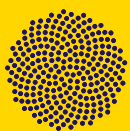


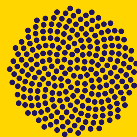
Ireland Where Digital Health Thrives



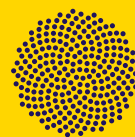
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Supporting healthcare software and services

Oisín Curran, Chief Executive at Odyssey Validation Compliance, talks about supporting life sciences companies in their implementation of computerised systems.



“We were seeing innovation in both services and technology happening in the life sciences sector,” says Oisín Curran, who has over 20 years’ experience in the life sciences industry and in designing and implementing GxP computerised systems.

“So, we decided to develop fully integrated GxP Cloud and Computerised System Lifecycle Management Services, to support regulated companies and connected health startups with their business processes.”

GxP refers to good practice regulations and standards, created to ensure pharmaceutical products are safe and meet their intended use. GxP software systems help companies comply with these requirements.

“We represent our clients in the implementation of computerised systems and ensure that they’re audited, ready and fit for purpose.”

Hosting

Oisín explains the company, which is based in Co Kildare, ventured into the digital health space back in 2015, when they were requested by a pharma customer to do an audit of cloud providers.

“We had to help determine which provider could provide a compliant hosting platform for a regulated application that this company was looking to put in the cloud.

“We conducted the audit for the company, and some well-known commodity cloud providers were not fit-for-purpose, in terms of their regulatory framework. And that’s where the second part of our business came from.”

Odyssey Validation Compliance developed a fully compliant global hosting platform called compliantcloud.com. This software as a service (SaaS) solution allows users to operate a software application and data entirely from the cloud, at a fraction of the cost of managing it in-house.

“Not only are we able to help people implement applications in line with regulations, but we’re able to host, manage and support them. This allows digital health companies to focus on what they’re good at, which is the digital health product or solution they provide. And we focus on the end-to-end compliant application delivery and maintenance at the backend.”

Oisín explains, “Take, for example, a medical device company that is looking at enabling wearables for use in hospitals. By their nature, they’re connected at the backend – the portion you don’t see, which sends and receives information – through a compliant hosting platform for data management and privacy. We’re the backend, or framework, for any digital solution.”

Compliance

Having once been a start-up company themselves, Odyssey Validation Compliance feels it is important to develop tailored solutions and use a collaborative approach, especially with clients that are startups.

“As we have grown ourselves as a company over the years, we have a start-up mindset. We’re aware of the barriers to entry across compliance, engineering, and product marketing. We know there are many challenges for startups, because we were once there.

“It’s really important that we understand the part we play in helping great products get to market, and particularly for Irish companies, being Irish ourselves. Generally, start-up companies require a lot of handholding and that can be expensive. So, we try to collaborate with a couple of key players in the market to make sure that what we do is scalable and reproducible in a more cost-effective way.”

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Oisín says this is the reason the company follows an OpEx model (an ongoing cost for running a product or system). “The idea is that we will onboard customers and make a commitment in terms of arranging a stake in the shares to recover the cost over time. This allows companies to onboard at a lower entry point, but allows them to see how they can scale up their product. And they’ll have an entire compliance team without the overhead.”

Oisín always advises startups to consider compliance from the beginning, “because compliance is essentially a barrier to entry and commercialisation. You cannot commercialise digital health products without covering your compliance aspects. And you do not want to discover that too late in your life cycles.”

Bespoke products for Fortune 500s

Odyssey Validation Compliance also works closely with a variety of multinational, Fortune-500 style companies. Oisín says, “For example, there’s a global Fortune 500 company that we’ve helped to develop a bespoke product focused on going paperless. It’s interesting, because this is a very large US Life Sciences company, with many heavyweight incumbents and consultancy firms. Yet, they came to us. People are seeing value in the real niche in what we do. “That’s something I’m really proud of us for, as a company. We have that bandwidth to be able to deal with small specific use cases for startups, but also on a larger scale.”

With experience working both internationally and in Ireland, Oisín says there are many benefits to doing digital health activities in Ireland.

“The Irish engineering skillset is relatively well-known right now. We have seen a lot of cases where manufacturing has moved to more cost-effective offshore manufacturing locations, but has subsequently moved back here. A lot of the time, it’s because of the engineering and compliance skills to be found in Ireland.

“Irish companies have a real focus on quality. I find people are focused on doing the right job, and doing a good job. Ireland has a fantastic breeding ground in terms of digital health companies and incubation hubs that are developed in some of the universities. We’ve got fantastic technology support hubs, to be able to solve real industry solutions.

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Oisín adds, “And I do think there are a lot of really strong technology providers that are not just looking at solving problems for the Irish market. They’re thinking on a global level.

“Across the board, we’ve always had that ability to think bigger. That ambition around how we can serve as a global customer base is something I see time and time again with Irish companies, which is great.”



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