The MDR Compliance Pathway Program

(EUROMCONTACT members)

Training leaves you at the start of your MDR Compliance journey. At ISO Life Sciences we take you all the way to assessment by your Notified Body and we do it for a cost you can afford.

How does this work?

You attend a series of four, three-day workshops and we take you through a structured programme using ISO Life Sciences' proprietary methodology, templates and tools. Before the first workshop we agree 'pilot' materials from your products, documentation and processes and during the workshops we develop MDR-compliant solutions with you using these examples.

In the workshops, using your 'pilot' examples, you will learn and practice how to:

Workshop 1: Determine the gaps between you and the MDR and the impact of those gaps

Workshop 2: Develop solutions to close the gaps and understand the costs

Workshop 3: Plan the implementation and set up Programme Management

Workshop 4: Implement your plan and gain recertification under the MDR

After each workshop you take your worked examples and apply what you have learned and practiced across your business. If you need our support between the workshops to do this, we'll be there for you. If you don't then we'll confirm your work and answer any questions at the start of the next workshop before moving on to the next stage.

At every stage ISO LS will guide you with our experts in Product Development, Clinical, Regulatory, Quality, Post-Marketing, Supply Chain and Programme Management.

> *"We found the ISO LS experts to be both highly knowledgeable and experienced with the new regulations" … Tom Daunt, Executive Director Supply Chain, EAME (Allergan, Medical Aesthetics)*

If you've already started on your MDR Compliance journey then we will validate what you have done to make sure nothing significant has been missed and we will modify the workshops accordingly, we won't ask you to just start again from scratch.

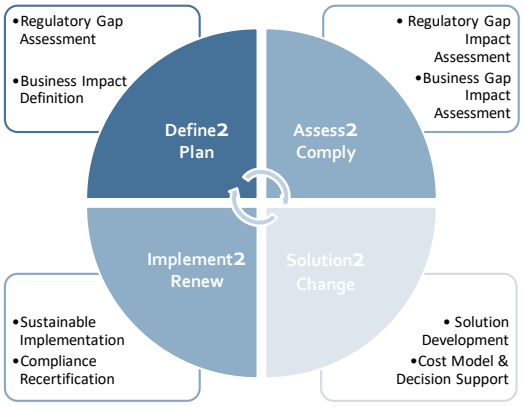
The benefits to your business are:

- We explain the MDR and take you through ALL of the potential impacts which you as a contact lens manufacturer will have to deal with to transition from MDD.
- You work face-to-face with compliance specialists in all aspects of the new regulations (clinical, regulatory, quality, testing, verification & validation, supply chain and post-marketing) and we transfer these capabilities to your organization.
- We help you at a time when experienced and competent technical resources are increasingly expensive and scarce.
- You share the cost with other EUROMCONTACT members in joint sessions whilst maintaining confidentiality in company-specific and private break-out clinics
- We offer flexible options based on individual need – if you require additional support between workshops, we can help.

In more detail…

ISO LS has a proprietary approach and methodology for MDR Compliance that is:

- Highly structured in four stages
- Supported by comprehensive templates and tools
- Guided by experts in Product Dev, Clinical, Regulatory, Quality, Post-Marketing, Supply Chain and Programme Management



ISO LS will support you from gap assessment of all products and impacted processes and systems to submission to your notified Body.

Your Commitments and Preparation:

You commit to the complete sequence of four workshops and identify your representative pilots for your break-out clinics. These pilots will be agreed in advance of workshop 1. You nominate up to five of your people, typically from Regulatory, R&D, Clinical, Post Marketing, Supply Chain and Quality. Your people should attend all four workshops and be responsible for the follow-up work between workshops where you apply what you have learned from your pilots.

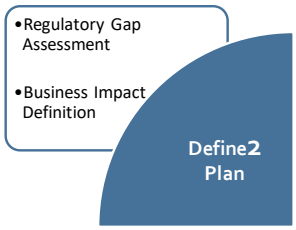
Our Commitments and Preparation:

ISO Life Sciences will assess your current status in MDR compliance and tailor the workshop sessions accordingly. We will provide experts in MDR compliance (Product Dev, Clinical, Regulatory, Quality, Post-Marketing and Supply Chain) and give you access to ISO Life Sciences proprietary templates and tools to support you through your MDR compliance journey.

Workshop clinics are structured into 4 Product clinics (Technical Doc & Labels (Annex I & II), Clinical, Post Marketing (Annex III) and Restricted Substances) and 3 Operations clinics (QMS, Supply Chain (EO, UDI and Traceability), Vigilance & Surveillance).

The four workshops have clear scope, objectives, activities and deliverables, each workshop takes three days:

Workshop 1: Define2Plan



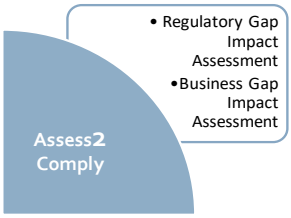
- **Scope & Objectives:** Education and Business Impact Classification
- **Workshop Activities:** ***Training:*** ISO LS MDD/MDR Reference Model & Assessment templates
  Clinics: Your specific 'pilot' assessments
- **Deliverables:** Your specific critical impacts summary
  Completed pilot gap assessment
  Plan to complete full gap impact assessments

Applied Learnings 1: 8-10 weeks to complete gap assessments (supported if required)

"The ISO LS team worked hand-in-hand with our people, were positive and fun to work with which not only progressed us in our journey but also ensured we understood and owned the changes which we felt would be important for long-term sustainability"

……Robert Madjno Global Regulatory, Dentsply Sirona (Endodontics)

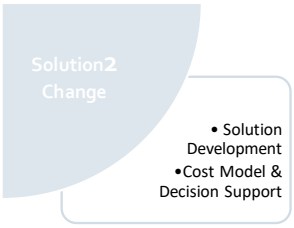
Workshop 2: Assess2Comply



- **Scope & Objectives:** Product & Process Impact Assessment Validation and Solution Development
- **Workshop Activities:** ***Validation:*** Full Gap Assessment Review
  Training: Solution proposal development (ISO LS solution library)
  Clinics: Pilot solutions & costing
- **Deliverables:** Pilot solution proposals & cost estimates
  Plan to complete solution proposal development & costing

Applied Learnings 2: 6-8 weeks to complete solution proposals and costs (supported if required)

Workshop 3: Solution2Change



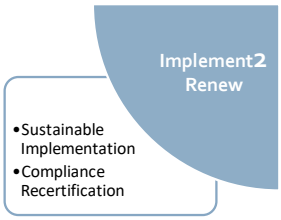
- **Scope & Objectives:** Solution validation and implementation planning
- **Workshop Activities:** ***Validation***: Full solution proposal validation
  Training: Case for compliance (retire, replace or retain)
  Clinics: Implementation planning (sequencing and interdependency mgt.)
- **Deliverables:** Pilot transition plan
  Plan to complete full transition roadmap

Applied Learnings 3: 4-6 weeks to complete transition roadmap and initiate long lead-time compliance activities (supported if required)

"MDR brings a major change to the business. The ISO LS approach is a well-structured approach to take you step by step through the program, ensuring all requirements are being met when completing the sessions"

……MDR Program Leader, Top 10 Global Med Tech (Ophthalmology)

Workshop 4: Implement2Renew



- **Scope & Objectives:** Transition execution and recertification
- **Workshop Activities:** ***Validation:*** Transition roadmap validation
  Training: Pre-assessment preparations
  Clinics: Driven by your priorities
- **Deliverables:** Comprehensive MDR compliance solutions
  Transition Roadmap and PMO framework

Applied Learnings 4: Implement Transition Roadmap and prepare submission to Notified Body (supported if required)

Program Costs

Event	Client Cost € (ex-applicable taxes)	Notes
Workshop 1	€7,750	1. Up to 5 delegates/client 2. *excludes* accommodation costs
Workshop 2	€7,750	
Workshop 3	€7,750	
Workshop 4	€7,750	
Total Cost	€31,500 (ex-applicable taxes)	

Costs are per Medical Device company and include up to five delegates from each company. We can offer the above client rate based on the participation of 10 to 12 Medical Device Companies and attendance at all 4 workshops. Your confidentiality is assured by company-specific break-out clinics working on your representative product, business/quality processes and supply chain information.

On-site support from ISO LS Experts between workshops can be made available as needed by separate negotiation. Each event workshop fee is payable 7 days in advance of the scheduled workshop date.

Program Schedule:

Program Events Schedule	EUROMCONTACT (venue tbc, Brussels)
Workshop 1	3rd-5th April 2019
Applied Learning 1	8-10 Weeks
Workshop 2	5th-7th Jun 2019
Applied Learning 2	6-8 Weeks
Workshop 3	17th-19th July 2019
Applied Learning 3	4-6 Weeks
Workshop 4	TBC
Applied Learning 4	*subject to cohort implementation schedules*

Why choose ISO Life Sciences?

- ISO Life Sciences was formed by partners with extensive experience of the Med Tech and consulting world to offer a tailored proposition for clients looking to undertake change.
- ISO Life Sciences offers a responsive, results-focussed and innovative approach to our clients in partnership with their teams.
- Our experts have an enviable track records, they are all individuals with extensive experience who have successfully responded to the many, diverse changes required in today's MedTech sector.

Contact us:

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