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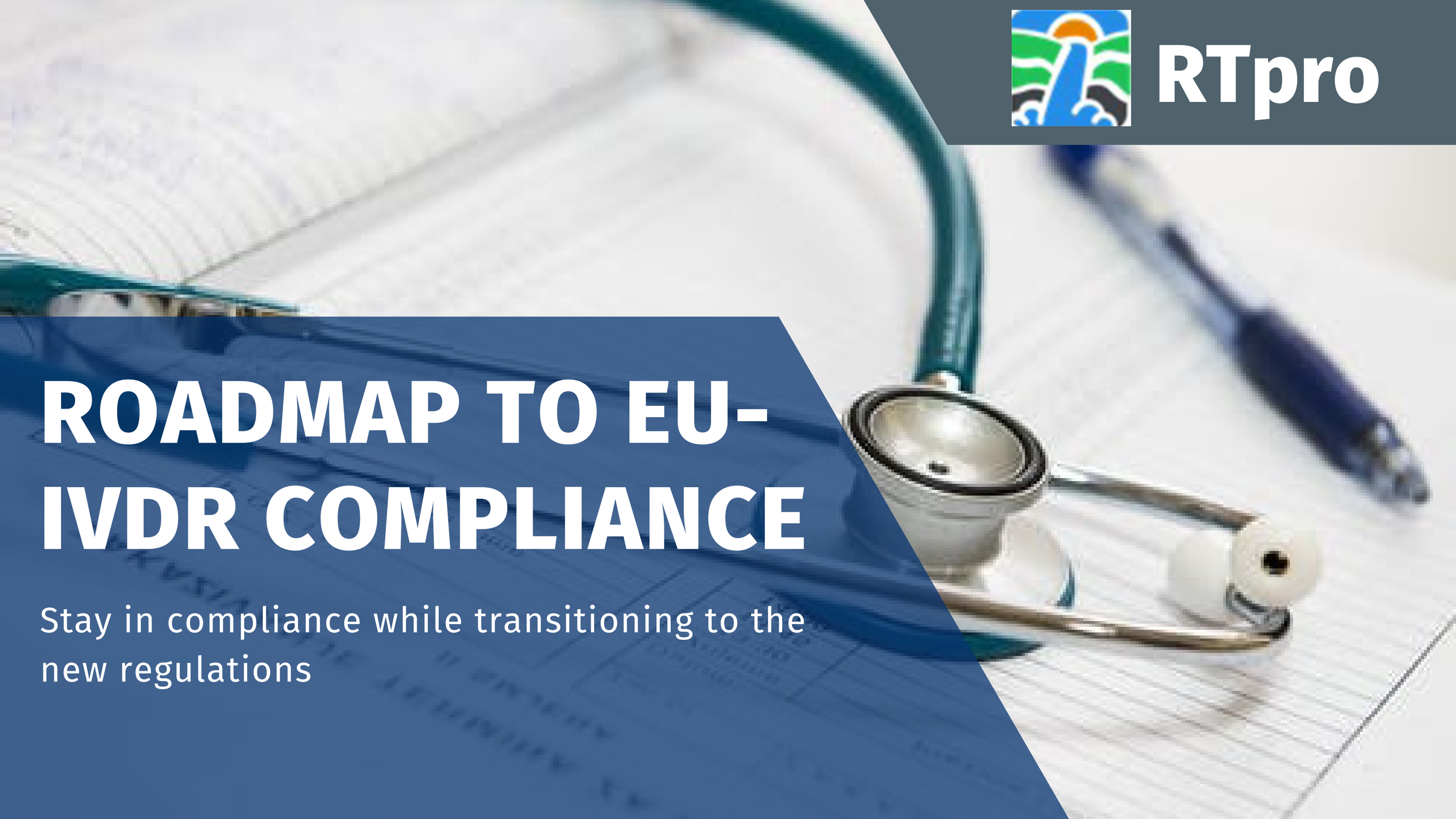
ROADMAP TO EU-IVDR COMPLIANCE

Stay in compliance while transitioning to the new regulations



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Agenda

Part 1: About us

Part 2: Roadmap to IVDR Transition

Part 3: Our Services

Part 4: Our Key Deliverables

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Our goal:

To empower businesses by offering CUSTOMIZED REGULATORY SOLUTIONS

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Why us?

Expertise across sectors

Sound knowledge of National & International Regulations

Dedicated team bring exceptional values to projects

Know Our Team

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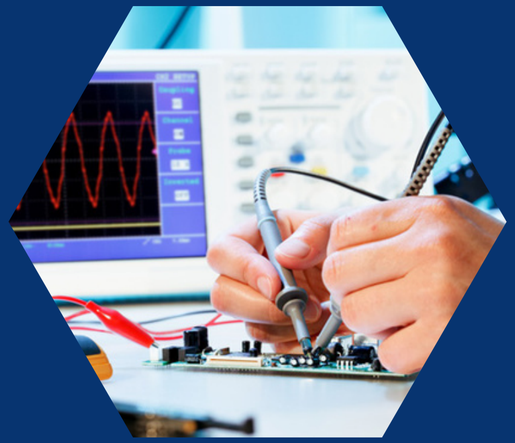
With exceptional teams to provide solutions to be up-to-date with EU-MDR/IVDR transition guidelines

Team - Medical Devices

MDR (EU) 2017/745 Lead Consultant
Technical Specialist (Medical Device)
CQI and IRCA Certified Lead Auditor for ISO 13485:2016 QMS

Team - Invitro Diagnostic Devices

IVDR (EU) 2017/746 Lead Consultant
Global regulation consultant
Technical Specialist (Invitro Diagnostic Device)



Team - Engineering Devices

CE Marking Consultant
Regulatory/Quality Consultant
Global regulatory Auditor

Team Expertise

Gap Assessment (MDD to MDR)

Performance Evaluation

Post Market Surveillance Report (PMSR)

Technical File Remediation

Summary of Safety and Clinical Performance (SSCP)

Clinical Evaluation Plan (CEP)/Report(CER)

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OUR ROADMAP TO EU-IVDR TRANSITION

How do we help you to get there?

We have a seven-step plan to make this transition happen

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MDR & IVDR IMPLEMENTATION MODEL

1

SCOPE & PLAN

Checklists/Benchmark

2

GAP ASSESSMENT

Impact assessment checklist for product & QMS

3

MASTER COMPLIANCE ROADMAP

Implementation plan/Resource requirement/Prerject charter

4

EU-IVDR COMPLIANCE

Notified body checklist

5

EFFECTIVENESS CHECK

Audits

6

IMPLEMENTATION OF ROADMAP

Plan progress sheet/status dashboard

7

REGULATORY TRAINING

Workshopds/ Training

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OUR SERVICES

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These are our services we offer, an end to end regulatory solution

REGULATORY SUPPORT

- End to end support for all regulatory requirements applicable for the product life cycle
- Product understanding and identification of regulation and standards for the product
- Technical gap assessment as per applicable standards and regulations
- Approach for regulatory submission, classification, reclassification of devices
- Assessment and compliance for global regulations applicable to reagent instruments and software

TECH FILE REMEDIATION

- Gap assessment and remediation of the below technical files against standards and regulatory requirements
- Device description and specification
- Information to be supplied to the manufacturer
- Design and manufacturing information
- General safety and performance requirements (GSPR)
- Benefit risk analysis and risk management
- Product verification and validation
- Remediation SOP and templates

PERFORMANCE EVALUATION

- Performance studies performed as per CLSI standards and global best practice criteria
- Preparation of plan and report for performance evaluation as per
- Scientific validity report strategic assessment of analytes to formalize the approach
- Analytical performance: preparation of study plan, testing, data analysis and report as per standards and global best practice criteria
- Clinical performance: preparation of study plan, testing, data analysis and report as per the intended clinical use of the device

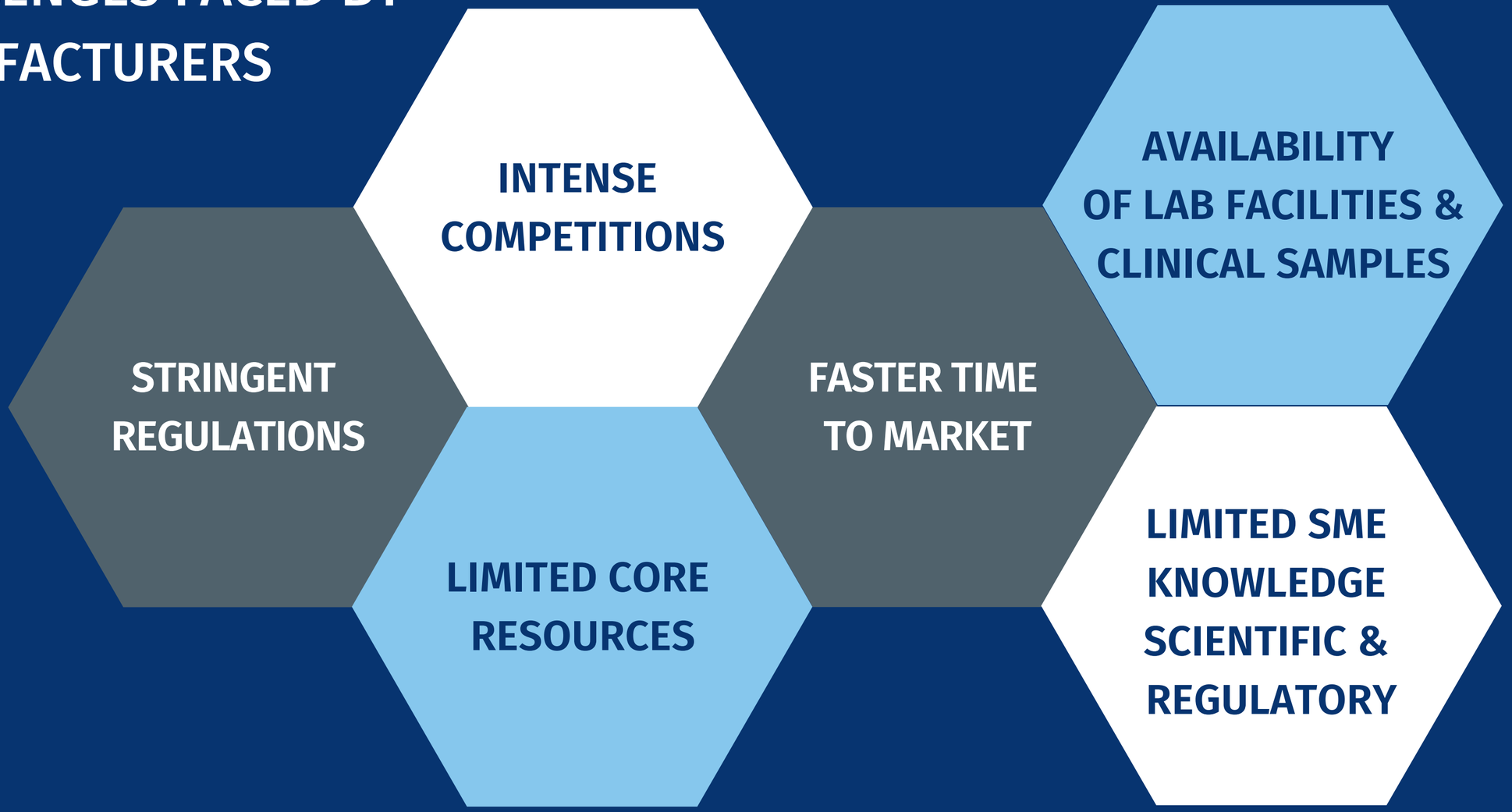
POST-MARKET SURVEILLANCE

- Update PER annually or whenever it is required
- Support for field safety corrective action
- Implement trend reporting
- Preparation of post market surveillance plan and report (class A & B)
- Preparation of periodic safety update report (class C & D)
- Conduct post market performance follow up studies (plan and report)
- Preparation of summary of safety and performance report
- Vigilance support

OTHER RELATED SERVICES

- Stability testing (onboard, stress, real time and in use testing)- preparation of stability plan, testing, data analysis and report
- Gap analysis of existing QMS (SOP, work instruction, checklist, template) with the new IVDR and ISO 13485:2016 requirements process for compliance
- Evaluations can be carried out to extend the claimed period
- Support during NB submission, response to NB comments and resubmission support
- Risk management file (RMF)- updated based on compliant data and clinical evaluation as per IVDR

CHALLENGES FACED BY MANUFACTURERS



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OUR KEY DELIVERABLES

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- PERFORMANCE EVALUATION PLAN
- SCIENTIFIC VALIDITY REPORT
- ANALYTICAL PERFORMANCE REPORT
- CLINICAL PERFORMANCE REPORT
- PSUR (CLASS C& D - WITH PMPF)
- PERFORMANCE EVALUATION REPORT
- PMS PLAN (WITH PMPF)
- PMS REPORT (CLASS A & B - WITH PMF)
- SSP (CLASS C & D)
- STABILITY REPORT PREPARATION
- DEVICE DESIGN DOCUMENT PREPARATION
- REDLINING OF IFU, LABEL & RMF
- IDENTIFYING THE GAPS FROM SOURCE DOCUMENTS
- GSPR CHECKLIST PREPARATION
- STED PREPARATION AND COLLATION

Thank you!

CONTACT US

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