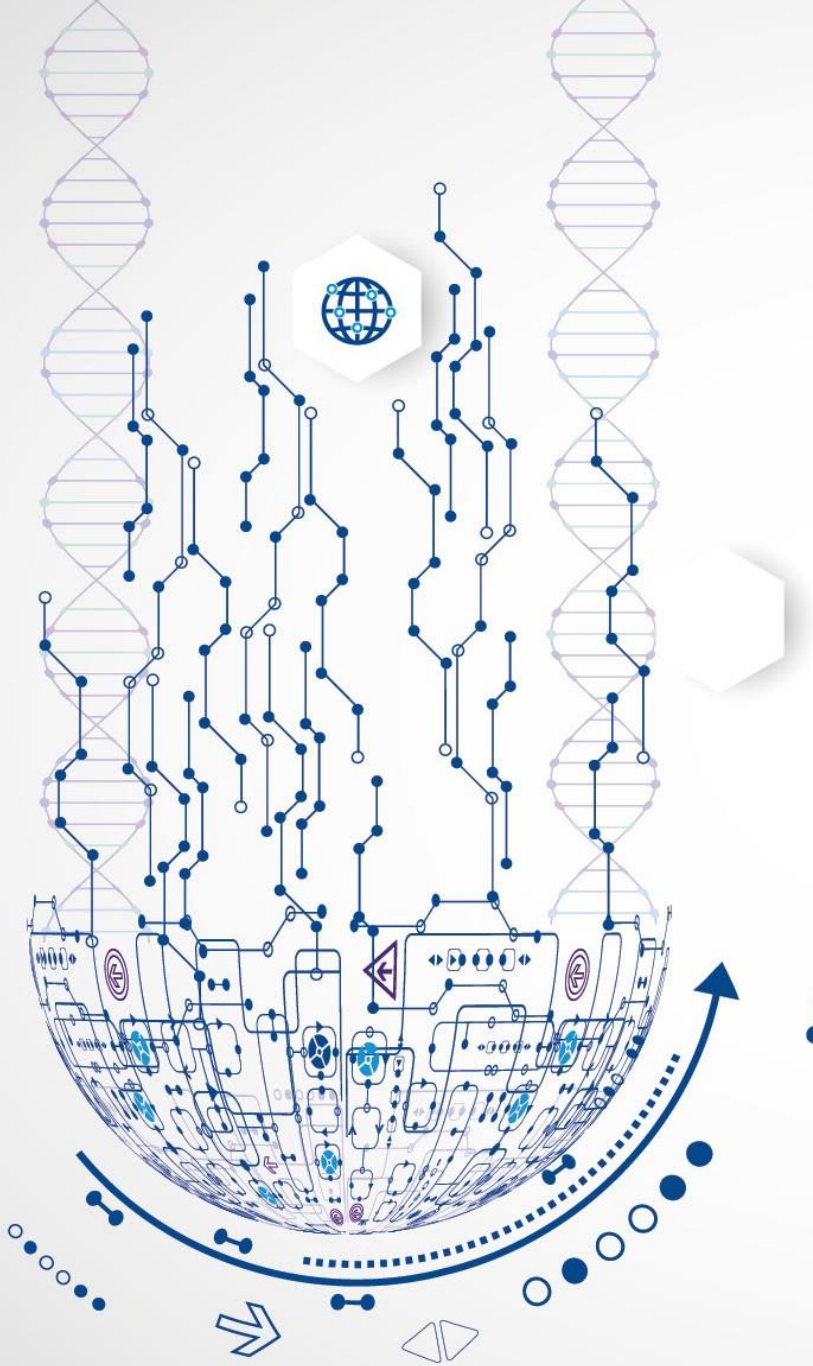


KPMG

Outline to EU MDR Transition Service

A capability statement for successful remediation

Agenda

Your self-assessment GAP analysis

Have you already assessed…

- ☐ … all products' risk classification?
- ☐ … all products' technical documentation, and the process for maintaining that documentation?
- ☐ … the current compliance level to relevant ISO standards (Risk & Quality Management)?
- ☐ … the ability of the Quality Management System and Product Lifecycle System to meet the MDR's increased focus on detecting device changes, based on UDIs, and documenting accordingly?
- ☐ … the data governance process for readiness to comply EUDAMED reporting?
- ☐ … labeling processes' speed and capacity to handle extensive changes to physical product labeling and electronic Instructions For Use (IFU) labeling?
- ☐ … the increased scope of clinical evaluation and Post-Market Surveillance (PMS) system's ability to meet the new 15-day reporting requirement and produce the new reports, including the IT systems capability?
- ☐ … all existing contracts with suppliers, distributors and importers for EU MDR compliance?
- ☐ … the program's structure, including communications strategy, training strategy, cascading of management by objectives across the project team, and format for executive reporting?
- ☐ … the total cost and increased personal requirements of the program, by year, by function, by EU MDR requirement and determine incremental opportunities to gain value beyond compliance ?

New regulation landscape for medical devices from May 5, 2017 : EU Medical Device Regulation (MDR)

The EU Medical Device Regulation was published on May 5, 2017. MDR will replace the EU's current Medical Device Directive (MDD) (93 / 42 / EEC) and active implantable Medical Devices Directive (90 / 385 / EEC) with a three year transitional period.

Law published
May 5, 2017

EU MDR takes effect
May 26, 2017

MDR certificates available
Summer 2018
(projected date)

End of transition period
May 26, 2020

Key changes

- **Increased control** for national regulators
- **Interaction changes** with Notified Bodies
- New / Updated **classification rules**
- New **EU database** on devices (EUDAMED)
- Better **traceability** of medical devices (UDI)
- New clinical **evidence & safety** requirements
- Increased periodic safety update and vigilance **reporting requirements**

Time line strategy

- There is an **opportunity** to certify under MDD in the available timeline to **extend the time available** to sell MDD product in the supply chain for **four additional years** if there are no significant modifications in design (certificate expiration)
- **Allows flexibility** to bleed out product in a company's supply chain with short turn cycles, long shelf life, and increases ability to manage global product demand
- If companies do not decide to re-certify to MDD, only MDR compliant product can be sold in the EU on May 26, 2020
- This strategy may also provide company's the **opportunity to mitigate obsolescence / scrap costs** for both finished goods inventory and component materials

KMPG's broad expertise makes it a valuable partner for EU-MDR compliance

The KPMG Team offers the following set of EU MDR related services to meet your compliance needs

Clinical & Medical Safety
- CEP, PMCF, PMSP, PSUR development
- Clinical trial strategy & post-market surveillance systems enhancements
- Medical & safety writing

Master Data
- EUDAMED data risk assessment
- Data governance & change control
- Data collection & validation

Quality Assurance
- SOP analysis & changes
- QMS ISO13485:2016 assessment
- Document management strategy
- Compliant intake redesign
- Contract analysis & support for contract alignment (OEM/PLM)

Regulatory Affairs
- Technical File Remediation
- Labeling strategy & coordination
- Regulatory submission management

IT
- Impact assessment, incl. cost/risk analysis
- System enhancements: evaluation & implementation of IT-tools, incl. systems validation (DMS, CLMS)
- MDR system architecture & EUDAMED integration

PMO
- Project governance
- Communications
- Training
- Cost controlling

Supply Chain
- Economic operator remediation
- Labeling implementation
- Inventory transition planning

Manufacturing
- UDI impact assessment
- GS1/GTIN education
- Packaging line changes

KPMG's structured approach ensures successful EU MDR compliance

Phase	Impact / GAP assessment	Prioritization & pilot implementation	Implementation & Remediation	Monitoring & Improvement
Focus	– Identify the **effect of requirements** on the overall product portfolio – Identify **key gaps**, **remediation needs** and develop a **compliance roadmap**	– Conduct a **pilot project** identifying a comprehensive selection of candidate products for remediation – Conduct **remediation activity lifecycle**, including reviews with the Notified Bodies	– Includes comprehensive **remediation activities** – Includes a **multi-year schedule** that accommodates products with long lead times – Consideration for **functional area dependencies**, resource alignment, and critical risk management issues	– **Continuous monitoring** and updates of key documents across regulatory, safety, clinical, and other channels – Establish a comprehensive device **lifecycle management process** across various cross functional areas

Across Towers

- Process evaluation and redesign for EU MDR compliance
- Project management
- Device lifecycle management support
- Notified Body interaction support
- IT enablement
- Portfolio and change management

Brexit impact on the MedTech industry

Changes arising from Brexit

Action Items

Distributors & Importers

- **Currently, countries located outside of the EU are considered "third countries."** Economic operators who place products from a third country on the European market are considered importers and must comply with specific Union legislation requirements that differ from those applying to products sourced from within the EU-27
- **As of its formal withdrawal from the EU, the UK will be considered a third country and all of the same regulations will apply**. At that time, operators who were previously considered distributors will now be considered importers and will have to adhere to all importer obligations

Action Items

- Investigate the potential impacts of the Product-Liability-Directive 85/374/EEC
- Gain an understanding of the key differences between regulations affecting distributors and importers and how they relate to your products

Manufacturers & Authorized reps

- **Medical device manufacturers based in the UK will need to designate an authorized representative established in the Union** – a requirement for all operators located outside of the EU
- **As of 30 March 2019, this will include UK-based operators who wish to continue placing specific devices on the European market, including medical devices and IVDs.** Manufacturers are advised to pre-establish their representatives in the EU-27 before the withdrawal date

Action Items

- Manufacturers based in the UK must establish an authorized representative within the EU-27
- Manufacturers outside of the EU with an authorized representative in the UK must designate a representative within the EU-27

Certification process

- **As of the withdrawal date, UK Notified Bodies will no longer be considered EU Notified Bodies.** Additionally**, all EC certificates issued by UK-based Notified Bodies could be void as of March 30, 2019**
- **Economic operators based outside of the EU (including the UK) must ensure that they have valid certificates issued by an EU-27 Notified Body before the withdrawal date**
- **Operators holding certificates issued by a UK Notified Body should apply for a new certificate** or arrange for a transfer in order to ensure that they continue meeting all EU-sanctioned conformity procedures

Action Items

- Manufacturers holding EC certificates issued by UK-based Notified Bodies must obtain new certificates issued within the EU-27
- … or arrange a transfer of existing certificates before the UK's withdrawal

KPMG's Brexit approach

We recommend holding a cross functional triage event in which empowered decision makers come together to prioritize and mobilize the Brexit response. We see three categories of mitigations

	Examples
No regrets No-brainer decisions that could be kicked off immediately to avoid expected delays	– Obtain Authorized Economic Operator (AEO) status – Provide residency assurance and information for EU-nationals – Initiate supplier risk and resilience assessment down to Tier 3
Tactical Mitigations required to keep your business running in the event of a 'no-deal' Brexit	– Secure extra warehouse space and increase inventory to reduce risk of stock outs caused by customs delays – Conduct cost-to-serve analysis and de-list non-strategic products
No returns Strategic mitigations necessary to help recover the business performance impact of Brexit	– Establish production line in UK and avoid increased tariffs – Re-formulate products – Invest in additional automation

We have highlighted four elements of our approach to bring to life what it would be like to work with us

Vertical and horizontal insights

Having supported you with several engagements, **we understand your business model**. Additionally, we are working with other Life-Sciences companies with similar Brexit exposures to yours. If we were successful, we would aim to unlock insights and dialogue with these Organizations to better inform the actions and priorities you make.

Brexit briefings

Even before the referendum took place, KPMG was the first major professional services firm to establish a central Brexit team. Since then we have been at the forefront of supporting our clients with the business issue of a generation. Our Brexit team contains many specialist disciplines, not least specialists in convening stakeholders from across governments and specialist trade bodies.

Triage event

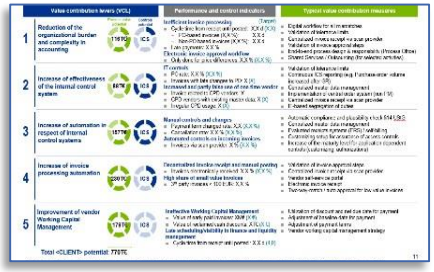
At KPMG we have a wealth of experience in rapidly achieving consensus with diverse groups of stakeholders. Through a heavily facilitated and interactive workshop, we would quickly level-set all participants with the important information they need to make a decision, and jointly develop the most appropriate Brexit response plan to survive and even thrive in the Brexit environment.

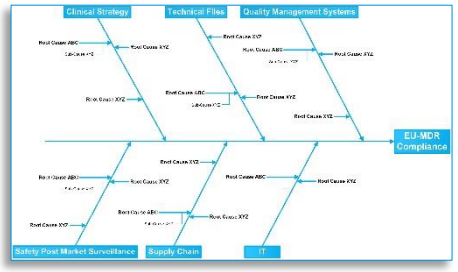
Bespoke Brexit Navigator

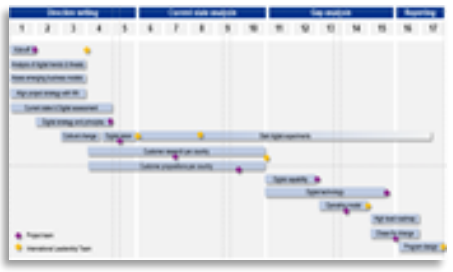
A key feature of our Brexit methodology is our Brexit navigator. Our KPMG SMEs and external Brexit-Intelligence team will be present throughout the entire engagement, ensuring all the latest insights are reflected in our agile and responsive contingency plan.

KPMG proposes a workshop approach to agree on the right solutions for EU MDR compliance

	Module 1: **Introduction**	Module 2: **Breakout**	Module 3: **Project planning and Wrap-up**
Activities	– Introduction & alignment on workshop goals – Understand background & receive KPMG global EU MDR input – Understand the work streams	– Identify focus areas along the work streams – Breakout sessions according to defined work stream priorities – Cluster and organize information for Root Cause Analysis	– Consolidate breakout conclusions into actionable items – Project planning: prioritize and set a timeline for open items – Identify where 3rd party support is needed – Define quality gates
KPMG workshop deliverables	– KPMG work stream mapping – Root-Cause-Analysis to identify issues	– Prioritization of key issues and potential next steps – Five Why and Fishbone Diagram	– Define potential solutions for the Root-Causes – High-level work plan – Budget estimation for the project







Achieve complete product portfolio transparency: SKU Rationalization Matrix

Challenge: Identify most-effort consuming products in your portfolio

List and rate affected products and understand efforts along the different involved functions in working hours

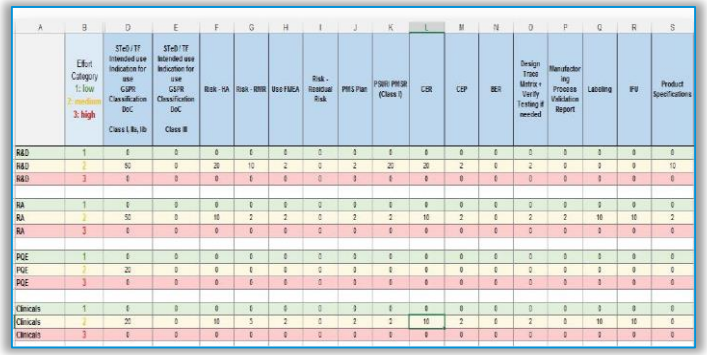
Solution: Rationalize product portfolio with KPMG Effort-Estimation-Matrix for MDR

Rank products according to their efforts driven by an economical model to precisely identify cost drivers in your product portfolio transitioning to MDR compliance. Valuate products referring to their complexity and apply clustering logic to notify peaks and take action

Involvement of multi-disciplinary team necessary

Involve your Subject Matter Experts (SME) to get the necessary buy-in for executing the SKU Rationalization Matrix

KPMG supports to rationalize your product portfolio based on actual efforts



Activities

Preparation

- Identify SME network
- Define evaluation criteria for clustering product portfolio per function (RA, Quality, IT etc.)
- Define product portfolio scope

Assessment

- Execute workshop to align on activities and effort in hours per product
- Apply SKU-Matrix to cluster products per complexity area
- Develop evaluation criteria for target DMS
- Align outcome of SKU-Matrix workshop with management

Implementation

- Implement agreed SKU-Matrix changes into MDR execution program and plan activities to priority and sequence
- Apply PDCA-Cycle-based on implementation learnings
- Benchmark effort drivers with other companies

EU MDR benchmarking reveals optimization potentials

Optimization potentials are revealed during a 12 week approach, divided into three phases, enabling adjustable benchmarking throughout the MDR transition.

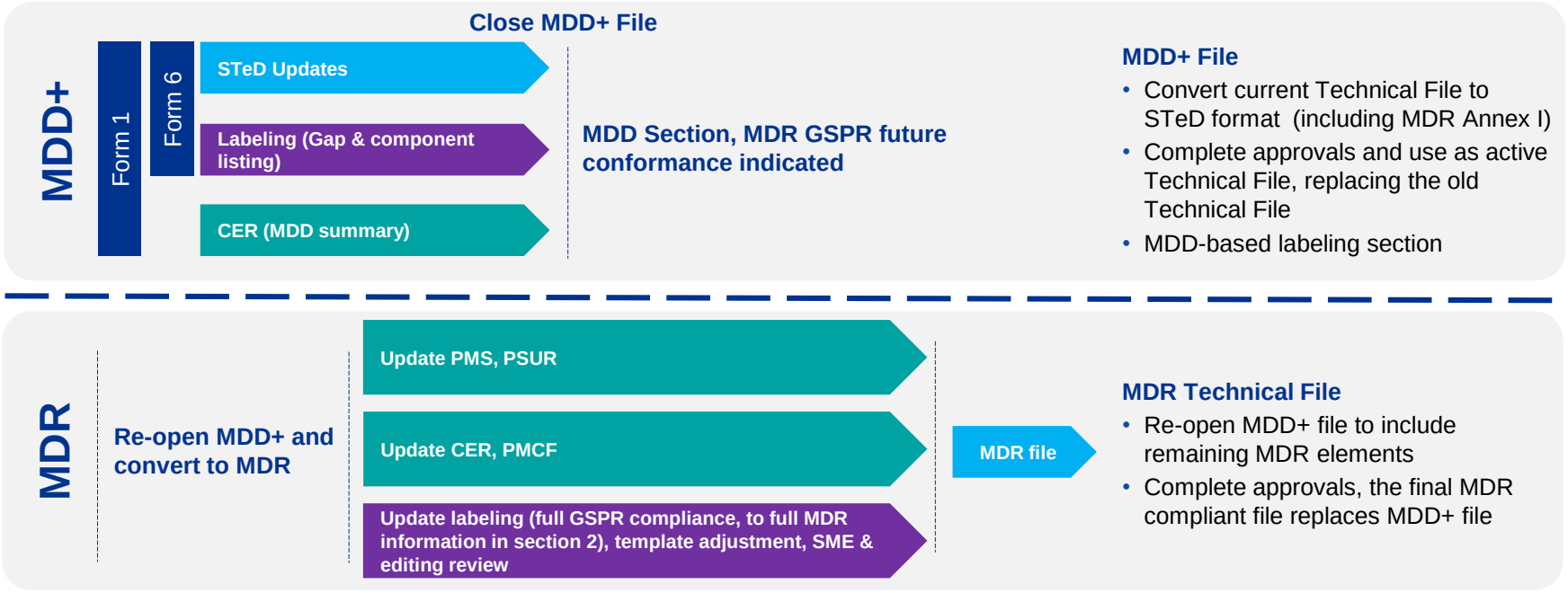
	Phase 1: Project preparation	Phase 2: Implementation of the benchmarking	Phase 3: Results and fields of action
	1-2 Weeks	6-7 Weeks	4-5 Weeks
Activities	— Determine the scope and level of detail for the benchmarking study — Define peer groups and data sources (e.g. selected companies, associations and public agencies) — Create a project plan	**A Recording actual situation** — Status and cost calculation of EU MDR transition in-house **B Interviews for data collection** — Data collection — Comparison of in-house EU MDR transaction costs with peer group	— Analysis of the evaluation results — Identification of the main optimization levers and derivation of specific recommendations for action on the basis of KPMG experiences and references — Realize quick-wins
Output	Presentation of a quality-assured **benchmarking concept**	Submission and presentation of the **evaluation results**	Submission and presentation of the **complete benchmarking study**

Project management

Ensuring and coordinating the continuous communication / coordination with the client as well as a smooth project process

Technical Files Remediation: Reach EU MDR compliance with the KPMG 2-step update strategy

The 2-Step approach for Technical File Remediation: completion of resource mapping, identification of the roles and responsibilities for the affected resources and the development of a plan to update documentation for MDR compliance



Benefits

- Optimal efficiency and use of STeD conversion resources
- Limited time that Technical File remains open

Drawbacks

- Approval/Certification process executed twice

Combat the increased documentation effort with structure: Document Management Systems (DMS)

Challenges

Reclassification

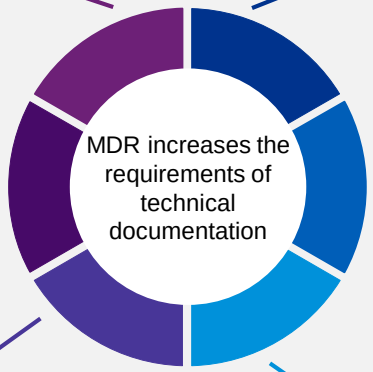
For a variety of medical devices, MDR will require a re-classification, resulting in a significant increase of the amount of technical documentation required

EUDAMED

The manufacturer must provide information to the electronic system EUDAMED on incident reporting, corrective actions, periodic summary reports, periodic safety update reports (PSURs) and trend reports

Quality Management Systems

The documents and records created during the development and production of medical device products are important for demonstrating compliance



Labels and Languages

Some manufacturers treat their user information as controlled documentation and may find it relatively easy to get all these documents organized. However, other firms may have outsourced translation responsibilities to local distributors. Now they must gather these documents and organize them

Clinical Evidence

The new requirements for clinical evidence will increase the documentation effort – especially for class IIa / IIb and III products. Even for products that are already on the market, a clinical evaluation report (CER) and its annual update are required

Periodic Safety Update Report

For class II and III medical devices, a Periodic Safety Update Report (PSUR) must be prepared

Activities

Assessment

- Prepare for interviews with defined stakeholders
- Communicate and review questions for assessment
- Execute interviews and consolidate results
- Define evaluation criteria for a DMS solution based on interviews, document analysis and EU MDR requirements

Proof of Concept

- Define scope and goal of PoC
- Develop evaluation criteria for target DMS
- Evaluate test runs provided by solution providers
- Identify key learnings and specify technical requirements

Implementation

- Identify key learnings and specify technical requirements
- Detailed target picture of DMS implementation
- Implement selected solution

Contract adjustment with cleverness: Contract lifecycle management

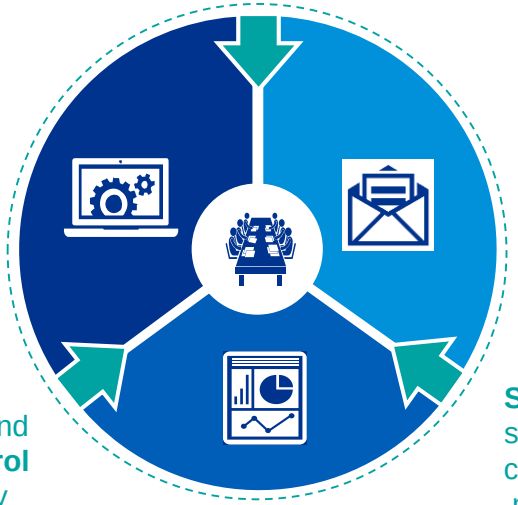
Stringent differentiation between manufacturer and distributor under EU MDR regulation results in new challenges for contract management

- Companies that bring medical devices which they previously bought from “original equipment manufactures” (OEM) into the market under their own brand are known as a "private label manufacturer" (PLM)
- Under EU MDR, existing OEM / PLM relationships are no longer valid. In the future, market players must be classified as either legal manufacturers or as distributors
- The EU MDR requires that the legal manufacturer has full access to the technical documentation
- The legal manufacturer must be identifiable at the label

Which value contribution is generated by contract management?

Standardized and centralized contract and **template management**

Transparent and compliant **archiving** and **analysis** of existing and future contracts



Contract design according to local procurement law and EU MDR regulation

Progress monitoring and **version control** which clearly identifies changes

Simple and **efficient** step-by-step contract creation, enabling for non-lawyers to draft contracts

Transparent and **effective** risk and quality management due to workflow-based contract approval triggers

Legal Support - Our specialist consulting services

Obligations

01

Legal advice to match the legal requirements concerning new obligations on information provision in databases, quality management, risk management, the Post-Market-Surveillance system, the incident reporting system and safety corrective measures in regard to the specific regulatory and general civil product liability requirements in cooperation with colleagues of the KPMG AG

Compliance

02

Implementation of new regulatory requirements into existing compliance management systems (risk assessment, implementation measures, training concept, etc.) in cooperation with colleagues of the KPMG AG.
Training concept in detail: Training of the various business units and responsible persons for the relevant changes (e.g. concerning transparency and traceability, classification rules, UDI, conformity assessments, clinical trials, EUDAMED and Vigilance and tasks of the medical device safety officer

Contracts

03

Draft or adjustment of contracts between OEMs / manufacturers/participants in the distribution chain/authorized agents/importers regard to the new regulations and associated new duties, in particular for marketing under own name (is now considered production with the associated obligations)

Protection

04

Legal advice concerning intellectual property rights (i.e. trademarks, patents, design rights, know-how and copyrights regarding software).
Drafting of licensing agreements and license management.
Evaluation of marketing materials, especially regarding sector-specific requirements like pharmaceutical-advertising law

Computer Systems Validation (CSV)

Sustaining Regulatory Compliance

Policy & Procedures
Detailed analysis of agreements with various regulatory bodies

Global Portfolio of regulatory services across manufacturing, laboratory and enterprise systems in pharma, biotech and medical devices. Framework addressing global and local requirements

Improved capabilities through proprietary **Tools & Accelerators** and robust methodology

Proactive Compliance
Execution of identified regulatory functions with high quality, low cost and increased efficiency

Integration & Harmonization of regulatory and security controls into the overall design of the engagement for a compliant solution

cGxP: Computer Systems Validation

CSV AT A GLANCE

KPMG's CSV service offering proactively manages **regulatory risk, improves quality** in operations and addresses the **overall risk posture** as an integral component of the business strategy. Our principles are based on global **regulatory requirements, industry guidance** and leading **industry practices**. We take a risk-based approach to validation across technologies that encompass business functions as well as the technical aspects.

Activities

cGxP Assessment

- Compliance assessment against USFDA, EMA, MHRA and other global regulations
- Compliance planning and implementation
- New systems assessment
- Legacy system gap analysis
- Risk methodology for risk assessment, controls, communication and review

Validation Services

- Implementation, remediation and revalidation against US FDA
- Training and management of project deliverables to meet regulatory standards
- Design Sop's and regulatory documentation as per GAMP 5.0 and industry best practices
- Infrastructure qualification
- CSV assessments and supplier audits

Validation Testing

- Test strategy, planning and management
- Development of validation protocols - installation qualification, operational qualification, performance qualification
- Test script and requirements traceability matrix
- Test execution and pre and post approvals, documentation
- Qualification reports

EU MDR Workshop & GAP-Assessment

EU MDR Workshop

Client Challenge: A leading global provider of medical products for advanced wound care, ostomy care, continence and critical care as well as infusion devices. Cooperation with 12 suppliers needed to be inspected to achieve appropriate level of conformity and traceability. Decentralized nature of the client organization: new regulation will impact manufacturing sites located a.m. in Europe, North America and Asia Pacific region.

Activities & Deliverables: Support in the EU MDR concept phase, working out the organization structure, defining work streams but also prioritizing product portfolio and planning the program. Assessment of the extracted data from ongoing projects. Development of a roadmap, focusing on clinical, safety, regulatory documentation and other impacted activities in supply chain, quality assurance and IT areas.

Key results: KPMG's advisory and delivery experience on similar projects was an important factor for client which helped to identify gaps or unclear requirements on the work in scope and data that needs to be received.

EU MDR GAP Assessment

Client Challenge: A multi-billion dollar medical device manufacturer in the ophthalmic sector, required assistance in coordinating a gap assessment to gain insights about the MDR legislation, and its associated impact on the organization. The assessment included the evaluation of all functional business areas with an output of a preliminary budget to achieve compliance.

Activities & Deliverables: Coordination of all affected business functions to identify the scope of documents, procedures, SOPs, data, systems, etc. affected by the legislation. The requirements of the legislation were then extracted and mapped to the affected scope areas. Evaluation of business impact from the stakeholder perspective, evaluation of risk and amount of effort required for meeting compliance. Budget reconciliation including capital investments for software and equipment required and development of a recommendations document.

Key results: Documented MDR business requirements checklist and draft budget proposal. Approval supported of the MDR budget across each affected functional area and business unit and creation of the program remediation and implementation framework for pilot execution.

EU MDR Remediation Projects

EU MDR Remediation Pilot

Client Challenge: A global medical technology company, required assistance in coordinating a pilot project to gain insights for achieving MDR compliance across the enterprise ahead of the compliance timeline. The pilot included remediation of 8 technical files and strategy for clinical data sufficiency leading to valuable lessons learned for future execution.

Activities & Deliverables: Identification of GAPs and requirement per each affected area for remediation during implementation. Coordination of the implementation plan with all affected business functions to identify the activities associated with remediation, the team required, cross functional dependencies, and risks associated with achieving remediation. Implementation of a clinical trial evaluation strategy and Technical Files Remediation as well as review with the Notified Body for pre-alignment to help ensure the approach and strategy was consistent with their interpretation of the legislation.

Key results: Successfully remediated Technical Files for compliance with the MDR, requirements and budget approval for MDR remediation activities for 2017 through 2020, achieved alignment with Notified Body on strategies and templates to be utilized for the transition period and development of an enterprise implementation plan to meet compliance.

EU MDR Remediation

Client Challenge: A multi-billion dollar medical device manufacturer in the ophthalmic sector, required assistance in becoming EU MDR compliant across all impacted functions. The three year program involved coordination of a global PMO, remediation for 180 Technical Files and their input documents, economic operators compliance and coordination of global re-registration coordination.

Activities & Deliverables: Global PMO, updating 180 technical files including template development and creation support for STeD, CER, PSUR, PMS plan, SSCP and PMCF, updating QMS, analysis of updates required in manufacturer, importer and distributor definitions, planning for product information management system, defined UDI-DI business rules and application, labeling and re-registration planning and consolidation of other projects with EU MDR (e.g. SKU rationalization, Brexit impacts) as well as Notified Body consolidation.

Key results: Maintenance of two concurrent QMS's (MDD & MDR compliance in parallel) while going through remediation to become fully EU MDR compliant. Update of 165 SOPs. Development of the future-state process for lifecycle and maintenance of the technical documentation, reduction cycle time of CER updates from ~90 days to ~60 days and of regulatory assessments from 2-3 months to 2-3 weeks.

5 | Contact

Why KPMG? We will support your EU MDR/ IVDR project

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