KEY IMPACTS OF EU MDR ON PRODUCT DEVELOPMENT AND QUALITY

Mizanu Kebede
Chief Regulatory & Quality Officer
Smith & Nephew

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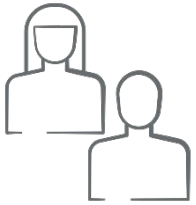
Smith+Nephew at-a-glance

What we do…

- A portfolio medical technology business
- Focused on the repair, regeneration and replacement of soft and hard tissue.
- We exist to restore people's bodies and their self-belief by using technology to take the limits off living.
- We call this purpose… **Life Unlimited!**

3 global business units:

- Orthopaedics
- Sports Medicine & ENT
- Advanced Wound Management



17,000

Employees serving ~100 markets

14+ million

patients treated with our products p.a.

$289 million

R&D investment in 2024

FTSE100

A constituent of the UK's FTSE100, our shares are traded in London and New York

16

New product launches in 2024

$5.8B Revenue in 2024

Our History

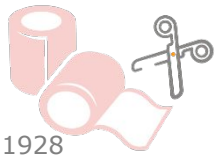
1856
Smith+Nephew established

1856-1896
Thomas James Smith opened a chemist shop in Hull, UK and develops a new method for refining cod liver oil. In 1896 Horatio Smith entered a partnership with his uncle forming TJ Smith & Nephew

1914
Days after the outbreak of WW1, we received an order to provide surgical and field dressing supplies to French army within 5 months

During WW1, staff grew from 50 to 1,200

1928
We produced an experimental bandage Elastoplast™



1937
We were listed on the London stock exchange

1937
We developed a special low-temperature plaster for the Everest climbers on the 1953 expedition. It enabled them to send back camera films, sealed and airtight!.

1986
Key acquisitions of Richards Medical in Memphis, specialists in orthopaedic products and DYONICS, an arthroscopy specialists based in Andover

1995
Acquired Acufex Microsurgical Inc, making us a market leader in arthroscopic surgical devices

1995
We were listed on the New York Stock Exchange and in 2001 became a constituent member of the UK FTSE-100 index

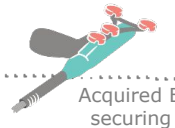
2001
Introduced OXINIUM◇, a new material that improves performance and increases the service life of total joint replacement systems

2011
PICO◇, the first pocket-sized, single-use system, revolutionizes the negative pressure wound therapy market

2013
JOURNEY◇ II BCS sets a new standard in knee implant performance, designed to empower patients

2014
Acquired Arthrocare Corp. to expand our sports medicine portfolio

2015
Acquired Blue Belt Technologies securing a leading position in orthopaedic robotics-assisted surgery

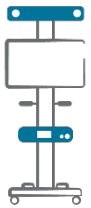


2017
Acquired tissue regeneration developer Rotation Medical

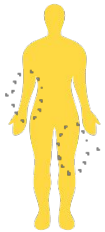
2019
Expanding in technologies of the future, we acquired:
- Osiris Therapeutics
- Ceterix Orthopaedics
- Leaf Patient Monitoring System
- Brainlab Orthopaedic Joint Reconstruction Business

2020
Acquired Tusker Medical Inc. to expand even more our ENT medicine portfolio

2020
Launched Real Intelligence and CORI◇ Surgical System; next generation handheld robotics platform



2021
Launched SMART TSF Circular Fixator; WEREWOLF◇ FASTSEAL◇ 6.0 and LEGION CONCELOC; FASTFIX FLEX Meniscal Repair System; INTELLIO Connected Tower



2024
Acquired CartiHeal developer of novel technology for cartilage regeneration

19,000+ employees over 100 Countries

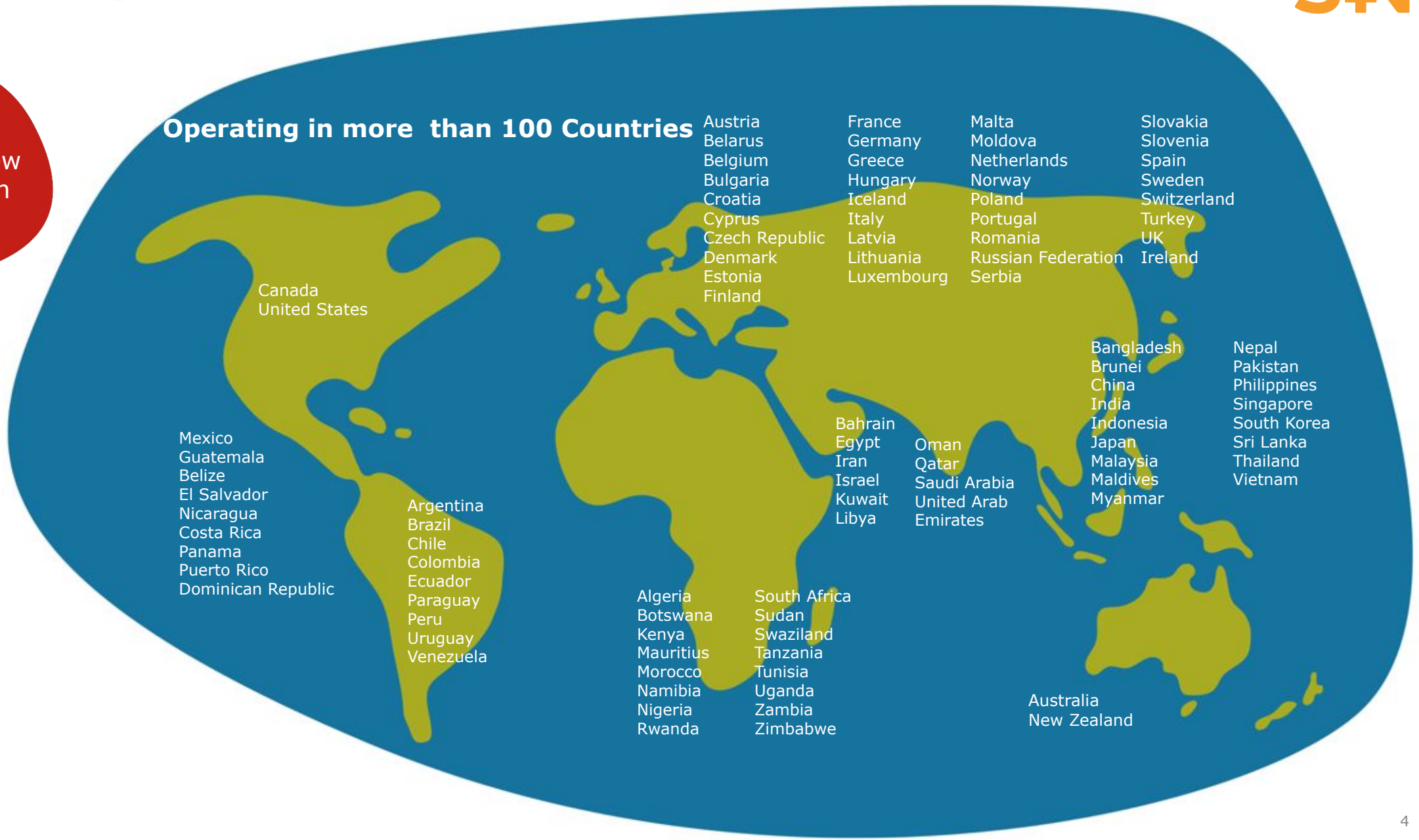
Today

We exist to restore people's bodies and their self-belief by using technologies to take the limits off living. We call this purpose "Life Unlimited"

Global Footprint

1856

Smith+Nephew starts off with presence in the UK



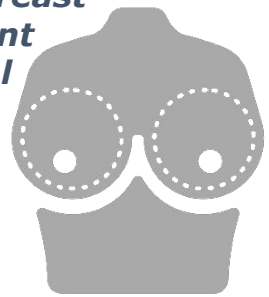
Topics Covered

- EU MDR Overview
- Key impacts of EU Medical Device Regulation (MDR) on product development and quality
- Gaining a competitive edge by proactively aligning with MDR standards
- Navigating new post-market surveillance requirements
- Short and long-term implications of MDR on market access
- Gaining a competitive edge by proactively aligning with MDR standards

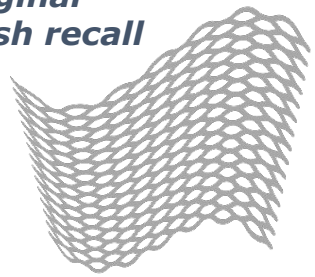
What are the drivers for EU MDR?

High profile cases that have raised concerns

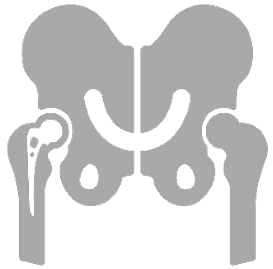
PIP breast implant scandal



Vaginal mesh recall



ASR MoM hip implant scandal



US FDA whistleblower controversy

- **The Medical Device Directives date back to the 1990s** – have not kept pace with the enormous technological and scientific progress in the past 20 years.
- **Clarity to be provided** in classifications and scope of inclusions.
- **Substantial divergences in the interpretation and application of the rules** have emerged, undermining the main objectives of the Directive.
- **The EU MDR, aims to provide a robust, transparent and sustainable regulatory framework** for all Medical Devices (MDR/IVDR) that is 'fit for purpose'.
- The revision to EU legislation has been introduced as **a Regulation instead of a Directive**. A Regulation has been determined to be the appropriate legal instrument as it imposes **clear and detailed rules which do not give room for divergent transposition** by Member States.
- A Regulation **ensures that legal requirements are implemented at the same time** throughout the EU.
- **All medical devices supplied in the EU need to be re-CE Marked under the EU MDR** - there is no grandfathering.

EU MDR is a Significant European Law Change

A paradigm shift in the way CE-marked medical devices are placed on the market

20 articles
60 pages
12 annexes

Under the MDD the **manufacturer could certify** meeting technical requirements and place on the market

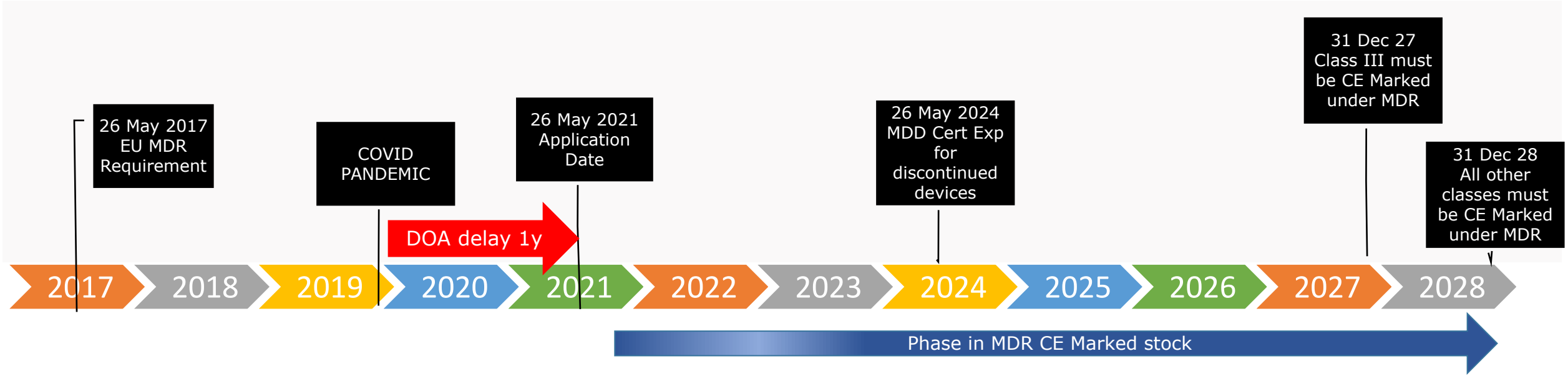
97 articles
369 pages
16 annexes

Under the MDR manufactures **MUST** provide evidence on clinical benefits to patients

MDR rules to be fulfilled **to CE mark a medical device** and make it available on **CE-recognizing markets**

Stands alone, **not following FDA or other bodies**

EU MDR Timeline



- **26 May 2021** – Class I devices must be CE Marked under MDR to be placed on the EU Market
- **26 May 2024** - All MDD Certificates expire for devices that are not being CE Marked under MDR
- **31 Dec 2027** – MDD Certificates expire for Class III devices being CE Marked under MDR. Only MDR CE Marked Class III devices can be placed on the EU market after this date.
- **31 Dec 2028** - MDD Certificates expire for all other classes of devices being CE Marker under MDR. Only MDR CE Marked Class IIB, IIA, IS, IR, IM devices can place on the EU market after this date.

Critical MDR Impacts on Product Development & Quality Systems

Impact on Product Design and Development

Stricter Clinical Evaluation Requirements

- Greater emphasis on clinical data and clinical evaluation reports (CERs).
- Clinical evidence to support claims for Legacy devices .
- Increased need for post-market clinical follow-up (PMCF) and real-world data.

Rigorous Risk Management

- Risk management & requirements throughout product life-cycle.
- Risks reduction as far as possible, not just to an acceptable level.

UDI (Unique Device Identification) Requirements

- UDI for traceability for each devices.
- Impacts labeling, packaging, and traceability systems from design through distribution.

Expanded Technical Documentation

- Detailed technical files requirements
  - Benefit-risk analysis
  - Justification for equivalence (if claimed)
  - Complete design history
- Documentation update availability to Notified Bodies.

Stringent Classification Rules

- Possible reclassification of devices to higher risk categories (e.g., some software or implants).
- Influences on development timelines and regulatory pathways.

Stronger Emphasis on Usability Engineering

- Human factors and usability must be integrated into design from the start.
- Requires compliance with standards like IEC 62366.

Lifecycle and Post-Market Surveillance Integration

- Design must support post-market surveillance (PMS) and vigilance activities.
- Requires integration of feedback mechanisms into product design.

Quality Management Systems and Compliance

Alignment with ISO 13485:2016

- MDR mandates QMS compliance aligning with ISO 13485:2016.
- Broader scope (i.e. supplier controls, risk management, and software validation).

Enhanced Documentation and Record-Keeping

- Requirements for **permanent accessibility** of certain documentation (e.g., Declaration of Conformity).
- Emphasis on **traceability**, audit trails, and structured document control.

Mandatory Person Responsible for Regulatory Compliance (PRRC)

- Organizations must designate a **PRRC** with defined responsibilities.
- Adds accountability and formalizes regulatory oversight in QMS.

Stricter Supplier and Subcontractor Controls

- Must ensure **contractual clarity** and oversight of outsourced processes.
- Expanded requirements for supplier qualification and performance monitoring.

Vigilance and Post-Market Surveillance (PMS) System Integration

- PMS must be **proactive and systematic**, not just reactive.
- Devices need a **PMS plan**, **Periodic Safety Update Reports (PSURs)** for Class IIa and above.

Increased Scrutiny by Notified Bodies

- Audits are more frequent, detailed, and include **unannounced inspections**.
- QMS must be audit-ready at all times with clear, structured evidence trails.

Change Control and Re-certification Burdens

- Even minor changes may trigger reassessment under MDR.
- Companies must implement robust **design and change control** systems

Optimizing Recertification Strategies to Minimize Disruption and Ensure Continuity

Understanding Recertification Requirements

Valid Certificate Transition

- MDD certificates issued before 26 May 2021 can remain valid until:
  - 31 December 2027 (Class IIb implantable and Class III)
  - 31 December 2028 (Class IIa and I devices under NB involvement)

Reclassification Considerations

- MDR includes stricter classification rules (i.e. some devices previously Class I or IIa under MDD may now fall into higher classes).

Clinical Evaluation Requirements

- Robust clinical evidence
- Legacy devices without sufficient clinical data will need new data generation or clinical trials.

Risk Management

- Must be lifecycle-based.
- Updated per ISO 14971:2019.

QMS Compliance with MDR

- QMS must be certified or aligned with ISO 13485:2016 and MDR requirements.
- Tech Documentation must meet Annex II and III .

UDI System Implementation

- All devices must comply with Unique Device Identification (UDI) rules.
- Technical documentation must reference the UDI-DI.

Post Market Surveillance/Vigilance

- PMS Plan, PSUR, PMCF as applicable.
- Regular surveillance audits by Notified Bodies.
- Increased scrutiny Class III/implantable devices .

Optimizing Recertification Strategies to Minimize Disruption and Ensure Continuity

Portfolio Prioritization & Risk Assessment

- Conduct a full portfolio review.
- Rank by market impact, regulatory complexity, and certification risk.
- Consider rationalizing low-margin or low-volume SKUs.

Timeline Management & Proactive Planning

- Map certificate expiration dates and key milestones.
- Apply the "Start Early" principle: Begin MDR recertification planning 24–30 months before expiry.
- Establish clear internal deadlines ahead of NB timelines.

Documentation Readiness & Gap Closure

- Perform a gap analysis of all documentation against MDR Annex II & III.
- Update technical files, CERs, and risk documentation early.
- Prepare device-specific documentation modules for faster scalability.

Early & Continuous Notified Body (NB) Engagement

- Secure a Notified Body slot early — demand is high and capacity is limited.
- Share preliminary documentation to get feedback before formal submission.
- Maintain an open line with NB for changes, interpretations, and reviews.

Continuity & Contingency Planning

- Implement buffer stock and explore parallel market registration for continuity.
- Develop an emergency plan.

Strengthening Post-Market Surveillance to Meet Rigorous MDR Expectations

Strengthening Post-Market Surveillance to Meet Rigorous MDR Expectations

PMS System

- Implement robust data collection and monitoring mechanisms.

PMCF Planning

- Design PMCF studies to fill clinical gaps and assess long-term safety.

Vigilance & Reporting

- Establish a vigilance system for reporting adverse events to EUDAMED.

PSUR & Clinical Evidence

- Regularly update PSURs and clinical evaluations with post-market data.

Continuous Monitoring

- Utilize data analytics to detect trends and adjust PMS strategies.

Transparency & Compliance

- Maintain auditable records and ensure timely reporting to regulators.

Evaluating MDR's Market Access Implications Across Product Lifecycles

Market Entry and Registration Hurdles

Complex Registration Processes

- Market entry involves navigating complex registration processes that can be time-consuming and challenging for manufacturers.

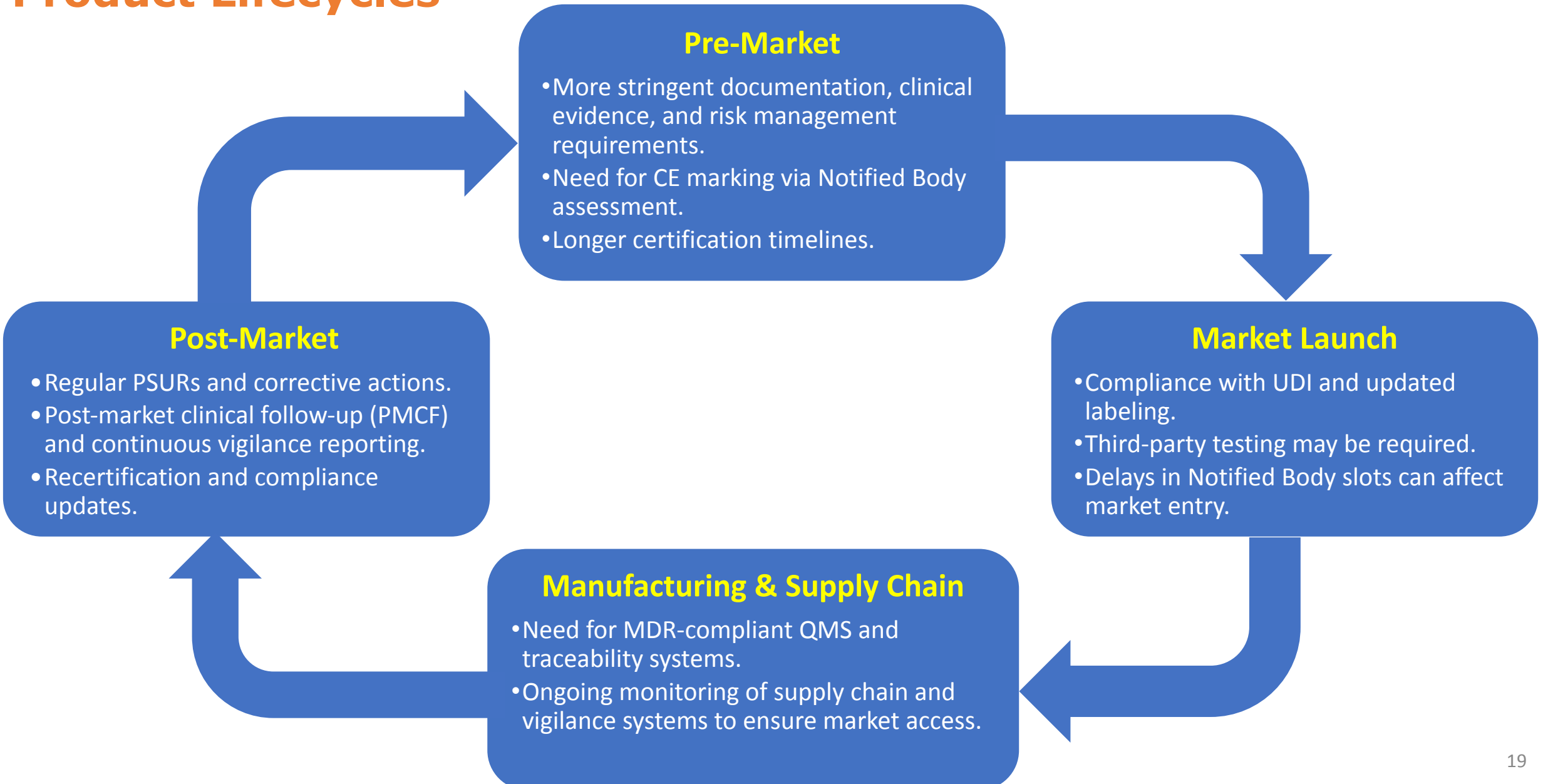
Stringent MDR Requirements

- Manufacturers must adhere to stringent Medical Device Regulation (MDR) requirements to ensure compliance before market entry.

Preparation for Challenges

- Establish a vigilance system for reporting adverse events to EUDAMED.

Evaluating MDR's Market Access Implications Across Product Lifecycles



Gaining a competitive edge by proactively aligning with MDR standards

Leveraging Compliance for Competitive Advantage

Market Access	• Timely product certifications with reduced risk of revenue disruption • Continued access to EU market, one of the largest medical device markets globally • Positions the organization for faster approvals in other global markets
Competitive Differentiation	• Builds a trusted brand reputation with clinicians, regulators, and patients • Fosters smoother interactions with Notified Bodies and auditors
Data-Driven Decision Making	• Promotes use of clinical evidence and real-world data in product development • Supports continuous improvement through systematic performance monitoring
Regulatory Compliance as a Value Proposition	• Enhances brand reputation by meeting stringent standards • demonstrate their commitment to quality and safety standards.
Foster Innovation	• Accelerated product development timeline • Enable efficient use of clinical evidence and user feedback • Encourages design with clinical evidence and real-world data in mind • Increased speed to market for next-generation devices

Key Takeaways

Regulatory Challenges

- Navigating EU MDR is essential for medical device manufacturers for market access and compliance.

Proactive Strategy

- Early planning strategy minimizes risks and enhances resilience.

Product Development Impacts

- Aligning with EU MDR ensures compliant, market-ready devices

Optimizing Recertification

- Streamlining recertification cuts time and costs.

Post-Market Surveillance

- Strong monitoring ensures safety and performance.

Competitive Advantage

- MDR compliance fosters trust and long-term competitive advantage.

Smith+Nephew

Life Unlimited