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A FemTech innovator's guide to regulation:

Navigating the nuanced regulatory landscape to maximize the potential of FemTech opportunities

The rewards are big for those who can deliver better outcomes for females through technology: in 2019, the FemTech market was valued at $18.7bn and is expected to **grow to $60bn by 2027.** [1]

Searching for a 'period tracker' on the Google Play store returns almost two hundred results. Hair removal devices come with companion apps to personalize treatment. [2] Everyday items, such as tampons, may soon save lives by diagnosing disease. [3]

Amid this wave of innovation – much of it driven by entrepreneurial start-ups – an essential part of the design process can be overlooked: regulation.

This is true of any rapidly expanding sector, and there's often a lag between advancing technology and procedural mandate as regulators work hard to undertake due diligence and evolve and develop new standards – take, for example, the Tobacco Products Directive, which lagged behind the explosion of the e-cigarette market by several years as regulators sought to gather evidence and determine what was appropriate. [4]

Regulation can be nuanced, not just by product type and category, but also geography and market – which we'll explore in more detail here.

The future of FemTech:

Why regulation matters

FemTech has three attributes that make it a particular target for regulatory attention:

- FemTech addresses issues that solely or disproportionately affect women, and solutions often cross the divide between the consumer and medical sectors. While the term is broadly applicable – encompassing consumer electronics to oncology, sportswear to nutrition – many FemTech concepts focus on feminine care and reproductive health, whether that relates to menstruation, fertility, conception, pregnancy, menopause, longevity, personal hygiene, sexual play, or beauty. Innovators need to be clear on what claims they'll be making, and particularly whether what they're building can be classed as a medical device – just because a product might be branded or retailed like a consumer good, doesn't mean it isn't subject to much stricter medical regulations.
- FemTech increasingly deals with sensitive data – an app, for example, might hold data on someone's desire to get pregnant, how they're feeling on a particular day, and even how often they have sex. Following the proper regulatory guidelines (and even going beyond) is vital to ensuring consumer trust and meeting stringent data handling mandates.
- FemTech is dominated by start-ups. Medical device regulatory compliance requires a structured approach, and evidence for claims and efficacy, which is often the antithesis of how many start-ups operate. [1] Limited funding coupled with a lack of expertise on compliance can lead to young companies overlooking regulation until it's too late.

Failure to adhere to regulations can cause brilliant products to fail at the last hurdle, miss a launch window, or lose money (and health- or lifestyle-enhancing design opportunity) through clumsy remedial engineering.

Using a range of case studies here, we aim to highlight some of the considerations around regulation and show FemTech innovators how to robustly build it into the design life-cycle. It's not an exhaustive collection of examples, but these showcase forward-thinking FemTech innovations that have embraced regulation. Many of today's most progressive FemTech solutions are pushing the edges of traditional regulatory classifications – which makes it critical for those who are pioneering new experiences to work with a knowledgeable partner to help navigate the pitfalls.

US

UK

EU

Where in the world?

Each international market has its own regulatory structure. This report includes examples from the US, the UK, and the European Union, indicated by the tabs shown to the right.

FemTech is becoming universally recognized as a term speaking to smart solutions that solely or disproportionately affect women. We put people and context at the center of our thinking and our multi-disciplinary approach to help our partners create meaningful innovations that improve lives.

Case study:

Clue Birth Control gains FDA clearance

In February 2021, the Food and Drug Administration (FDA) gave Danish FemTech company Clue clearance to market digital contraceptive, Clue Birth Control, as a feature of its period-tracking app. [5] Among other things, the FDA ensures the safety, effectiveness, and security of medical devices.

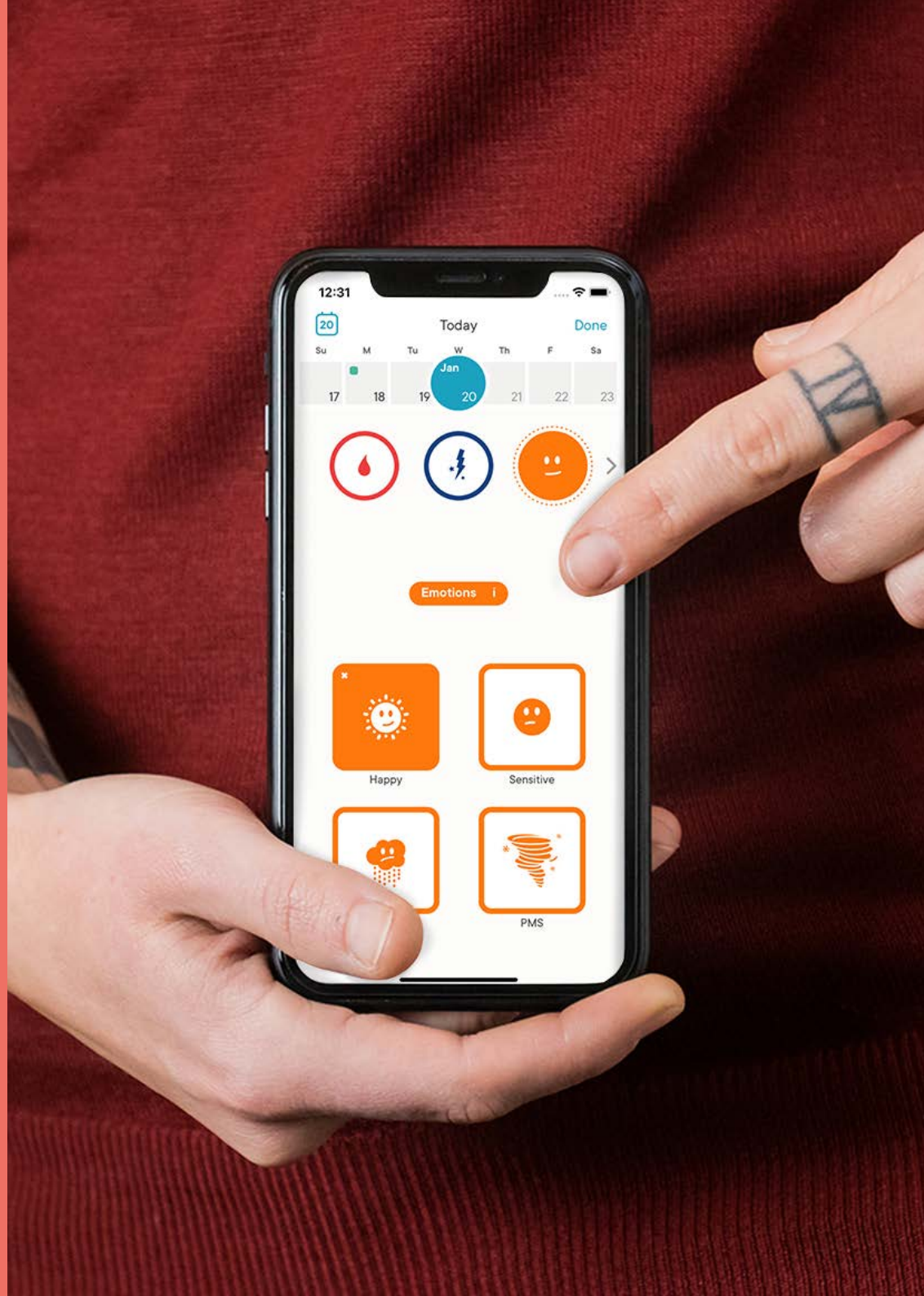
Who's it for?

Clue Birth Control is a software application for contraception aimed at women aged 18-45. Its goal is to monitor their fertility and prevent pregnancy. It's suitable for women with predictable 20–40-day cycles who haven't recently used hormonal birth control.

How does it work?

Clue Birth Control requires its users to document the start date of each of their periods. It applies Bayesian modeling to the data to alert its users when they are at a high risk of pregnancy.

Clue's website states that Clue Birth Control is 92% effective at preventing pregnancy with typical use. This figure is based on a peer-reviewed, published clinical trial conducted by researchers at Georgetown University in Washington, DC. [6]



What does regulatory clearance mean for Clue?

Competitive advantage

Clue Birth Control's FDA clearance as a software application for contraception sets it apart from the hundreds of apps available from Google and Apple stores, which can only market themselves as period trackers.

Increased brand value

The key to this differentiated position was that the parent app, Clue, built Clue Birth Control's foundations through science-based marketing and transparency as to how it handles user data. People put their lives in the hands of Clue Birth Control, so trust is non-negotiable. There's no stronger endorsement than clearance from a powerful third party, so it's no surprise that FDA clearance makes the first headline on the landing page of the Clue Birth Control website.

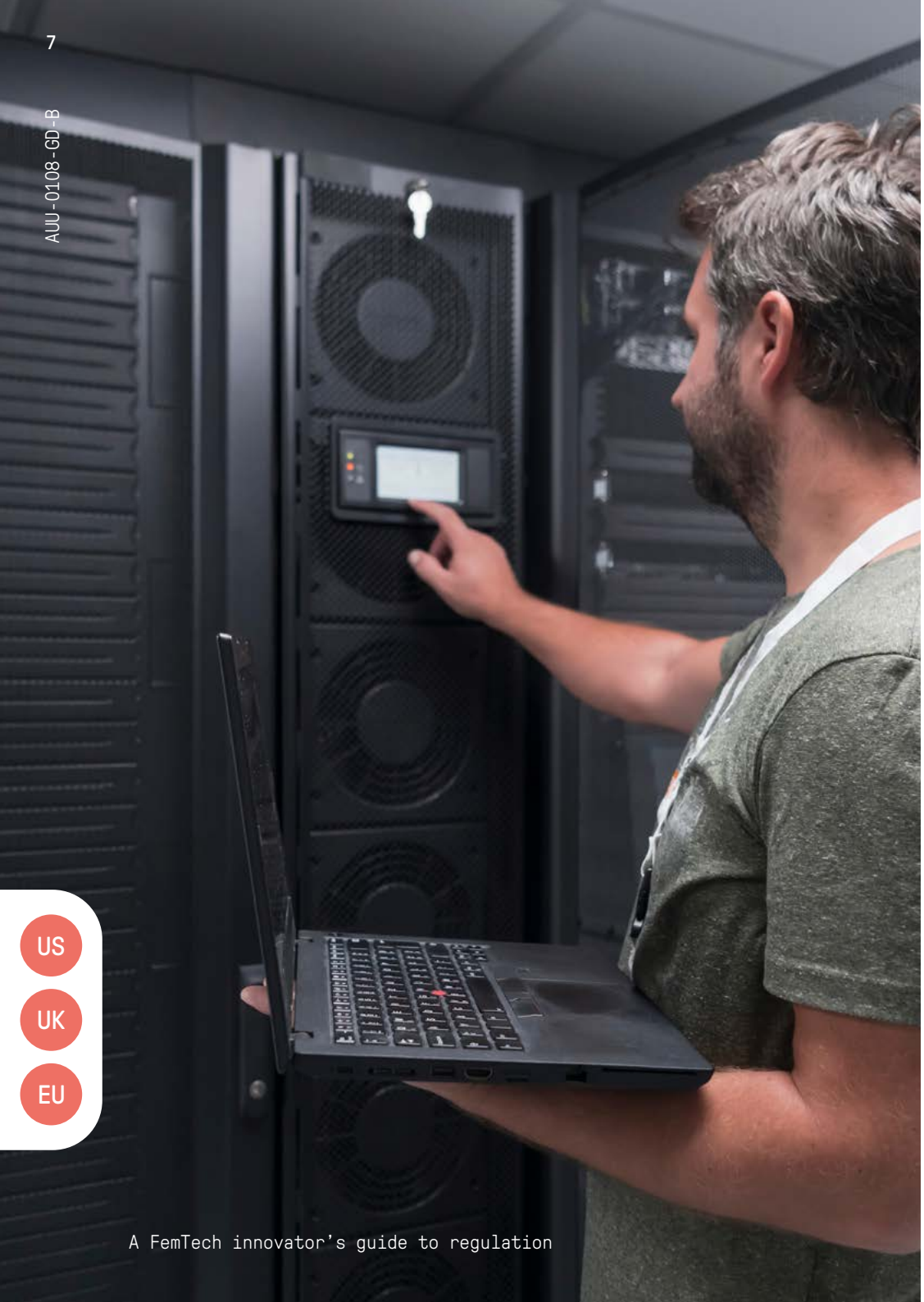
The benefits of regulation

Clue offers an excellent case study for the value of regulatory compliance, but it's certainly not an isolated example.

For emerging sectors such as FemTech, regulation can provide the infrastructure to ensure everyone is pulling in the same direction, though many rapidly evolving categories may not immediately fit, which is why it's so important to seek specialist advice. Regulatory frameworks enable onlookers, including potential funders to better understand a new sector's potential and make it easier for start-up companies to pitch for funding using robust proposals for their route to market.

They also provide a focus for companies during the early stages of the innovation process. This can bring opportunities for cost reduction and minimizing delivery time lines. Managing compliance throughout the whole development cycle can shape product development, from concept generation to manufacture. Adhering to regulatory frameworks ensures that crucial steps aren't missed, and helps address risk, reducing the likelihood that work will need to be repeated, saving time and money.

The benefits of compliance aren't just the ease of ticking a box at the end of the design process. It can help companies develop products in an efficient, sustainable, and cost-effective way while building brand reputation for quality. Importantly, in a highly competitive market, ensuring differentiating claims can be substantiated will also have a positive impact on investment valuations and outcomes, as well as consumer interest.



Protecting user data:
Going above and beyond

Personal data is at the core of modern consumer product innovation. FemTech is no exception and is covered by well-documented data and privacy regulations. However, given the sensitive nature of the data FemTech typically deals with, there's an argument that innovators should go beyond the minimum requirements.

Consent

Your user must understand which of their personal data is being used and for what. This communication should happen at the point of sign-up before an app is used and never tucked away in the small print.

The below explainer from Pelvic floor trainer Elvie is a model example of a well-communicated data policy. [7] For connected devices, a 'data flow' diagram is another way to clearly communicate the journey of personally identifiable data (PID).

Is my data stored securely and kept confidential?

When you use Elvie products, data about your session is sent to your phone. Any data that is then sent to our servers is sent encrypted (using TLS) and stored on our servers on encrypted disks. To ensure that data remains anonymous, we separate it from any personally identifiable data, such as your name and email address, and store it on different servers.

Regulatory landscape

FemTech innovators must understand the regulatory landscape in all markets in which they wish to use, store and transport data. Example protocols include the USA's HIPAA (Health Insurance Portability and Accountability Act, 1996) and the EU's General Data Protection Regulation (GDPR).

GDPR, for example, specifies that the rights of the data subject (the user) must be respected and implemented by the manufacturer. These include when and where data is collected, right of access, right of rectification and erasure, right to data portability, and right to object.

US

Case study:

Period tracker accused of sharing data with Facebook

Complying with regulations gives potential customers confidence that their data will be treated within the law and their confidential information won't be exposed to unsolicited parties.

In June 2021, the US Federal Trade Commission finalized a settlement against a US-based fertility tracking app. It instructed the developer to obtain the affirmative consent of users before sharing their personal health information with others and to obtain an independent review of its privacy practices. This followed an earlier complaint that it shared sensitive health data from millions of users with marketing and analytics firms, including Facebook and Google, despite promising to keep users private.

Is your product a medical device?

When does a product become a medical device? This is a crucial question for many FemTech start-ups and essential to consider early in the design process: remediating a design downstream can cost a company time, money, and resources.

The challenge for FemTech companies is to recognize the nuances between a consumer product and a medical device. For example, in most jurisdictions, an app that tracks a woman's health isn't classed as a medical device if it's simply displaying information. However, if it starts to diagnose a condition based on that data, it crosses the line to becoming a medical device. An app that posts medical information, for example, the best vitamins to take in pregnancy, is usually not classed as a medical device.

Even the name 'medical device' can be misleading. A hand-held IPL body hair removal wand sits firmly in the beauty aisles alongside cosmetics, yet the FDA classifies it as a medical device. The same is true of a toothbrush. In the case of an app, the product may not be a physical 'device' at all yet will be classed as SaMD (Software as a Medical Device).

One 'highlighted dot' in any example column to the right means the product is a medical device.

	Period tracker	IPL hair removal device	Wearable personal security alarm	App documenting stages of fetus development in pregnancy	Software as a contraceptive
Is it intended for use in diagnosis, cure, mitigation, treatment, or prevention?	○	○	○	○	●
Does it do more than just promote a healthy lifestyle, for example, attempt to diagnose or treat?	○	○	○	○	●
Does it interpret or analyze data (rather than just store or display it)?	○	○	○	○	●
Is your device like an existing product that's already classified as a medical device?	○	●	○	○	●
Is it intended to affect the structure or any function of the body?	○	●	○	○	○
Medical device	No	Yes	No	No	Yes

This table provides a number of examples, which highlight the importance of checking individual regulator's websites and seeking expert guidance.

US

How to futureproof against regulation

The following examples demonstrate how FemTech innovators can (and must) future proof against change.

Intimate durables with software as service

Software is becoming the norm in medical devices, and there have been updates to the regulation and guidance relating to Software as a Medical Device (SaMD) to keep pace. For example, the MHRA has published recently updated guidance for medical device stand-alone software including apps. [8] Elsewhere, the USA's FDA has provided an action plan for using Artificial Intelligence (AI) and Machine Learning (ML) as and within medical devices. [9]

Software incorporating AI and its subset, ML, has become increasingly prolific. There are several medical devices, for example, in which algorithms and models analyze CT scans, MRI scans, and X-rays to measure the extent of disease in a patient. Microsoft's Project InnerEye is developing ML to help clinicians plan radiotherapy treatments for cancer patients. [10]

However, there have been a few wrinkles as with all new technology. A study in Science, 2019 [11] showed that risk prediction in healthcare in the US exhibits significant racial bias. In general, this was due to the data sets used to train the AI. If the data inputs are biased, the AI will amplify that bias.

The sphere of FemTech is particularly vulnerable to this due to a lack of clear datasets for females, as painstakingly detailed in the book Invisible Women – Exposing Data Bias in a World Designed for Men by Caroline Criado Perez (a must-read for any FemTech entrepreneur).

The fallout for stakeholders can be significant, as any increase in the scale of bias could affect millions of people. This could expose the company to legal action and put its brand reputation at risk.

What can companies do to protect themselves?

1. Assess the impact of outcomes: if there's a risk to the user's safety or satisfaction, a human judgment check could be used to ensure the algorithm output is expected and correct.
2. Consider and communicate the nature and scope of how your product uses AI. For example, it's easy for a user to accept the decision of an ML system that processes billions of well-defined data points from a scan (compared to that of a doctor who might only process a few thousand over their career). However, where diagnoses aren't binary, such as mental health conditions, it may be sensible to add human input to any ML decision.
3. Document everything. Although regulation of AI is still in development, companies must document all algorithms and the data used to train them to avoid the adage bad data in equals bad data out.

Regulation often lags category growth, and many industry observers highlight one of the longest overdue for regulatory oversight is that of sex toys, given their intimate nature. There aren't any standards that ensure the safety of sex toys beyond the electrical compliance that applies to, for example, a blue tooth speaker. This is set to change with the publication of ISO/PC 325, a new standard outlining design and safety requirements relating to products that come into direct contact with intimate body parts for sexual use. [12]

As these are standards rather than regulations, they are optional. However, compliance with these will serve to ensure consumer trust and protect users from harm.

Case study:

Design well and compliance will follow

CDP worked with sex-toy start-up MysteryVibe during the design and manufacture its Crescendo vibrator. Our medical expertise meant that the materials met the same biocompatible standards as a medical device that operated on similar parts of the body. At the time, no regulations existed to enforce this, but the design was made from a risk-based perspective to protect the end-user (good design practice). The new ISO standards are yet to be published, but we hope this decision will position our client well should it decide to seek compliance.

This image shows prototype samples from MysteryVibe's development to help engineers select materials with the correct technical and sensory properties.

US

HIPAA

Call for reform

HIPAA is a US federal law that requires the creation of national standards to prevent the disclosure of sensitive patient health information (PHI) without the patient's consent or knowledge (the closest thing in Europe is GDPR). It was created in response to the digitization of healthcare records. Its scope, therefore, is focused on traditional healthcare providers, meaning that, in general, FemTech mobile applications are exempt. There have been calls from legal, compliance, and consumer groups to change this. [13]

Case study:

Plan to avoid a PR disaster

In September 2020, the California Attorney General announced a landmark settlement against a technology company that operates a fertility-tracking mobile app. The case was made for "serious privacy and basic security failures that put women's highly sensitive personal and medical information at risk". Since the data breaches were uncovered by a US website in 2016, the firm has pro-actively sought to provide protections that protect the user to a greater degree than the regulatory minimum standard and is now reportedly the only US FemTech company to gain HIPAA compliance. For other FemTech companies, this is a warning to act 'as though you're regulated' even if you're not.

Get involved:

How to stop regulation hampering innovation

In a young sector such as FemTech, there are exciting opportunities for brands to become pioneers in mapping the regulatory landscape while establishing themselves as leaders in high-quality product development. Indeed, regulators actively look to the forefront of a new sector as they do their due diligence, and work to evolve or develop new frameworks. [14]

In contributing to the development of regulatory infrastructure, companies are helping ensure requirements will align with their values and are relevant to and appropriate for their industry.

The International Organization for Standardization (ISO), which actively invites companies to help form its standards, lists the following benefits to getting involved: [15]

- Access to information that could shape the market in the future
- A voice in the development of standards
- Keeping market access open.

Building regulations that ensure users have a safe and positive experience means that the value of regulatory compliance remains front of mind throughout the entire development process.

How to bake regulation into the design process

The easiest way to make sure you get regulation right is to think about it early in the design process. Having successfully identified the user-led opportunity and concept, the next step is to identify the regulatory landscape for each of your target markets and get a plan in place for achieving compliance. Ask yourself if it's a product durable, or service concept – or, as is increasingly common, a 'system' comprising both; if software will be involved, what data will be stored and how. This will point to specific international standards and regulations. Knowing this upfront can help plan time lines and budgets.

An obvious but still too common error is to assume that regulatory compliance is something that can be rushed at the end of production. Failure to factor this in early on can lead to poor capture of technical specifications resulting in a product that doesn't meet the needs of the user, or the mandated standards. Many start-ups spot an opportunity to leverage an under-served consumer insight, but the quality of insight doesn't automatically translate to quality of product, and it's critical to meet both user needs and mandated standards.

Seven steps to ensure that regulation can enhance your business success:

1. Keep the user's interests and needs at the heart of your conceptual product or system.
2. Consider regulation from the beginning.
3. Build compliance, cyber security, and data privacy risk assessment into product design and requirements.
4. Engage with the authorities in your chosen market early, thoroughly, and often.
5. Pro-actively follow product controls even if a product is 'on the fence' between a consumer and a medical device.
6. Partner with subject-matter experts to ensure that compliance is built into your product design life cycle. This should include quality experts who will keep the development team accountable throughout the entire process.
7. Embrace regulatory compliance as a helpful framework to protect the end-user, enhance brand reputation, improve delivery timeliness, and boost cost-effectiveness.

How can we help?

CDP's FemTech approach centers on issues and opportunities that solely or disproportionately affect women but takes a more inclusive view; perspectives and experiences can be shared and understanding this is critical to optimizing a successful solution.

For over 25 years, CDP has worked in FemTech categories, with high-growth start-ups and global corporates, across fast-moving consumer markets and the highly regulated area of medical devices. This lens enables us to develop new, branded products and services that meet the consumer experiential needs and market behaviors and the exacting demands of global regulatory authorities. Working at the cutting edge means our team is familiar with emerging product and service opportunities that test the scope of historic regulation and enable our clients to make robust, informed choices. We apply appropriate quality and compliance principles to all our work and can advise on how new and emerging opportunities can be best positioned for success.

Please get in touch if you'd like to talk to us about anything in this report.

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