JEMMDx

We are a consultancy service uniquely focused on patient-centric diagnostics and devices: Point of care tests, Consumer Diagnostics, medical devices and FemTech.

- In-depth knowledge and expertise in:
  - Product Strategy and Messaging/ claims substantiation
  - Clinical and Regulatory pathway development and clinical trial support
  - IVDR Pathway
  - Gap analysis and remediation
  - Regulatory submissions (UKCA, EU IVDR, FDA, WHO, PMDA etc)
  - Studies/RWE: Regulatory, Post Launch, RWE and Usability, PMS reporting (PMPF)
  - Stakeholder engagement/ advocacy – KOLs, NGOs, DHSC etc
  - Medical communications- journal papers, White papers, conference symposia

We offer an industry-experienced, pragmatic and hands on approach to deliver what is required for you.

Bespoke capabilities across the product lifecycle

JEMMDx
EXPERTS IN Patient-centric Diagnostics & FemTech

Concept	Feasibility	Development	Launch +
• Product Strategy • Regulatory strategy • Patient and User Journey mapping • Landscape analysis • User Insight • KOL input • Product specifications – device, user interface, connectivity • Quality & Compliance Team Training	• Clinical strategy • Regulatory strategy - device, software, connectivity, accessories • Product specifications – device, user interface, connectivity • Analytical testing strategy • Market Access planning • IVDR Gap analysis • Design Review support • Risk Management support	• Clinical protocol and ethics support • Clinical site access and study management • KOL Advisory Board • Investigator Meetings • Funding discussion support incl NIHR • Analytical report review • Claims Substantiation • Product Insert and labelling • Human Factors Trials • IVDR Document pack submission support	• Scientific narrative development • Product Key messages • Website copy • Performance data journal publication • White paper • KOL & Early adopter strategy • Cost Effectiveness analysis • NICE Consultation • Post launch evaluations • Conference symposia • Webinars

25+years of Product Development & Launch Experience

JEMMDx
EXPERTS IN
Patient-centric Diagnostics & FemTech

Start with the End in Mind!

What

- Who are you design for?
- Compliance by design needs to consider the users and stakeholders.
- What do you need to comply with?
- BUSINESS by Design

Top tips and lessons learned….

How

- Understand your user and user needs, understand the environment of use, and what governance required.
- Understand the system- Many people don't know what the system is. Design Silos in big companies-
- How to incorporate the regulatory requirements which includes human factors and standards
- What are the trade-offs and how to manage them
- How to manage the Design lifecycle and include quality requirements-QMS and D&D
- How to verify and validate user needs are met…clinical data
- Interdisciplinary Thinking and Collaboration. **The "Im alright Jack" attitude. Be a TEAM.**

Considerations for Design process

understand your user and user needs, understand the environment of use, Designing Lay users/ professional Women or children??

Older people

WHO are the TEAM?

Conscious and Unconscious BIAS

intended use, indicated users Understand the full lifecycle and Product and use **RISKS**

Useability Engineering

Human Factors iterative studies, learn from this!

What is the Full System-are you clear on that.

What is the USP, what is the action the user takes

How do you demonstrate its worth it.

What testing and data do you need?

TEST the design envelopes- test to failure before starting

Verification and validation

What is the cost model and **economic model for the product**. How do you convince payors. **Adoption studies**

Don't assume that you know how your product is best used or will fit into healthcare environment.

Build it and they will come can be flawed.

User groups, patient advocates

Ethnography

Don't forget connectivity – how will the data get into APPS or EHR?

Is the APP considered in system RISK

Can all users use APPS

Do you know **how your users will be trained**.

IFU eIFU

User interface

How do you fool proof? **What are the risks of getting it wrong**?

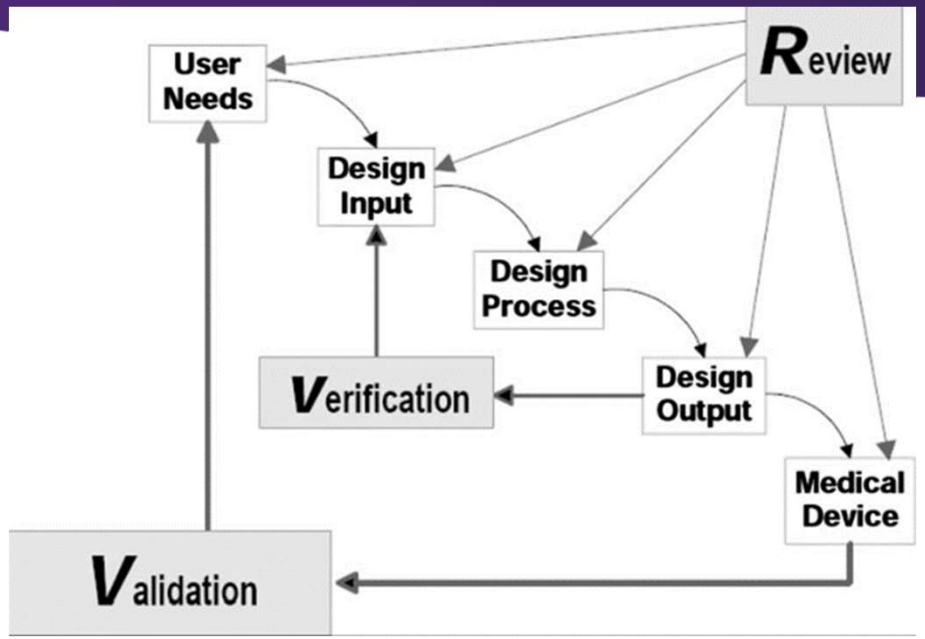
Other considerations for product.

Packaging and Labelling

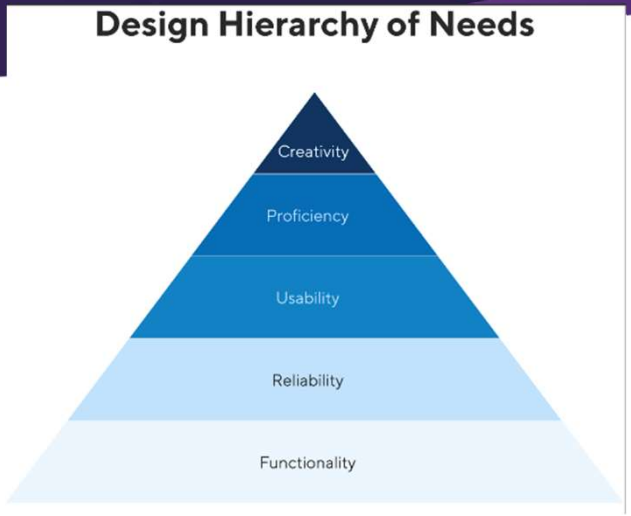
Transportation Accessories and consumables **Disposal,** complaints and recalls.

Search databases for competitor issues

Design Hierarchy- Mitigating Risk

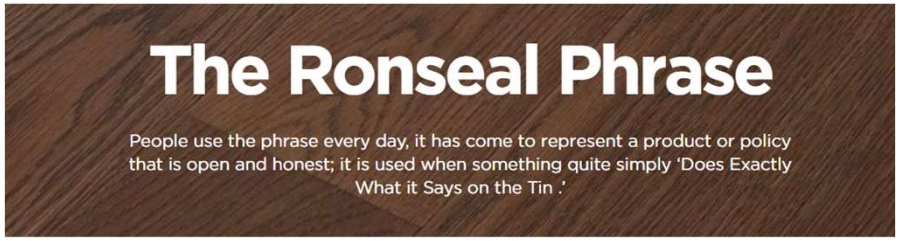


Right people involved!



Add regulatory compliance to hierarchy

- Use Design Control Process- it ADDS value and can help get it right first time!
- Do the TEAM really understand ALL the inputs and user needs



Get the right data to support the claims

- **The restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU)**
- — Appliances burning gaseous fuels (Regulation (EU) 2016/426)
- — Ecodesign requirements for energy-related products (Directive 2009/125/EC and all implementing Regulations for specific product groups that have been adopted under this Framework Directive)
- — Simple pressure vessels (Directive 2014/29/EU)
- — Toys' safety (Directive 2009/48/EC)
- **— Electrical equipment designed for use within certain voltage limits (Directive 2014/35/EU)**
- **— Machinery (Directive 2006/42/EC)**
- **— Electromagnetic compatibility (Directive 2014/30/EU)**
- **— Measuring instruments (Directive 2014/32/EU)**
- — Non-automatic weighing instruments (Directive 2014/31/EU)
- — Cableway installations (Regulation (EU) 2016/424)
- **— Radio equipment (Directive 2014/53/EU)**
- **— Medical devices (Regulation (EU) 2017/745, replacing Directives 90/385/EEC and 93/42/EEC as of 26 May 2021)**
- **— In vitro diagnostic medical devices (Directive 98/79/EC replaced by Regulation (EU) 2017/746 as of 26 May 2022)**
- — Pressure equipment (Directive 2014/68/EU)
- — Transportable Pressure equipment (Directive 2010/35/EU)
- — Aerosol Dispensers (Directive 75/324/EEC as amended
- Lifts (Directive 2014/33/EU)
- — Recreational craft (Directive 2013/53/EU)
- — Equipment and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU)
- — Explosives for civil uses (Directive 2014/28/EU)
- — Pyrotechnics (Directive 2013/29/EU)
- — Regulation on the Labelling of Tyres (Regulation (EU) No 2020/740)
- — Personal protective equipment (Regulation (EU) 2016/425)
- — Marine equipment (Directive 2014/90/EU)
- — Noise emission in the environment by equipment for use outdoors (Directive 2000/14/EC)
- — Emissions from non-road mobile machinery (Regulation (EU) 2016/1628)
- — Energy labelling (Regulation (EU) 2017/1369 and all delegated Regulations for specific product groups that have been adopted under this Framework Regulation and those adopted under Directive 2010/30/EU, the predecessor of Regulation 2017/1369)
- — Fertilising Products (Regulation (EU) 2019/1009)
- — Unmanned aircraft systems (drones) (Commission Delegated Regulation (EU) 2019/945

GENERAL Presumption of Conformity !

Each directive/regulation publishes the list of harmonised standards

EU framework

- Harmonised Standards - European Commission (europa.eu)
- Designers should know their standards for their SYSTEM based on the **product classification and understand competing requirements across the system**
- **General standards/Horizonal standards ISO 13485, ISO 14971 ISO 62366 and product specific standards for the following:**
- Hardware
- Software/Firmware/Connectivity/Communications protocols
- Biological/Chemical
- Labelling and Packaging/symbols IFU
- Clinical
- Performance- very product specific
- Sterilisation
- Transport
- Environmental/ Carbon Reduction
- **How to set acceptance criteria….Unless there is a CTS giving prescriptive requirements or other recognised consensus standards it is typically based on risk analysis and intended use that allows setting of the correct acceptance criteria and functional design Input**

For your product type:

which harmonised or non-harmonised standards?

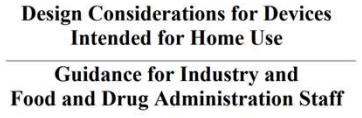
UK/EU/USA/other global markets differ….

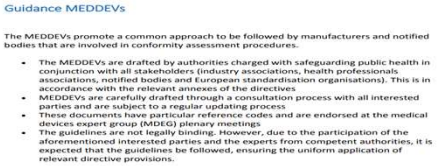
Include in your design inputs

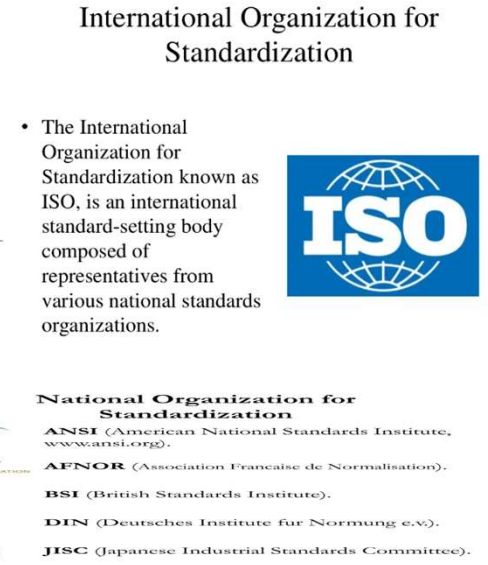
Standards are our friend- sources

- Directives
- Regulation
- Common Technical Specifications
- Guidance MEDDEV IMDRF etc. Specific design considerations for HOME use FDA and others
- Standards, International, National, Local and Product Specific
- Target Product Profiles
- Protocols- ISTA, CLSI
- Great design inputs- borrow ideas from other standards even if your product is not in scope and there is value

- **Don't be overwhelmed. JEMMDx support our clients to define their framework and support through the lifecycle**







Lessons learned over the years

- Look at competitor products and what works- and what doesn't work
- Look at other designs and think about similarities to yours "competitive intelligence"
- Marketing claims that cant be substantiated-Ronseal?!
- Designing for ageing populations, does one size fit all?
- Design hierarchy needs to include regulatory, costs **and good business sense!**

Summary JEMMDx support all areas

What

- Design Inputs defined the WHAT and the WHO- share the responsibility and build a great TEAM
- All stakeholders into the product have been considered, remove your BIAS
- Inputs include clear regulatory and risk reduction, test to failure or know the **design envelopes for the product**

How

- Use cross functional/Interdisciplinary teams who can live and breathe the product
- Use the regulatory requirements which includes human factors and standards
- Use the design control process with the appropriate phase gates, **design reviews**
- verify specifications and validate user needs are met…get the right data to demonstrate this
- **Interdisciplinary Thinking in the TEAM**
- **Collaborate**