance issues.

STRATEGIES TO THRIVE

The decision on how to approach regulatory compliance is a strategic one, and varies based on the size and state of your company. It's a risk/reward decision. However, given the strategic complexities and challenges that medical device companies will increasingly face, a well-constructed device compliance strategy will

Quality is an investment, and device compliance done right can create a sustainable competitive advantage.

[10] Medtech Insight 24 May 2016

be a **sustainable competitive advantage** in balancing speed with precision.

We have found that those companies which have accepted that **quality is an investment**, rather than an accounting cost center, are those that should expect to stay competitive in a tough marketplace. Investing in a system of accurate, effective, and sustainable compliance will protect profitability and shareholder equity in the long run, as well as serve to maintain brand equity amongst customers.

This requires a mindset shift away from being overly fearful of the winds of regulatory demands to proactively seeking ways – like proactive device compliance - to drive quality. With this in mind, we offer a few strategic tips to ensure your company thrives in this new era of consumer and medical device convergence.

Management	Product Development	Proactive Collaboration	Risk Management
•Remove the primary barriers reducing speed to market. Top of this list is reducing the risk of regulatory non-compliance.	•Create a culture of cross-discipline views of the product development lifecycle. From managment to UDI (Unique Device Identification) tracing to reporting, this will help reduce the time required to prove compliance. Along with proper controls and device ID management, this will help speed approval and reduce design cycles	•Collaborate with your regulatory agency, starting early in the product development stages. (Lachman can show you how.)	•As part of your strategic planning process, develop plans for quick response to inspections, 483s, adverse events, and recalls.

We Can Help

To better understand your risks and adequacy of medical device compliance, contact us. We will explore how your company can gain or retain a sustainable competitive advantage through our medical device compliance services.

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Lachman Consultants offers the following services to the medical device industry.

AUDIT
Gap Analysis & Preparation for inspection or as a proactive quality step

TRAINING
Proactively ensure strong QSR training & corporate culture training in advance of a problem;

ENHANCEMENT
Upgrade procedures and policies, address inspection observations or regulatory deficiencies identified in audits

SUSTAINABILITY & CONTROLS
Ensuring adequacy of staffing, internal and external audits, metrics and continuous improvement

PLANNING
Develop SOPs, risk-management plans, and quick response to inspections and regulatory actions

DUE DILIGENCE
Evaluation of compliance or regulatory status in preparation for potential M&A activity (buy-side and sell-side), including supplier evaluations.

NEW PRODUCTS
Training and assistance with submissions, acting as US agent for offshore activities, facilitation with regulatory bodies.

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