Medical Device
Usability Engineering
PDD designs innovative products, services and experiences. Our talented multi-disciplinary team delivers tangible results that help clients grow.

At PDD, everyone lives and breathes an approach to design that drives commercial innovation.

Established in London more than 30 years ago, PDD is a design and innovation consultancy working across multiple sectors with design studios in London and Hong Kong. We use human-centred design to help some of the world’s leading organisations achieve business success.

Our approach to innovative design echoes the way we do business: fuelled by insight, driven by creativity and focused on delivery.

We focus on product and service innovation that is appealing, relevant and profitable. To uncover and exploit your opportunities, we have built a balanced team across human sciences, design and technology with the breadth needed for meaningful innovation.

PDD is ISO 13485 and ISO 9001 certified and has in-house expertise in:

- People-centred research
- Design insight
- Design strategy
- Human-centred design training
- Industrial design
- User experience design
- Technology & invention
- Engineering design & analysis
- Human factors & usability
- Electronics & software
- Prototyping & verification
- Production outsourcing

People-centred research

- Human Sciences and Human Factors Specialists

Design insight

- Facilitators, Moderators and Translators

Design strategy

- Planners, Strategists and Project Managers

Human-centred design training

- Interaction and GUI Designers

Industrial design

- Trend and Cultural Analysts and Semioticians

User experience design

- Industrial, Product and Packaging Designers

PDD capabilities

Technology & invention

- Hardware Technologists, Engineering Designers

Engineering design & analysis

- Modelmakers, Prototype Engineers, Test Technicians

Human factors & usability

- Cad-Cam Specialists, Analysis & Modellers, Software Engineers

Electronics & software

- Production Engineers and Production Managers

Prototyping & verification

- Inventors, IT specialists and IP researchers

Production outsourcing

- Prototyping & verification
PDD has over 30 years Medical/Pharma sector experience. We are passionate about improving the interaction between people, products and environments.

We help clients identify opportunities to differentiate by understanding users’ met and unmet needs, while looking at the wider product ecosystem, including competitors’ product and the regulatory landscape. We focus on creating innovative design and engineering solutions that enhance the user experience and help our clients achieve commercial success. We manage projects from research through to design transfer, ensuring that solutions are technically feasible and robust to manufacture.

The FDA placed a greater share of the responsibility for use-related hazards on manufacturers when it replaced the term “user error” with “use error”. PDD’s usability engineering process ensures that we understand and optimize how users interact with medical devices to systematically mitigate use error.

**PDD’s usability engineering process**

Usability testing is the bedrock of usability engineering and is used to evolve and validate medical device design.

**Formative usability testing** - Using simulations and prototypes, we test early ideas about a design, iteratively exploring, comparing, and assessing the usability of a product. Formative usability tests can uncover design weaknesses and identify previously unanticipated use errors, reducing the likelihood of finding such errors later in the development process.

PDD integrates human factors throughout all design and development projects with the aim to understand and optimize user interactions.

PDD has specific expertise and experience in the highly regulated Medical/Pharma sector which requires a more formal approach, combining human factors, risk management and human-centred design within a fully integrated usability engineering process.

Usability or human factors is like quality - it is most noticeable when absent.

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Summative usability testing or validation - Using production-equivalent devices, often in a simulated-use environment, we validate whether the final design meets users’ needs and is safe and effective to use.

Complementing our usability testing skills, we also have other expertise for understanding users, environments and user interfaces:

- Ethnographic research
- Desk research
- Function and task analysis
- Usability risk analysis
- User needs and requirements development
- Comparison testing
- Heuristic analysis
- Cognitive walk-through

Our pragmatic, human-centred and evidence based approach identifies potential use errors and obstacles to acceptance, increasing the likelihood of successful submissions to regulatory bodies.

Regulatory landscape | Blaming injury or death on incompetent users of devices is no longer an option

Regulatory bodies have made usability engineering a mandatory requirement for optimizing medical device designs. PDD has a comprehensive understanding of IEC 62366 and ISO 14971 which are both harmonised under the Medical Devices Directive (MDD) and the FDA.

IEC 62366 is the primary standard for medical device usability and specifies a human-centred process as it relates to safety, efficacy and usability. ISO 14971 is the standard for device risk management which is closely linked to the usability standard. Compliance with these international standards provides a presumption of conformity with the relevant MDD essential requirements and the FDA’s quality system for design controls. PDD’s structured process complies with the requirements of these regulatory bodies.
Integrating usability engineering with our product development process

**Understand**
- User research
- Design concept development
- Exploratory testing
- Understanding user needs

**Conceive**
- Design requirement development
- Design refinement
- Performance testing
- Iterate testing

**Evolve**
- Design evaluation
- Formative usability testing
- Usability specification
- Use scenarios

**Prove**
- Regulatory submission
- Usability risk analysis
- Summative usability testing or validation

**Apply**
- Usability engineering summary report
- Application specification
- Use scenarios
- Usability specification
- Formative usability testing
Measure of success | Striking a balance

The goal of our usability engineering process is to strike a balance between the regulated and non-regulated components of device design optimization. This goal is realised when users accept devices freely because they are appealing and easy-to-use, both safely and effectively in realistic environments.

Striking this balance also helps us answer clients’ commercial questions such as “how do you differentiate your drug in a crowded market?” or “how do you add value to a commodity device?” This in turn leads to commercially successful, award winning designs.

Awards