● SME dedicated – MDR Conformity Assessment Routes in the AIMD space.

Thomas Doerge
Global Head of AIMD

Your Speakers Today

Jazzmyne Buckels

*Technical Team Manager,
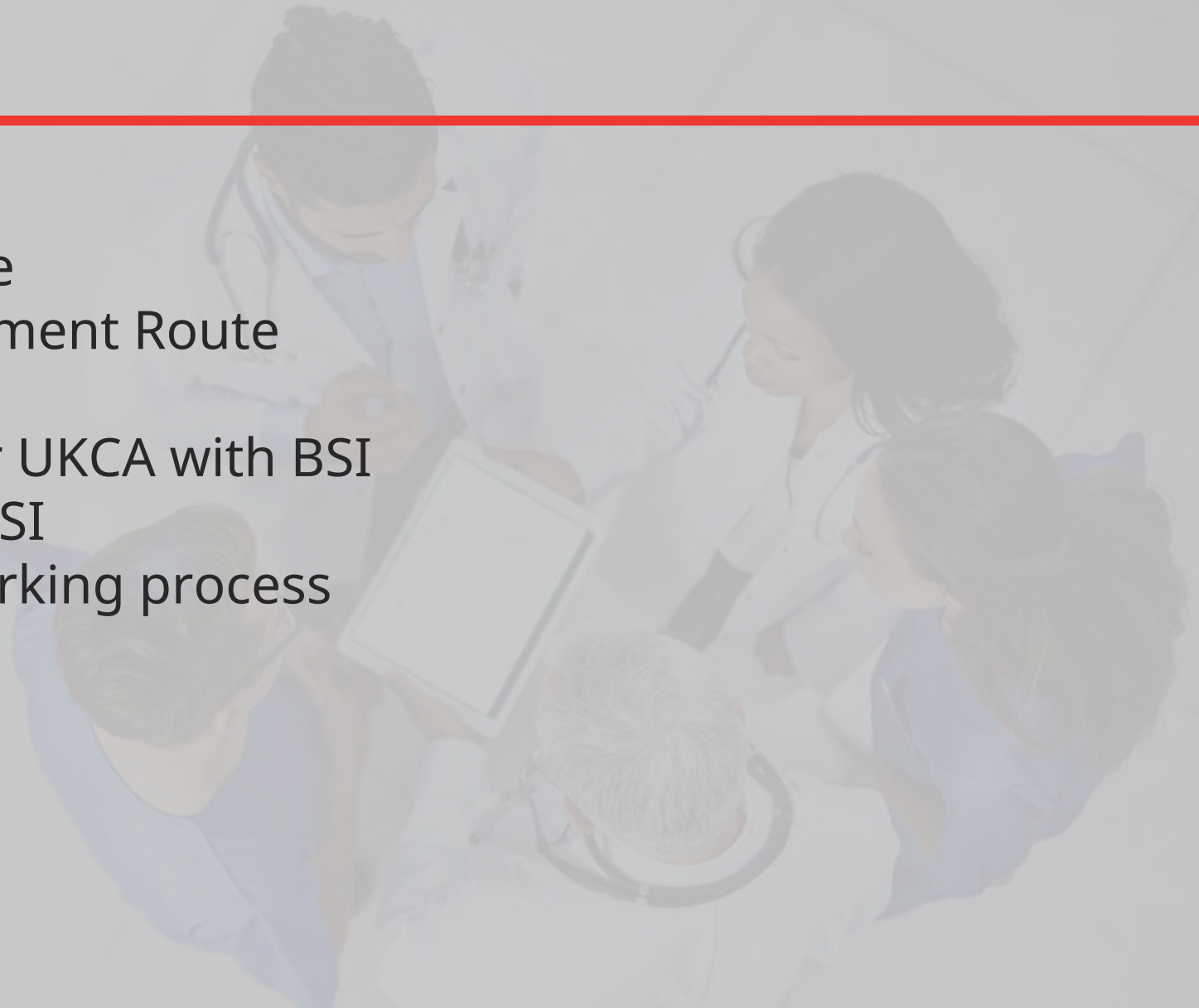Active Implantable Medical Devices
BSI*

Thomas Doerge

*Global Head,
Active Implantable Medical Devices
BSI*

Simon Lidgate

*Technical Team Manager,
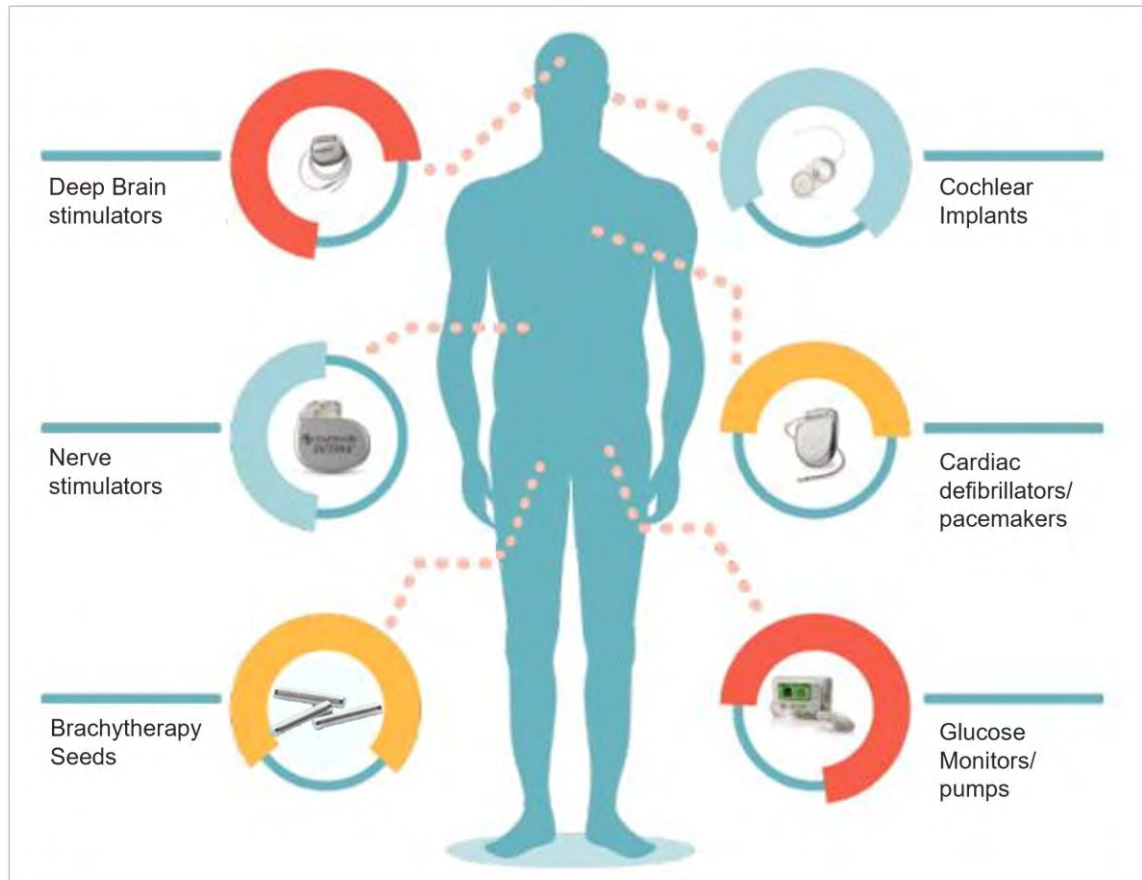Active Implantable Medical Devices
BSI*

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Agenda

1. Understanding AIMDs
2. Notified Body Landscape
3. MDR Conformity Assessment Route
4. Classification of AIMDs
5. 5 steps to CE marking or UKCA with BSI
6. CE marking process at BSI
7. Challenges in the CE marking process
8. Why BSI

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Poll

What % of our client base are considered small and medium enterprises "SME's"?

A. 35%
B. 65%
C. 85%

Understanding Active Implantable Medical Devices

- An Active Implantable Medical Device (AIMD) is an active medical device intended to be totally or partially introduced into the human body for diagnostic or therapeutic purposes and is to remain in place for an extended period

- Include a wide range of devices, i.e. pacemakers, defibrillators, infusion pumps, ventricular assist systems and devices, cochlear implants, and neurostimulators

- Have the highest risk classification for medical devices and are subject to rigorous standards and requirements to protect the health and safety of patients.

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● Notified Body Landscape

AIMD – Notified Body Landscape

As of May 2023
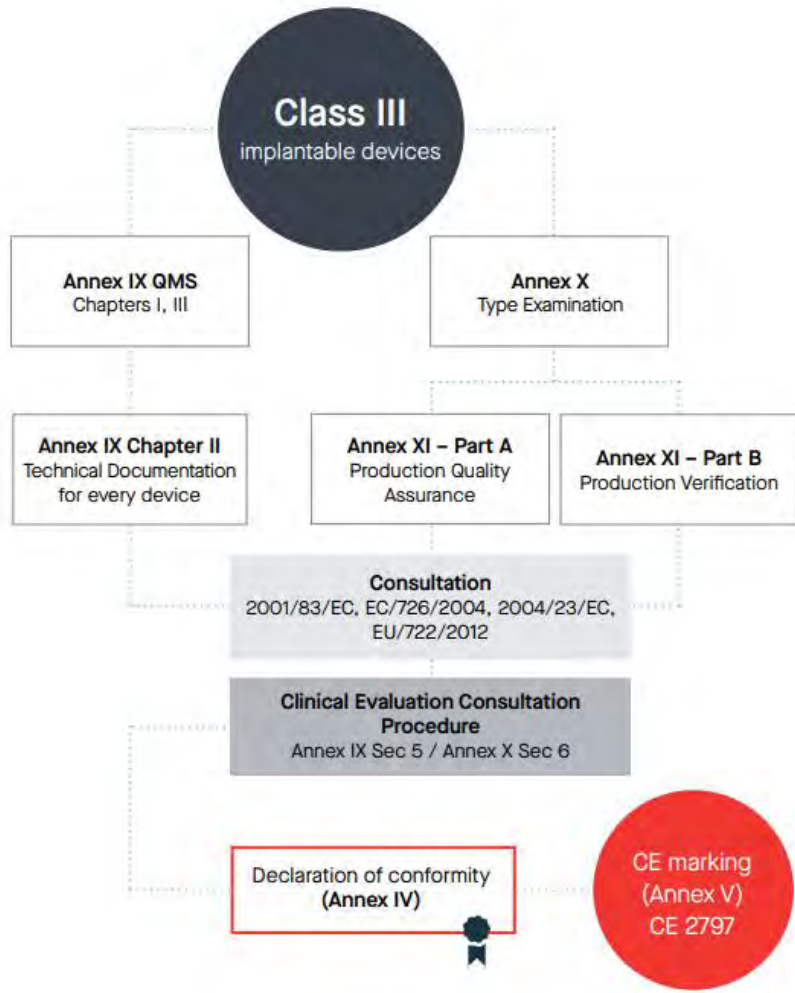
9 NB designated for AIMD devices listed

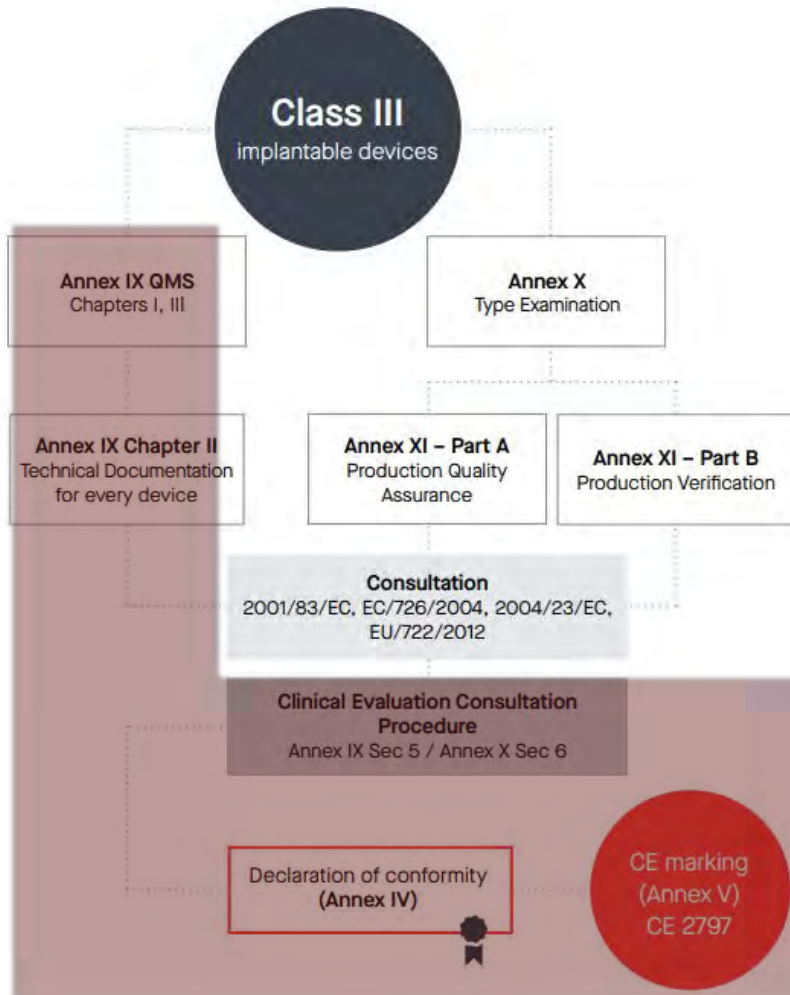| MDR	Description	Products	# of designated NBs
MDA0101	Active implantable medical devices for stimulation / inhibition / monitoring	Implanted defibrillators, Spinal cord stimulators, Implantable cardiac pacemakers, Implantable bladder stimulators,.....	7 2 limited conditions
MDA0102	Active implantable medical devices delivering drugs or other substances	Implanted drug delivery pump,....	4
MDA0103	Active implantable medical devices supporting or replacing organ functions	Active drainage systems, LVAD and Total artificial heart, glucose monitoring, cochlear implants	5
MDA0104	Active implantable devices utilising radiation and other active implantable devices	Brachytherapy	4

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● MDR Conformity Assessment Route

MDR Conformity Assessment Route for AIMDs

Class III implantable devices	Initial Conformity Assessment	Surveillance				
		Y1	Y2	Y3	Y4	Y5
QMS Audits	Yes	Yes	Yes	Recert**	Yes	Yes
Microbiology Audits	Yes*	N/A	N/A	Yes*	N/A	N/A
Technical Documentation Assessment	Review for every device	N/A	N/A	N/A	N/A	N/A
Clinical Evaluation Consultation Procedure (Article 54)	Yes, but exemptions may apply as per Article 54.2	May be required if any modifications to the device adversely affect the risk-benefit ratio				
Consultations (Rule 14, Rule 18, Rule 21)	If applicable	Modifications to the devices may need supplementary consultations; determined on a case-by-case basis taking into account the nature of the changes proposed				
Summary of Safety and Clinical Performance (Article 32)	Yes	Updated at least annually 'if indicated'. Notified Body to review at the time of PSUR assessments or substantial change reviews				
Clinical Evaluation Report updates		Updated as per manufacturer's clinical evaluation plan. Notified Body to review at the time of PSUR reviews or substantial change reviews				
Post Market Clinical Follow-Up Update Report (Article 61)		Updated at least annually. Notified Body review at the time of PSUR reviews or substantial change reviews				
Periodic Safety Update Report (Article 86)		Updated at least annually. Submitted to Notified Body via EUDAMED for Notified Body review				
Unannounced Audits		At least once every 5 years				

MDR Conformity Assessment Route for AIMDs

Class III implantable devices

- **Annex IX QMS** Chapters I, III
- **Annex X** Type Examination
- **Annex IX Chapter II** Technical Documentation for every device
- **Annex XI – Part A** Production Quality Assurance
- **Annex XI – Part B** Production Verification

Consultation 2001/83/EC, EC/726/2004, 2004/23/EC, EU/722/2012

Clinical Evaluation Consultation Procedure Annex IX Sec 5 / Annex X Sec 6

Declaration of conformity (Annex IV)

CE marking (Annex V) CE 2797

1° Step
- Compliant QMS per MDR
- Classification (MDCG 2021-24)
- Contracting for Conformity Assessment

How to prepare for the Conformity Assessment
1. How to consider regulatory guidance
2. Best Practice Guidelines
3. Quality of Technical documentation
4. State-of-the-art for your device under review

BSI Conformity Assessment
1. Completeness Check
2. MDR Technical Documentation Review Process
3. CECP process and Medicinal substances outside BSI

How BSI supports the Conformity Assessment
1. Structured Dialogues and Access to Notified Bodies
2. Predictability, transparency and approachability

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● **Classification of AIMDs**

● Poll

A company manufactures an implant kit for a spinal cord stimulation device that is sold as a kit and also has accessories sold separately from the kit. What is the MDR classification for the kit and the accessories?

- The kit is a Class III Implantable and the accessories are Class IIb
- The kit is Class IIb and the accessories are IIa
- The kit is Class III Implantable and the accessories are Class IIa
- Both are Class III

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Definition of accessory

MDR 2017/745
Article 2

(2) 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);

MDR 2017/745
Rule 8

All implantable devices and long-term surgically invasive devices are classified as class IIb unless they:
— are active implantable devices or their accessories, in which cases they are classified as class III;

MDR 2017/745
Rule 9

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III.

MDCG 2021-24
Reference to GHTF/SG1/N 77:2012

Accessory to a medical device: Means an article intended specifically by its manufacturer to be used together a particular medical device to enable or assist that device to be used in accordance with its intended use.

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Classification according MDR and MDCG 2021-24

MDCG 2021-24 Guidance on classification of medical devices

Rule 8 - Implantable devices and long-term surgically invasive devices (> 30 days)

III	- are active implantable devices or their accessories, in which cases they are classified as class III;	• Cochlear implants and accessories • Implantable cardiac pacemakers • Implantable cardioverter defibrillators (ICD) • Leads, electrodes, adaptors for pacemakers and implantable defibrillators • Implantable nerve stimulators • Implantable bladder stimulators • Implantable sphincter stimulators • Accessories to active implantable devices (with or without contact to the heart), be it implantable or non-implantable active or not[5]: • torque wrench for implantable pulse generator / implantable cardioverter defibrillator • cables for programmer / pacing system analyser • magnet for Implantable Pulse Generator / Implantable Cardioverter Generator • programmer or an external transmitter intended for activating or controlling the implantable part of the device • implantable pacemaker leads
	Note 5: Also **non-implantable** and **non-active accessories** to AIMDs should be classified as Class III under Rule 8.	

Active implantable device including accessories

BSI's Interpretation on the classification of non-active/non implantable accessories to an AIMD

- **Article 58 :** It is necessary, in particular for the **purpose of the conformity assessment procedures**, to **maintain the division of devices** into four product classes in line with international practice. **The classification rules**, which are based on the vulnerability of the human body, **should take into account the potential risks** associated with the technical design and manufacture **of the devices. To maintain the same level of safety as provided by Directive 90/385/EEC, active implantable devices should be in the highest risk class.**

- **As well non-active/non-implantable accessories** to an AIMD **support the intended use** of the **active implantable medical device** and therefore cannot be down-classified on their own right.

- **The intended use of the system needs to be considered** and therefore all accessories are **Class III**.

● 5 steps to CE marking or UKCA with BSI

Five Steps to CE Marking or UKCA with BSI

Step 1

BSI prepares a quotation

A BSI representative meets with your organization to discuss your needs and the available solutions. We will also discuss the best service for your requirements.

Step 2

BSI performs a conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your organization throughout the process. A QMS audit will then be performed and Technical Documentation reviewed by one of our experienced technical experts.

Step 3

Certification decision

Successful assessment leads to your BSI scheme manager recommending certification of your product. The BSI Certificate Decision Maker will then review the recommendation and, if satisfactory, approve certification.

Step 4

Issue certificate

Upon successful certification, you will be issued with a certificate. You will then be able to CE or UKCA mark your product and launch to market.

Step 5

Certification maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance. Your BSI scheme manager will be able to support you with any queries you might have.

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Application Process with BSI
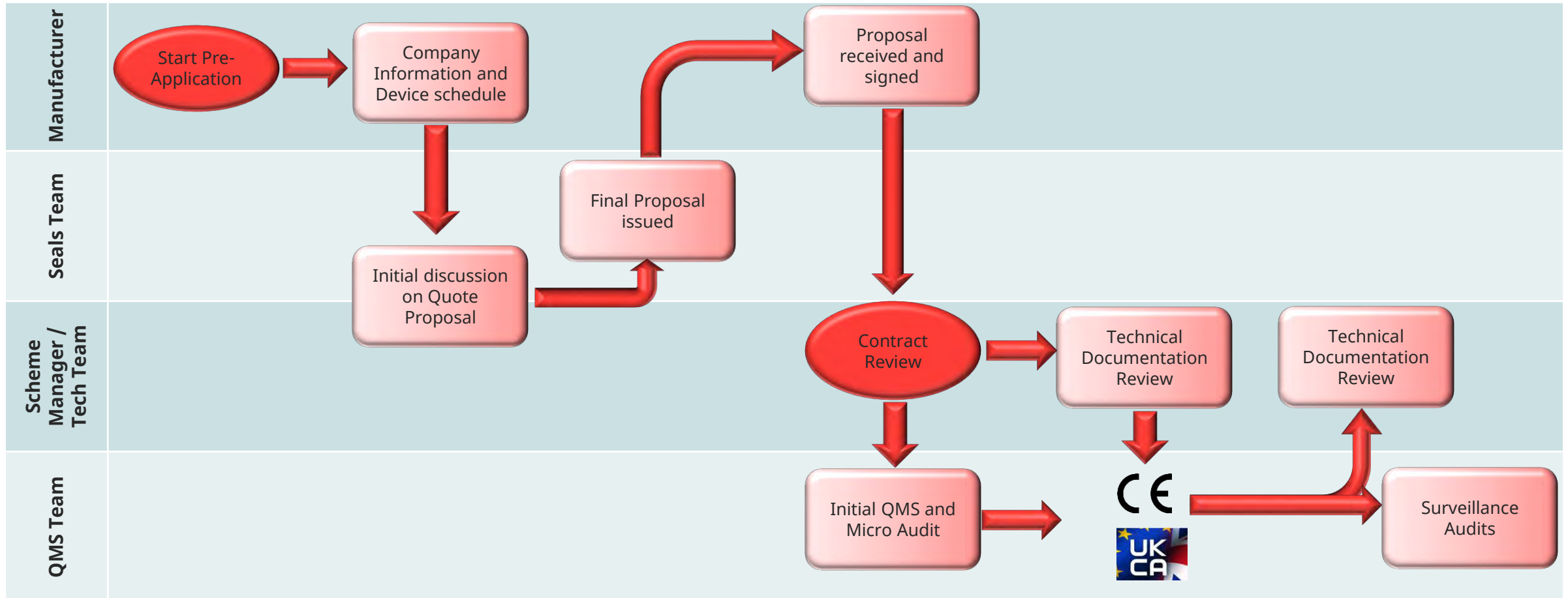
● CE marking process at BSI

● Poll
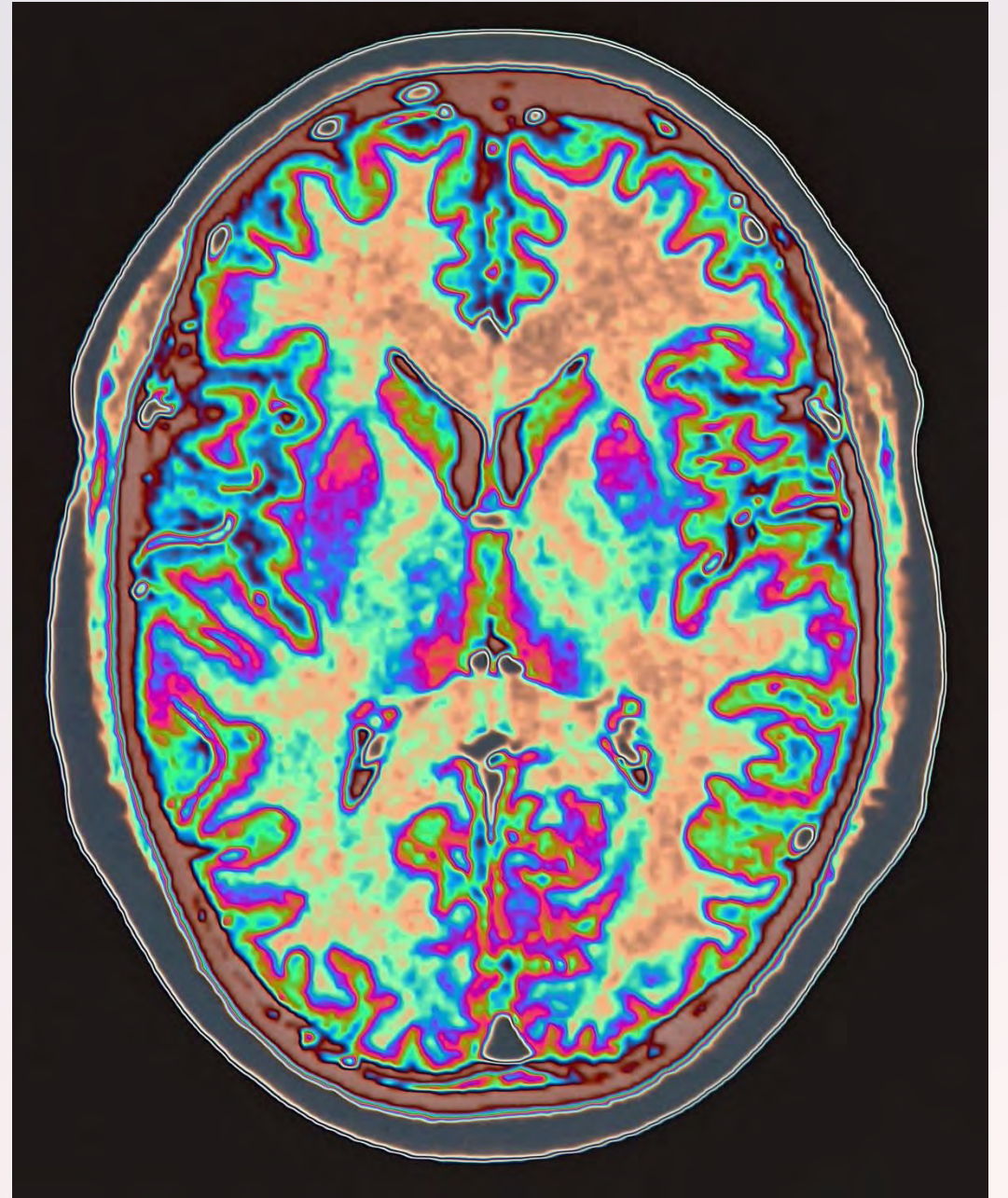
When should manufacturers apply for CE Marking?

A. After FDA Approval
B. After post-market clinical studies have been completed
C. After sufficient technical and clinical documentation is compiled and meets the requirements established by the EU MDR 2017/745
D. At the completion of the verification and validation phase of product development.

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MDR Technical Documentation Completeness Check

MDR TD Review Flow

Successful Completeness Check of submitted file

Review initial submission

Review Starts

Manufacturer submits R1 responses

Review Responses to R1Q

Round 1 Questions

Manufacturer submits R2 responses

Review Responses to R2Q

Round 2 Questions

Manufacturer submits R3 responses

Review Responses to R3Q

Round 3 Questions

BSI will be required to reject applications if gaps cannot be addressed in three rounds of questions

Questions Closed

Recommend

Refusal

Questions Open

Filed in EUDAMED

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Review Timing

Start-Up

Review & Questions

Finalization

Application
- Contact Account Manager
- Quote Initiated
- Approved Quote

Completeness Check
- Client Completes MDF 5007
- Review & Questions

Review Launch

Start of conformity assessment

R1 Qs/Response
- Full pass complete
- R1 Qs drafted
- Client Response

R2 Qs/Response

R3 Qs/Response
- Identify Deficiencies
- Cleared to Close

Certificate
- Mock-up approved by Client
- TDAR
- CEAR

Panel

Certificate Release

Technical documentation review

With BSI
With manufacturer %

23

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MDR TD Review Impacts – some specifics

Medicinal Consultation (MDCG 2020-12)

NBs are not designated to assess against 2001/83/EC and cannot make a decision on the quality and safety of the ancillary medicinal substance

Competent Authorities & EMA have responsibility for the approval and control of medicines

The medicinal products authority consulted shall provide its opinion to the notified body within 210 days of receipt of all the necessary documentation.

Complete Device schedule
To get contract in place it is mandatory that you present a full overview of your device.

Incomplete testing
You are LM and you have to conclude your testing. It is not the responsibility of the test house!

Resources lack
Have enough resources available at the time you get the round of question back to you

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MDR TD Review Impacts – The CECP, Article 54

- Clinical Evaluation Consultation Procedure (CECP) (Article 54), required for Class III Implantable devices and Class IIb devices intended to administer or remove medicinal substances.

- Is only not required in very specific circumstances, and on discretion of the NB. (Article 54 2b)

- Commences after ALL NB assessments have been completed (Tech, Clinical, Medicinal, etc.)

- The panel does not currently charge (but it may not stay that way)

- NB does not have control over the procedure once started.
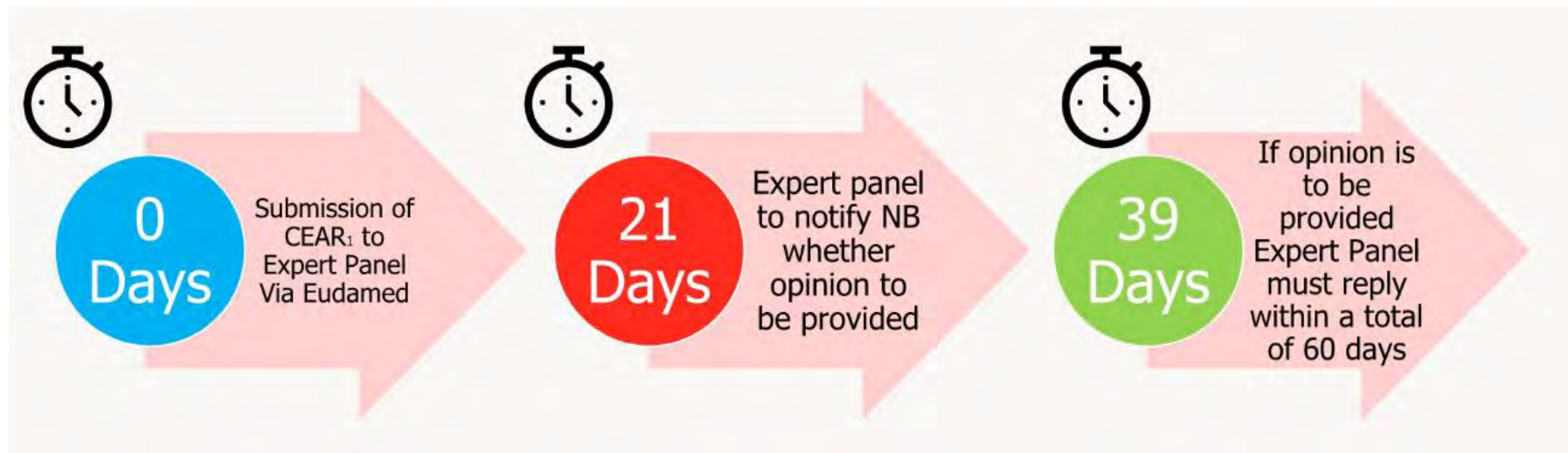
● Challenges in the CE marking process
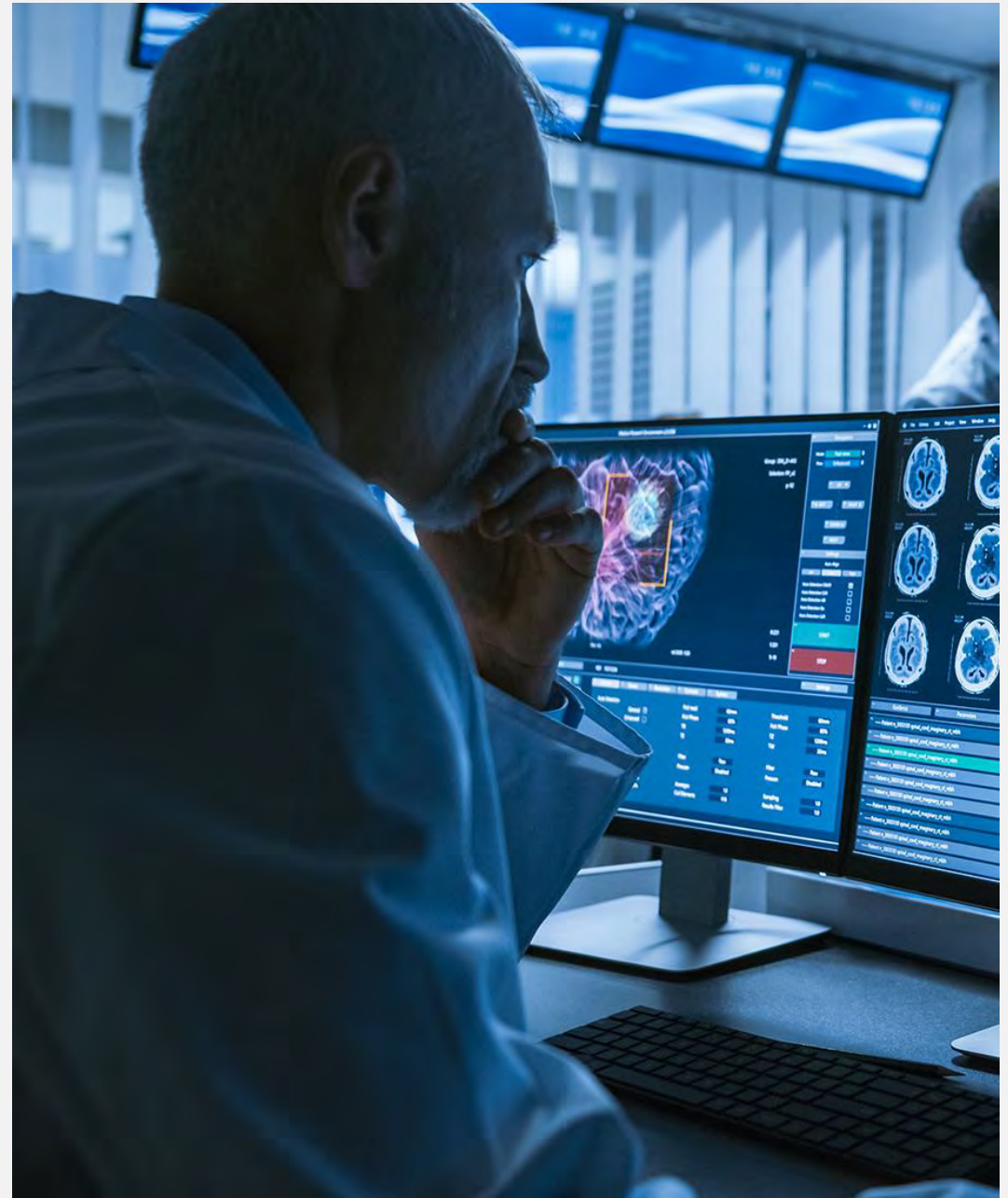
Technical Documentation Challenges – Quality

✓ The quality and organisation of the documentation provided by the manufacturer is the most impactful variable in predicting the efficiency of product review and its successful outcome.

✓ A complete and well-organised technical documentation file decreases time and cost of the review. (Searchable, bookmarked PDF files)

✓ Full coverage of Annex II and Annex III of the MDR must be presented. No modular submissions allowed.

✓ Support of review by the manufacturer regarding timely response to rounds of questions.

ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

CHAPTER II

ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation applicable to class III devices and to the class IIb devices referred to in the second subparagraph of Article 52(4)

4.1. In addition to the obligations laid down in Section 2, the manufacturer shall lodge with the notified body an application for assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III.

Technical Documentation Challenges – Typical Gaps

Clinical Evaluation:
- ✓ Equivalence Incomplete
- ✓ State of the art not fully established
- ✓ Clinical Evidence insufficient and/or does not support claims.

Risk Management:
- ✓ Feedback loop with Clinical and PMS data not clear
- ✓ Risk Mitigation links not properly documented

Labelling and IFU:
- ✓ Compliance to the eIFU regulation lacking
- ✓ Symbols reflecting the device specifications missing

PMS and PMCF:
- ✓ PMS procedures do not identify vigilance, and/or perform effective trending.
- ✓ PMCF plans not suited to gathering data through the device lifetime

Software and Cybersecurity:
- ✓ EN 62304 checklist/trace matrix - Missing or not detailed enough
- ✓ Software user interfaces not sufficiently tested for usability (formative and summative testing as per EN 62366-1);

Design V&V:
- ✓ Evidence of performance over lifetime of device not demonstrated
- ✓ Traceability Matrix between risks, requirements and V&V not present

Clinical Evaluation	Risk Management	PMS and PMCF
		Software and Cybersecurity
	Labelling and Instruction for Use	Design V&V
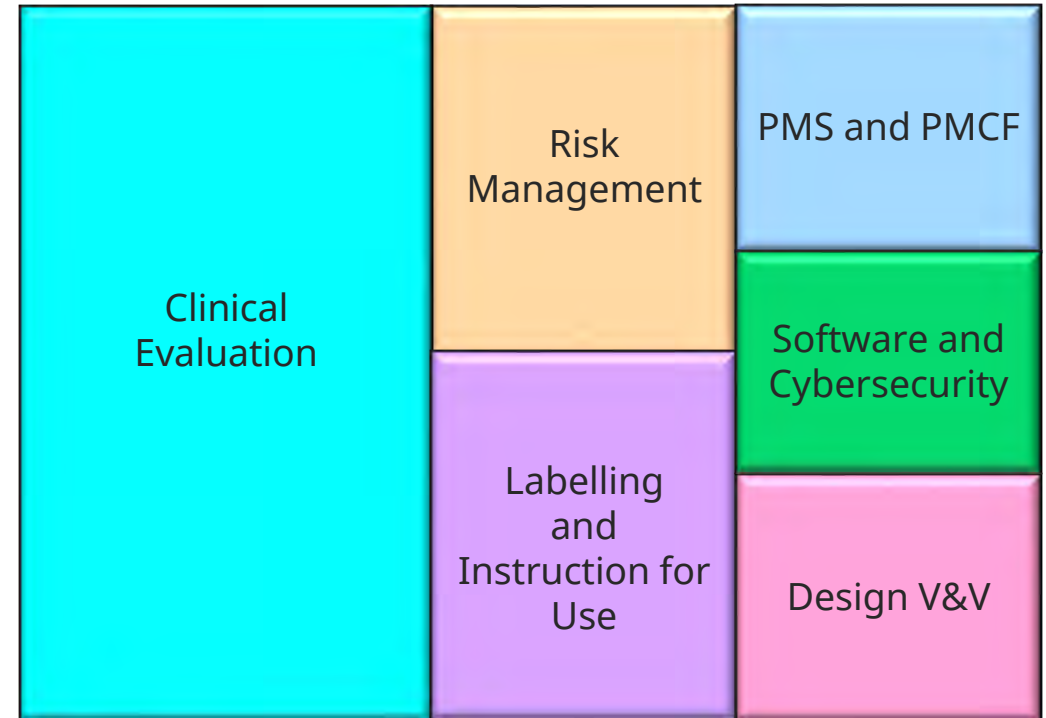
QMS challenges (seen in Stage 2 audits)

Inappropriate timing and procedures to report incidents

UDI and EUDAMED registration not ready

Design V&V not sufficiently planned

PMS process not detailed enough

Translation process not completely defined

DoC incomplete

Production Process not demonstrated.

Clinical Challenges – In a nut shell

Clinical requirements have got a lot more detailed over time.

Directives (clinical):

- AIMD released 1990, MDD released 1993, One Annex, 2 pages covering Clinical Evaluation and Post Market Surveillance.

- Guidance (not legally binding): Meddev 2.7.1 Rev 3 came out in **2009 – 46 pages**, Meddev 2.7.1 rev 4 came out in **2016 – 64 pages**, Others … Meddev 2.12/1, Meddev 2.12/2, ISO 14155, … etc.

MDR (clinical):

- Released in 2017, Articles 61-92, ~20 pages, Annex XIV & XV, ~10 pages. (~10x the detail?)

- Guidance: 13 ++ MDCG <u>documents</u>… many pages!

Legacy device manufacturers are struggling to meet requirements. * *

* MDCG 2020-6 : Guidance on sufficient clinical evidence for legacy devices

** BSI Webinars (Clinical Excellence Series) and White Papers

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Clinical Challenges – Device and State of the Art

Description
- MDR Annex II 1.,Meddev 2.7.1 rev 4 A3
- Unambiguous, clear, all relevant aspects covered.
- Intended purpose clearly defined, supported, unambiguous.

CEP
- MDR Annex XIV 1 a)
- Clearly Outline the Strategy to be followed.
- Summarise appropriate measures, endpoints, methods.

Equivalence
- MDR Article 61 4. , MDR Annex XIV 3. , MDCG 2020-5
- Between Current Version of Device and specific device with Clinical Data
- Identify all differences, provide proper Scientific Justification of "no impact"

State of the Art
- Meddev 2.7.1 rev 4 A4 & A5, MDR Annex 1 GSPR 1, etc.
- Characterise Clinical Condition, Identify all Treatments, Identify Similar Devices
- Extract properties, safety and performance measures, level of clinical data.

Claims
- MDR Article 61 1., MDR Annex XIV 3.,
- Identify properties, features, claims and performance and safety endpoints.
- Specify and justify level of clinical evidence to support GSPRs / Intended Purpose

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Clinical Challenges – Clinical Evaluation

Identification
- MDR Annex XIV 1(b), Meddev 2.7.1 rev 4 8., MDCG 2020-6
- Identify all clinical data relevant to the device, identify gaps.

Generation
- MDR Annex XIV 1(d) & Part B (PMCF), MDR Annex XV, MDCG 2020-6 App 3
- Through, properly designed, clinical investigations, any new or additional data necessary to address gaps.

Appraisal
- MDR Annex XIV 1(c), Meddev 2.7.1 rev 4 9.
- Methodical, objective, appraisal of all clinical data sources.

Analysis
- MDR Annex XIV 1(d), Meddev 2.7.1 rev 4 10.
- Methodical, objective, critical, analysis of all clinical data, weighted according to their appraisal. Extract all positive and negative aspects of safety and performance.

Conclusions
- MDR Annex XIV 4.,
- Relate back to all claims, objectives and the state of the art.
- Demonstrate support of relevant GSPRs & acceptable Safety and Performance

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(New Devices) Consultation with the Expert Panel

MDR Article 61 2. *For all … **devices referred to in point (b) of Article 54(1),** the manufacturer may, … **consult an expert panel** as referred to in Article 106, with the aim of reviewing the manufacturer's intended **clinical development strategy** and **proposals for clinical investigation**. The manufacturer **shall give due consideration** to the views expressed by the expert panel. Such consideration **shall be documented in the clinical evaluation report** referred to in paragraph 12 of this Article.*

Note:

- Panel is independent of NB review

- Pilot of the expert panel during 2023 (up to 10 requests)

- Likely to focus on: Novel devices, devices to diagnose or treat diseases with few other options, drug device combinations (where principal action is not the drug)

- Full implementation in 2024..?

● Why BSI?

BSI Highlights

Expertise

Notified body capacity/approachability

Predictability

Transparency in quoting

Review approach

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BSI AIMD Team Expertise

Map legend:
- United States
- UK
- Canada
- France
- Germany
- Italy
- Spain
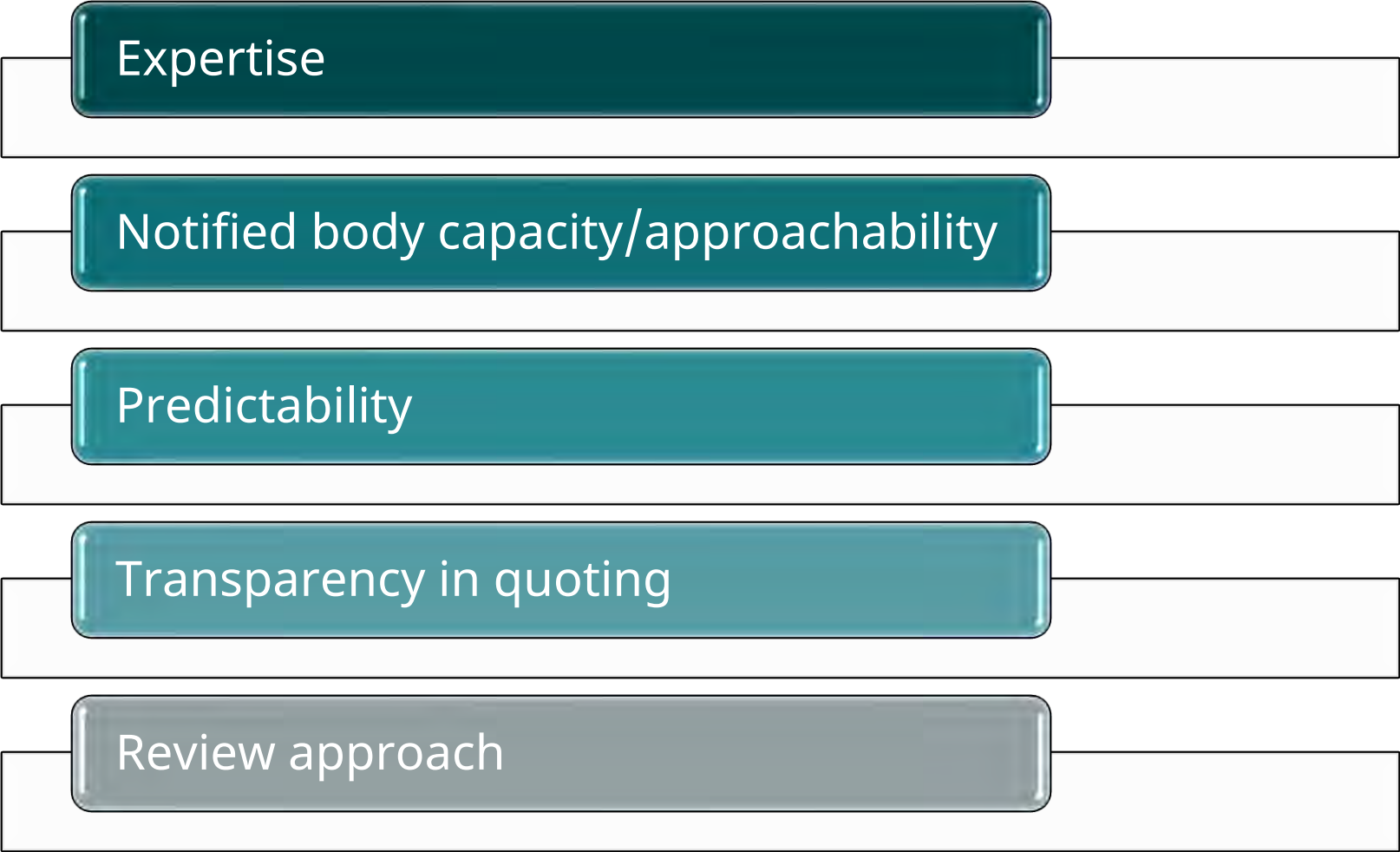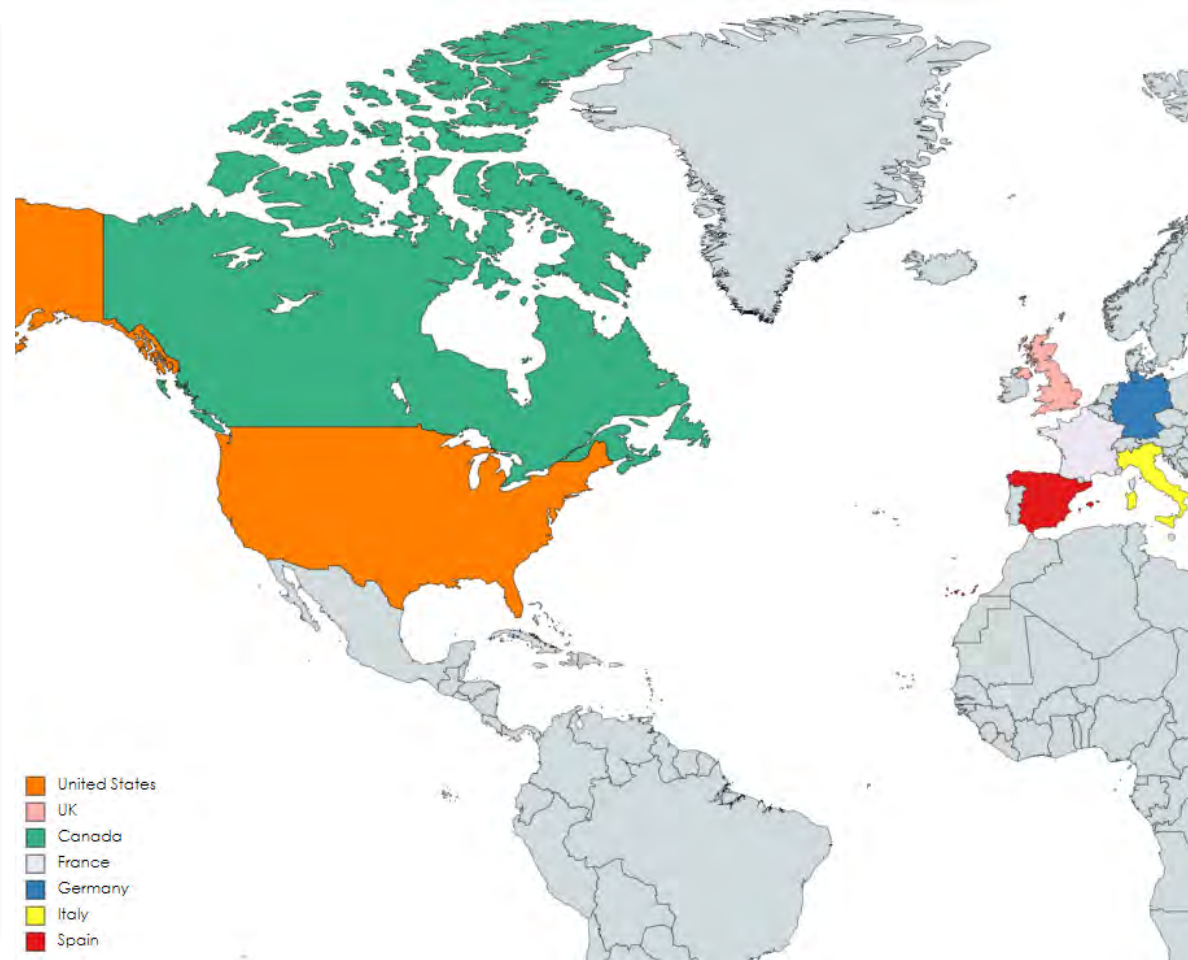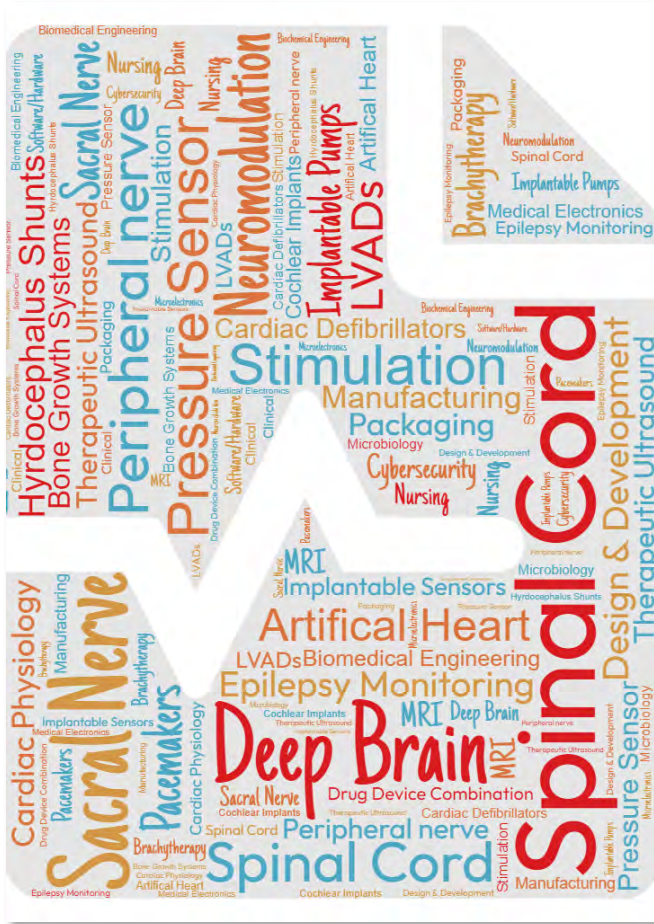
- AIMD team expertise spans **15 engineering disciplines and 11 unique device industry experience across 7 countries globally**

- The AIMD team includes **5 dedicated clinical experts, including accredited clinicians with experience in Cardiac Rhythm Management, Neuromodulation and Cardiac Critical Care**

- BSI has a pool of **internal practising physicians** who oversee all clinical review work undertaken

- BSI has a pool of external clinicians who provide specialist clinical support
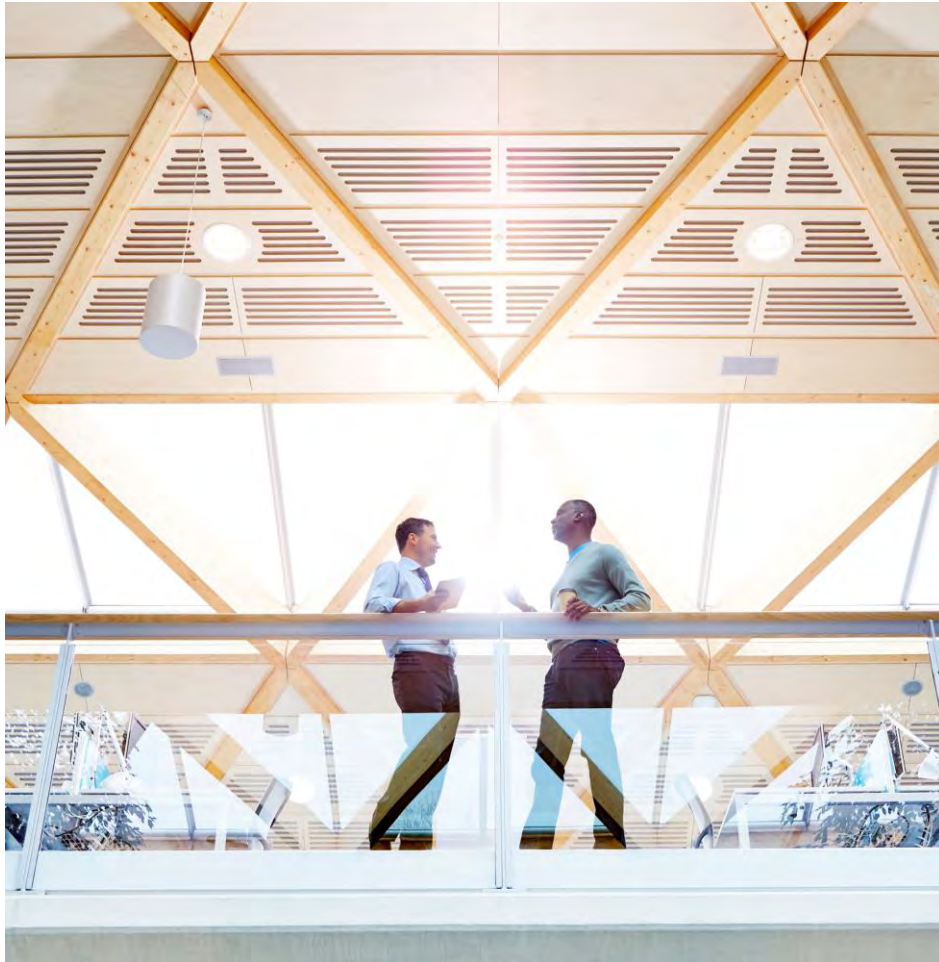
Capacity / Approachability

- ✓ We have **heavily invested in training and additional resources** resulting in a comprehensive understanding of the increased scrutiny implemented by the Regulation.

- ✓ Throughout the device review process, **BSI encourages open and frequent exchange sessions (structured dialogues)** between the technical team and the manufacturer to increase process efficiency and understanding of regulatory requirements for the device under review.

- ✓ A **dedicated Scheme Manager** will be assigned to you throughout the submission, review and QMS audit processes, ensuring timely market access and maintaining the certification for your AIMD.

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Quoting process

✓ **BSI provides a transparent quote**, including full coverage of the technical documentation review process **from completeness check throughout the final certificate issuance.**

✓ Manufacturers must provide a **full device schedule** before the quoting process takes place.

✓ **Commercial team assists throughout this process** and hands over to a dedicated scheme manager who supports throughout the submission, review and QMS audit processes, ensuring timely market access for your AIMD.

✓ BSI aims to provide **predictable review timelines** and a **full schedule of the review process** will be provided upfront at the application stage.

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Review approach

- ✓ **Lead reviewer** drives the review and **aligns with all involved experts** at the **beginning of the review**

- ✓ **Regular status meetings** between the internal experts

- ✓ **Minimizing duplication** of review questions

- ✓ **Frequent update meetings** with the manufacturer

- ✓ **All reviewers are part of one team → centralized approach → aligned priorities**

- ✓ **Team manager and Global head support**

AIMD Team

Lead reviewer Technical Expert

Clinical review

MRI review

Software review

Scheme Manager

1 Review Team

Team manager

Global Head

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Why BSI

Typically all Product Technical Specialist have

10+ years of industrial experience

in the design and manufacture of AIMD's

We provide you with

training, webinars and additional resources

to support you every step of the way.

We have

heavily invested in training and additional resources

resulting in a comprehensive understanding of the increased scrutiny implemented by the Regulation.

A

dedicated Scheme Manager

will be assigned to you throughout the submission, review and QMS audit processes,

ensuring timely market access for your AIMD.

BSI provides a

transparent quote, including full coverage of the technical documentation review process

from completeness check throughout the final certificate issuance.

All reviewers are part of one team → centralized approach

→ aligned priorities

Lead reviewer drives the review

and aligns with all involved experts at the beginning of the review

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BSI Medical Devices – Use Our Resources

Brochures, Guides and Documents

MDR guidance

MDD Best Practice Guidelines >
MDR Best Practice Guidelines >
MDR Mapping Guide >
MedDev 2.7.1 Rev 4 changes >
MDR Conformity Routes >
MDR Readiness Review >

SMEs dedicated support page

https://bit.ly/3od7WmH

Webinars

MDR Conformity Assessment Routes webinar

MDR - What we know

Download the presentation >

White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR

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https://www.linkedin.com/showcase/bsi-medical-devices/

Join and follow us on LinkedIn
Share your knowledge, challenges and news with others on LinkedIn.

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Summary

Expertise in the AIMD Team

| MRI | Clinical | Software | Product Technical Specialist | Scheme Manager |

Subject Matter Expertise

- **All subject matter experts are part of the team**
- **Direct access** to the experts
- **Priorities** defined by Team Management

Benefits

- **Internal kick-off meetings** involving all experts to cover the review
- **Scheme Manager** and **leading PTS** drives the review and provides updates to other reviewers involved
- **All experts** work towards **an agreed timeline** and do not operate independently (no pool of experts which will be utilized across all technology teams)

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How can we support you along the way?

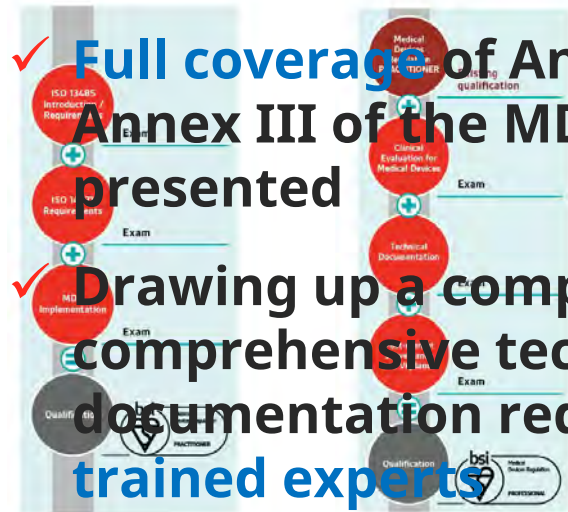**Each rectangular represents aspects of the technical documentation.**

The size of the rectangular correlates with the number of questions asked in this field.

Full coverage of Annex II and Annex III of the MDR must be presented

Drawing up a complete and comprehensive technical documentation requires well-trained experts

Medical device training courses

We understand the challenges of meeting regulatory requirements and maintaining quality management systems. We understand because it's what we do, every day of every week; for you, for your customers, and for your customers.

We have dynamic course owners around the world, allowing delivery of training in many local languages. Our course owners are subject matter experts and use practical examples from their experiences to bring each lesson to life.

Medical Devices Regulation Practitioner

Medical Devices Regulation Professional

Clinical evaluation

INSTRUCTOR LED
Clinical Evaluation for Medical Devices
Medical Devices

INSTRUCTOR LED
Requirements of the Medical Device Regulation (MDR) Training Course
Medical Devices

INSTRUCTOR LED
Introduction to ISO 13485:2016 Training Course
Medical Devices

PMCF and PMS

EVENTS AND WEBINARS
Clinical Masterclass Series 2023 - Preparing a Post Market Clinical Follow Up Plan & Evaluation Report

INSTRUCTOR LED
Post-market Surveillance and Vigilance under the Medical Device Regulation (MDR) and In Vitro Diagnostics Medical Devices Regulation (IVDR)
Medical Devices

Instructions for use

INSTRUCTOR LED
Manufacturing Process Validation for Medical Devices: Introduction to Concepts and Methods Training Course
Medical Devices

Labelling

EVENTS AND WEBINARS
Symbols to be used on labelling ISO 15223 & information to be provided by the manufacturer ISO 20417
Medical Devices

Design Specifications

EVENTS AND WEBINARS
AIMDD to MDR transition: What you need to know
Medical Devices

Verification and Validation

Software and Cybersecurity

EVENTS AND WEBINARS
Clinical Masterclass series: Clinical Evaluation Medical Software and AI Devices
Medical Devices

INSTRUCTOR LED
Risk Management for Medical Devices ISO 14971:2019
Medical Devices

Riskmanagement

Questions?