



**Planet  
Innovation**

# SERVICES

Planet Innovation is a HealthTech product development company that provides digital, design, engineering & manufacturing services to companies developing innovative new products. We offer end-to-end services with a flexible, commercial approach.





# Product Development

A flexible approach to developing and commercializing products your market will love.



## Complete development capability

PI has a team of 300+ experts that offer end-to-end product development and manufacturing capabilities – from identifying a market opportunity using our product-market fit process, through design and engineering to commercial launch.



## Regulated biomedical product specialists

We specialize in developing regulated biomedical products and hi-tech connected devices. We excel at exploiting the technology convergence between sectors such as diagnostics, life sciences, medical devices, and digital health.

## Our work

Our clients include some of the world's top medical device and healthcare companies, as well as some of the world's most exciting start-ups. Through our personalized service and breadth of offering, we enjoy long-term, strategic relationships with many of our clients.



HANDHELD,  
CONNECTED DEVICE



POINT-OF-CARE  
DIAGNOSTICS



IMAGING  
INSTRUMENTATION



COMPACT PROTEIN  
ANALYZER



FLOOR-STANDING  
MICROBIOLOGY  
INSTRUMENT

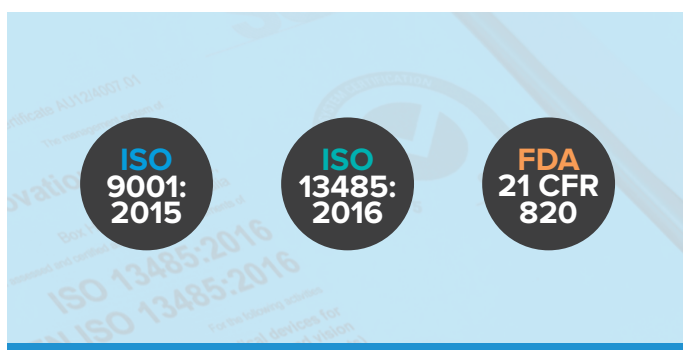




## PI has full engineering and design capabilities across all disciplines required to develop sophisticated products.

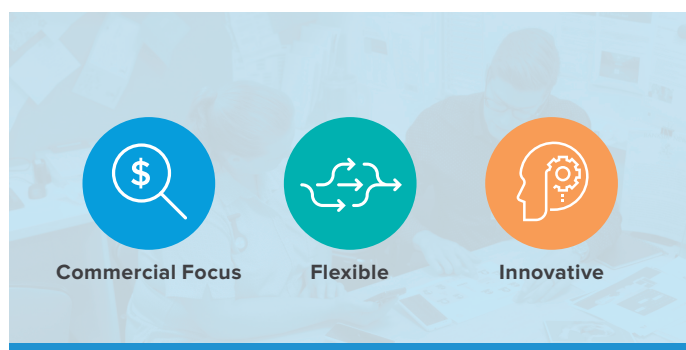
### Our capabilities include:

- Industrial design
- UX/UI design
- Systems engineering
- Mechanical/CAD engineering
- Electronics engineering
- Software engineering
- Science
- Optics
- Product-market fit
- BRIGHT® Innovation
- Project management
- Commercial strategy



### Regulatory and quality expertise

Our rigorous quality management system is certified to ISO 9001:2015 and ISO 13485:2016 for design, development and manufacture of medical devices, and compliant with FDA QSR, 21 CFR Part 820. Our Quality team is also available to help you with any regulatory or quality system issues.



### Commercially focused, flexible & innovative

Our goal is to help you create a commercially successful product that solves a real customer problem, not just meets a technical specification. Our flexible approach to product development means you can take advantage of our end-to-end service or draw on individual skillsets as needed.

### A CULTURE OF EXCELLENCE

We're proud of the recognition we've achieved. But getting good commercial outcomes for our partners and clients is what really drives us.





# Digital Services

Bringing a strong commercial focus to deliver customized digital health and IoT solutions for regulated medical environments.

Gold  
Microsoft Partner



## IoT and digital health specialists

We've delivered IoT, on-premise and Edge computing solutions for regulated medical and commercial environments. Our robust, scalable solutions allow you to integrate and analyze multiple inputs to gain real-time insights, improve efficiency and aid decision-making.

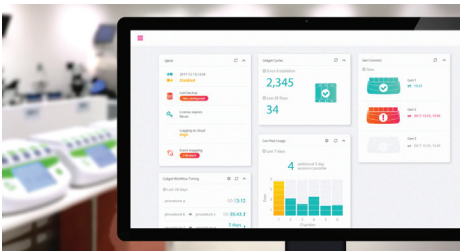


## Commercially-minded people

Everyone on the team, including programmers, testers and UX/UI designers, is dedicated to delivering successful products, not just playing with tech. This commercial focus drives everything we do — from ideation, through development, to delivery and support.

## Our work

We work with a broad range of businesses, from start-ups to established industry leaders.



### MERCK

QBOX® IVF — an on-premise solution that streamlines data transfer between instruments and Electronic Medical Records to improve efficiency in labs.



### RAMSAY HEALTH CARE

Non-invasive sensors connected to real-time algorithmic decision support tools to detect early signs of patient deterioration and falls, and prompt nurses to intervene.



### ZEN ECOSYSTEMS

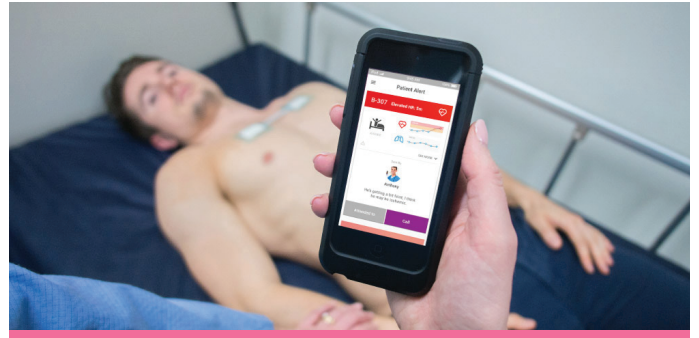
Zen HQ — a scalable, real-time IoT energy management solution connecting smart devices, such as thermostats, to allow users to manage energy consumption over multiple sites.





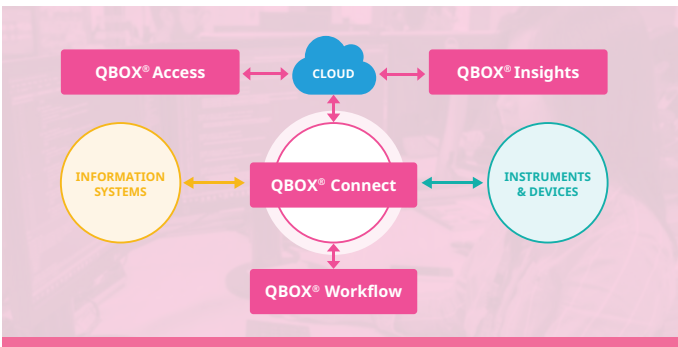
## Personalized engagement

PI Digital is more than just a development house. We work with you to understand your needs and the needs of your customers, so we can develop a tailored solution that delivers the greatest value to your business.



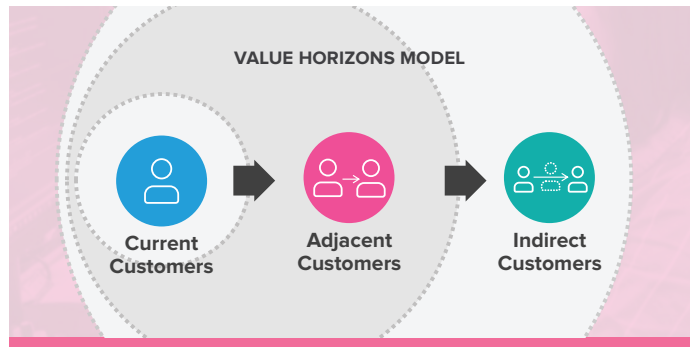
## Compliant with regulated medical environments

We are experienced in securely connecting systems within highly regulated environments, such as laboratories and clinics, to the cloud. Our internal Quality Management System ensures our developments are compliant with IEC 62304, ISO 13485, HIPAA, and GDPR.



## QBOX® Toolkit

The QBOX® Toolkit is a configurable digital product toolkit that can be used to develop a seamless, integrated ecosystem of healthcare and laboratory devices, with optional cloud connectivity, remote management and insights. This reduces the time, cost and risk of launching new software solutions.



## A focus on creating value

Our Value Horizons model helps you map out the big picture to identify and prioritize digital initiatives. Working closely with you, we'll then develop a product roadmap to incrementally build up value, so we can deliver the best solution in the shortest amount of time.

## PI offers a spectrum of digital solutions



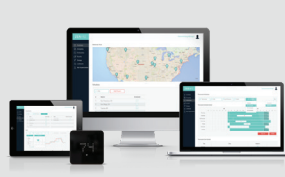
### Connected device interface



### On-premise integrated ecosystem



### Cloud application for device ecosystem



### Cloud application, insights & AI enablement





# Regulated Medical Product Manufacturing

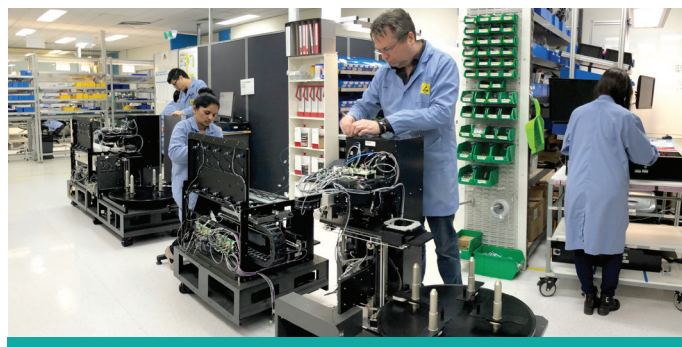
A 20,000 sq. ft. (2,000m<sup>2</sup>) fully-equipped FDA registered site for the manufacture of regulated medical devices.

*ISO 13485:2016 & ISO 9001 certified, FDA registered*



## Co-located engineering

PI's 300+ product development and manufacturing experts are co-located for fast transfer to manufacture and continued support. The development team is also available for any product enhancement activities that may be required now, or in the future.



## Complex diagnostic and medical devices

PI manufactures high quality, regulated products from small part count, high-volume devices to complex floor-standing in vitro diagnostic (IVD) instruments, as well as sterile consumables and software.

## Diversified manufacturing portfolio

PI manufactures medical products for use in various regulatory jurisdictions including the US (FDA), Europe (CE), Australia (TGA), Canada (Health Canada) and the APAC region. These include low risk devices to higher risk IVDs and medical devices.



**STERILE  
CONSUMABLES**



**POINT-OF-CARE  
DIAGNOSTICS**



**IMAGING  
INSTRUMENTATION**



**AUTOMATED  
MICROBIOLOGY  
INSTRUMENTS**



**CELL PROCESSING  
SYSTEMS**





### Cleanroom consumable manufacturing

We have an ISO 7 certified on-site cleanroom to manufacture sterile consumables. We are experienced in processes including solvent bonding, ultrasonic welding, leak testing, air particle testing, heat sealing, gamma sterilization, bioburden and sterility testing.



### Robust production processes

To ensure delivery on time and to agreed quality, PI uses processes such as visual management and daily team stand-up meetings to communicate priorities and issues. Our Manufacturing Readiness Review process, based on ISO 13485 Risk Management, sets out guidelines for delivering a launch-ready product and managing routine supply and quality risks.



### Lean principles

We apply lean manufacturing principles to achieve improvements in productivity, quality, reliability and lead-times by eliminating waste and optimizing operations. These principles include single piece flow, visual management, Kanban materials supply and continuous improvement.



### Flexible and responsive service

- Tailored open book supply and quality agreements
- Established Low Cost Region and Australian supply chains
- Dedicated product managers with technical and commercial capability

### Mature quality systems

PI manufactures high quality, regulated products under mature, audited quality systems. Our facility is ISO 13485:2016 & ISO 9001 certified, and FDA registered.

PI works with clients all over the world, with exposure to a wide variety of quality management systems, certifying agencies and regulatory bodies. We are regularly audited with our clients' practices to meet their obligations and to qualify us as a critical design or manufacturing partner. This strengthens our quality systems to benefit all our clients.

