Jacques du Preez

Future of Regulations – Up coming changes

Agenda

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5. United Kingdom
6. Regulatory Strategy
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About Psephos

www.psephos.com

Jacques du Preez

- 21 years experience in building companies
- Co founder of Psephos
- Currently seconded to UKHSA as Head of Regulatory, Quality Management Systems and Quality Control

Founded and exited a number of companies most recent was the sale of Mosaic Surgical (Galaxy II) to Spang Group (Angela Spang) in Sept 2019. The Galaxy II product has gone on to win the Queens award for Innovation

Psephos established in 2001

Focused exclusively on Medical Technologies. Wide range of clients from university spin outs, DHSC, NHSX, UKHSA, NHS Trusts, venture backed companies, technology transfer units, entrepreneurs as well as Multinationals such as Medtronic, Boston Scientific and Abbott and consultancies/CRO's such as IQVIA.

Provide traditional consulting service, EU Rep and Responsible Person, interim and executive management, NED, coaching, operational support & strategic input

Primary market access focus on US and EU27 + UK

We are doers and advisors having walked the path and earned the scars and trophies

Introduction

1. Change is our constant
2. Pandemic speed
3. Changing politics and boundaries
4. New regulations
5. New and revised standards
6. New guidance
7. Regulatory consultations
8. Post market surveillance, regulators and agency interactions

European Union

- MDR - Regulation 2017/745 MDR (26 May 2021)
- IVDR - Regulation 2017/746 IVDR (26 May 2022)
- EU Proposal for the regulation of AI (Proposal) - COM/2021/206 final
- Medical Device Coordination Group (MDCG) - guidance notes
  - Latest MDCG 2021-24 Guidance on classification of medical devices – Oct 2021
  - Covers topics such as Clinical Investigations, COVID-19, EUDAMED, Implant Cards, IVD's, New Tech (software), NB's, UDI……
- Notified Body Transition – NANDO

United States of America

1. Alignment of Quality System Regulations (21 CFR 820) with ISO 13485

2. Safer Technologies Program (STeP)

3. Breakthrough Device Programme

4. Cyber Security

5. Artificial Intelligence / Machine Learning Action Plan

6. 21st Century Cures Act (Cures 2.0 legislation). Only 4 years after the original bill (2017). New Proposal Focusses on boosting research and development and streamlining regulatory processes with expedited path to market. Providing more guidance for manufacturers and create an Advanced Research Projects Agency for Health. Clinical trials that reflect the diversity of the patient population; leveraging real-world data to create closer alignment between medical progress and patient need.

United Kingdom

Current UK Legislation covering Great Britain - Medical Devices Regulations 2002 as amended (UK MDR 2002)

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices

CE marking will continue to be recognised in Great Britain until 30 June 2023

- Medical devices (Coronavirus Test Device Approvals)(Amendment) regulation 2021

Consultation on the future regulation of medical devices in the UK
Consultation on the validation of Covid-19 tests: Laboratory Validation
Challenge - Mapping the CTDA process onto the regulatory process

Northern Ireland Protocol

- Regulation 2017/745 MDR (26 May 2021)
- Regulation 2017/746 IVDR (26 May 2022)

Regulatory strategy

Per product or family of devices

Market		Classification	Pre Market Requirements	Post Market Requirements
USA UK EU Japan Canada …	Market 1 Qualification	I,II,III,IV I,II,III I,IIa,IIb,III A,B,C,D	• QMS • Technical • Clinical • Labelling • Risk • Local	Pre Market Requirements + **PMS**
	Market 2 Qualification			
	Market 3 Qualification			

Final Comments

- Build a product system and **strategic framework** that can adapt to change
- Commonality about what good looks like – nuance is in how it is shown and what required. The **fundamentals remain**, a quality product that is effective in meeting a therapeutic need that can be evidenced
- Changing regulatory environment offers **opportunity**
  - Short term supply advantages - be the product that meets the requirements
  - Ability to influence regulations
  - Opportunity to relook at how you run your Quality, Regulatory and Clinical functions – departments add to “strategic edge”
- EU – **Managing the process** – timelines, securing services & resource, upscaling evidence and closing gaps
- US – **Established routes to market**, approval processes resourced, encouraging new tech with expedited routes.
- UK – **Significant Change**, Planning for alternatives, keep up and influence the process

Strategy Regulation Clinical Quality Operations

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