

# Medical Device Usability Engineering

 | Product and Service Design Innovation Consultancy

# Delivering Meaningful Innovation

PDD is a product and service design innovation consultancy.

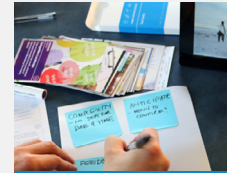
We work with our clients to innovate new products and services that delight users and help create business growth.

Our team of 50 are based in London, Hong Kong and Shanghai.

Our core capabilities encompass end-to-end design and innovation services, which we apply in interdisciplinary teams, enabling us to understand and resolve complex human, technology, cultural and commercial challenges.

## PDD services

Our integration of multiple disciplines means we offer a comprehensive and holistic approach to product and service design that delivers success. PDD services include:



Innovation Training



Design Insight



Design Strategy



People-Centred  
Research



Human Factors &  
Usability



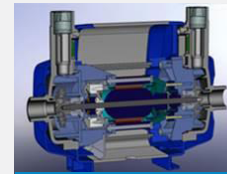
User Experience



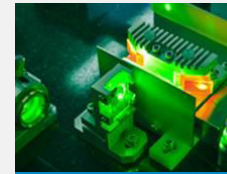
Industrial Design



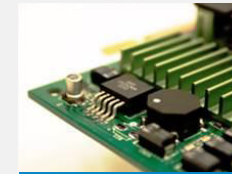
Prototyping &  
Verification



Engineering Design



Technology &  
Invention



Electronics &  
Software



Production  
Outsourcing

Please get in touch to discuss any of the above services in more detail.

e. [contact@pdd.co.uk](mailto:contact@pdd.co.uk)

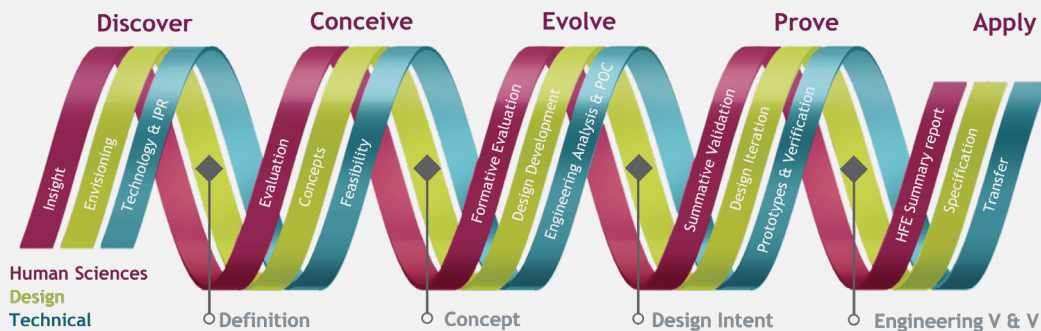
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# Innovation in the medical sector

PDD has been developing medical devices for over 35 years, leveraging human-centred design methods to drive innovation from insight through to production.

- Pharma & Drug Delivery
- Surgical & Interventional
- Wound Care
- Emergency Services
- Diagnostic & Monitoring Systems
- E-Health
- Patient Mobility

Our diverse **Human Sciences**, **Design** and **Technical** skills are integrated into a seamless innovation approach that identifies and responds to opportunity and manages risk from early market research through to production transfer.



## Human Factors & Usability

Human factors is not a stage in our process it is a fundamental foundation that runs throughout the course of every project, from desk-based research through to post-market surveillance.

### Usability Engineering

The concept of Usability Engineering (UE) brings together Human Factors, Risk Management and User Experience design to understand and optimise how users interact with medical devices.

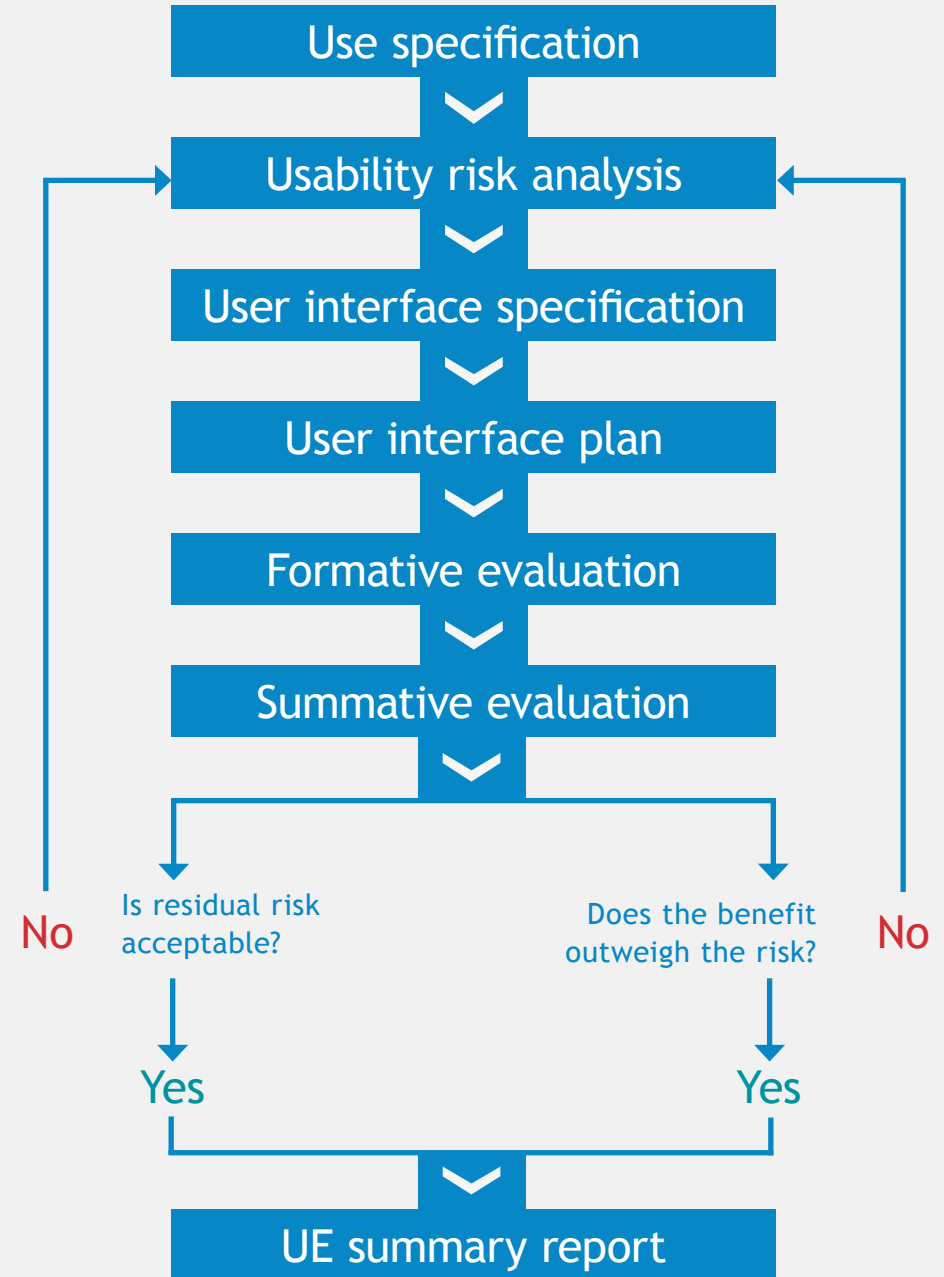
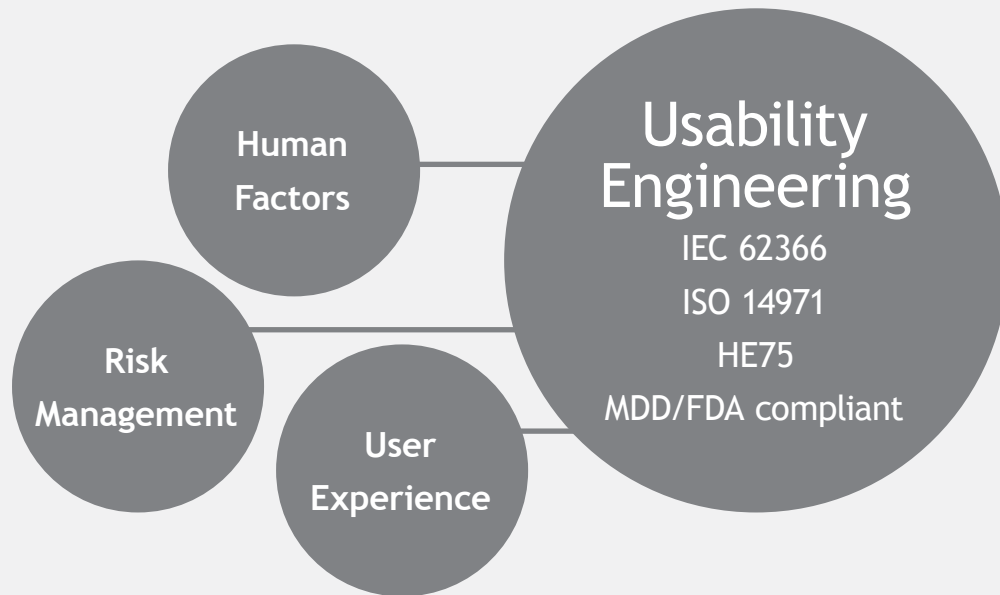
UE is a regulatory requirement and PDD can fully integrate UE throughout the medical device design and development process or support stand-alone usability testing for your own development projects.

# Regulatory Landscape

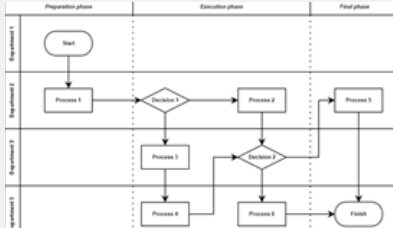
PDD has a comprehensive understanding of IEC62366 and ISO14971 which are both harmonised under the Medical Device Directive. PDD operates in compliance with the FDA and design guidance documents such as HE75.

## Process

In-line with regulatory requirements to develop a UE file for pre-market submissions, we can provide you with a full suite of regulatory documentation to suit the needs of your project.



# Human Factors: What we offer



Workflow optimisation



Ethnographic research



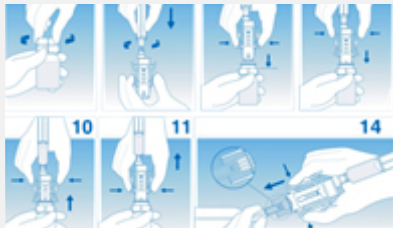
Exploratory studies



Heuristic reviews



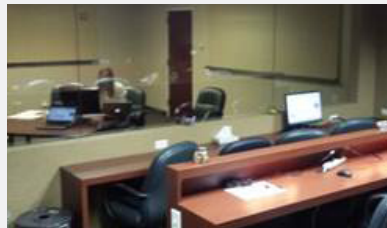
Use error risk analysis



IFUs



Training



Formative evaluation



Summative evaluation



Post-market research

## On-site facilities

There are two usability testing rooms at our London studio.

The private rooms can be used for formative or summative evaluations and are equipped with twin ceiling mounted cameras and microphones for recording and remote client viewing.

A wide range of use-scenarios can be simulated such as the home, outdoors or hospital environments. Furthermore, our flexible spaces can facilitate focus groups, training sessions, workshops and interviews.

Our London location allows us to take advantage of the scale and diversity of the London catchment area for recruitment.

## Recruitment

We only work with experienced recruiters who have an extensive international network of contacts.

Our global team has the collective knowledge of recruiting and conducting evaluations in different cultures and languages.

We can gain access to a wide range of simulation suites within UK hospitals and have a network of connections with other testing facilities globally.

# Our experience

## Therapy Areas

We have evaluated over 1000 participants in clinical areas such as COPD, Hepatitis C, Multiple Sclerosis, Chronic Bronchitis, Emphysema, Asthma, Peripheral Arterial Disease, Psoriasis, Invasive aspergillosis, Haemophilia, Ventilator-Associated Pneumonia, Diabetes, Neonates and Haemophilia.

## Stakeholders

We have worked with a diverse range of stakeholders: Patients, Health Care Professionals (including Physicians/Nurses/Hospital Pharmacists) and Carers.

## Countries

We have conducted formative and summative evaluations in the UK, USA, China, Japan, Germany, Australia, Switzerland, Italy, Spain, Denmark, France, Holland, Brazil, Mexico, Turkey and Belgium.



# What our clients say

“It has always been a great pleasure to work with PDD. The knowledge and experience of PDD on the subject of Human Factors evaluations has been of great value for our projects. I enjoyed the professional and goal oriented way this work has been organized and conducted and I appreciate the focus on your customer’s specific needs, the flexibility to accommodate our timelines and the ability of the PDD team to deliver right on target in terms of time and budget”.

*German inhalation therapy device company*

“PDD’s work was very useful in helping us to understand what was needed and how best to develop a protocol. Our interaction with PDD was key in identifying and addressing areas of concern - we felt there was enormous value in their depth of expertise. PDD worked hard with us to make sure the timetable was met despite delays in finances - this was very much appreciated”.

*Swiss Pharma company*

“PDD’s excellent processes, timely, unique and innovative approach to our challenges resulted in a very successful and effective outcome for the project. They were extremely professional and always exceed expectations. The cross-functional session PDD held with us was excellent, the prototypes were great, detailed and accurate costings, and the exploration sessions held with pharmacists were extremely informative”.

*Canadian Pharma company*

“High quality work through expertise - PDD exactly know what they do. Passionate and enthusiastic - PDD love and enjoy what they do. Pleasure to work as a team - PDD listen, PDD care, PDD is open minded and value different opinions.”

*US Pharma company*



**London studio**

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