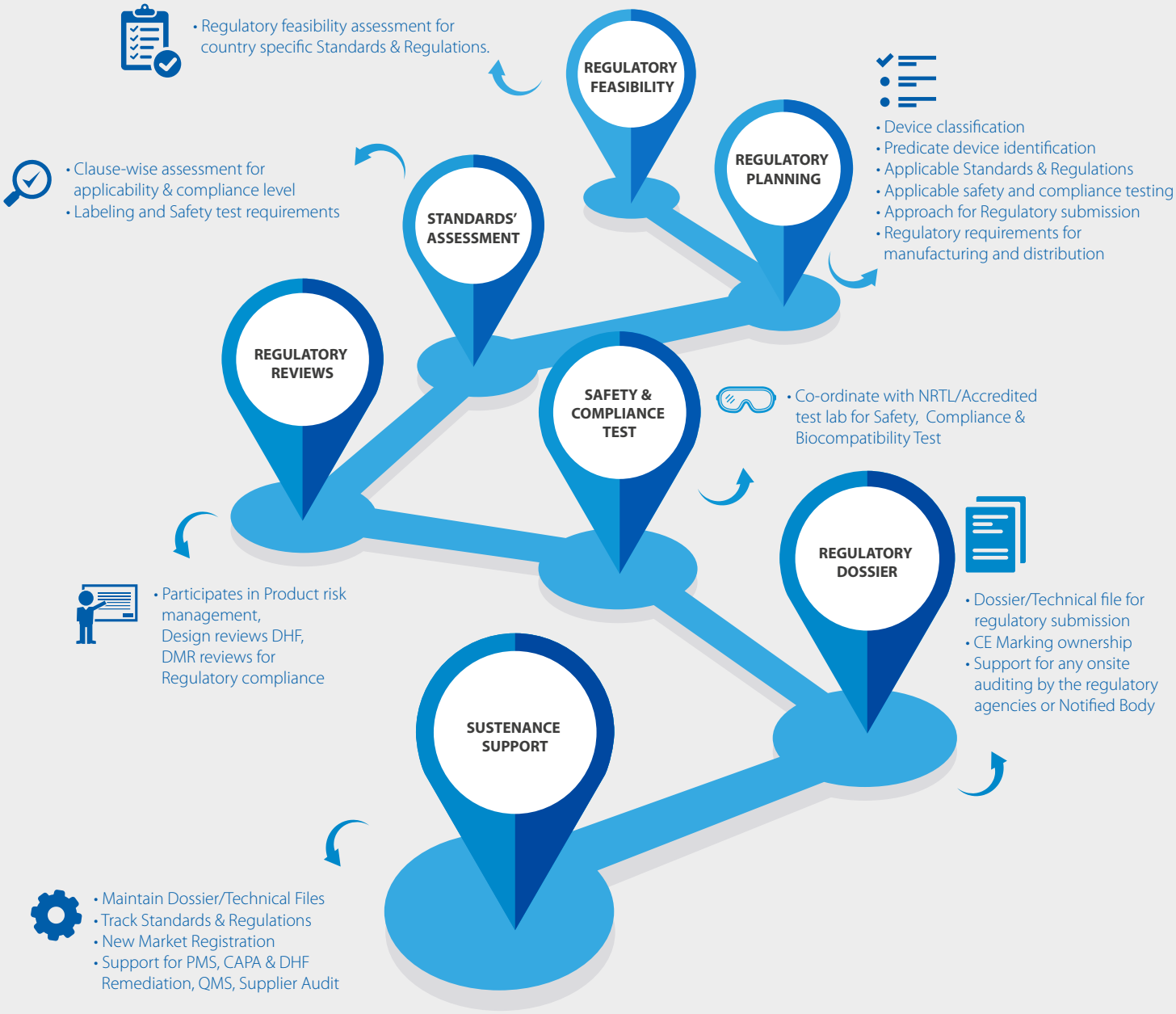
HCL REGULATORY COE PROVIDES AN END-TO-END SERVICE



NEW MDR/IVDR REGULATIONS

Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMD)

Council Directive 93/42/EEC on Medical Devices

Medical Devices Regulations 2017/745

Council Directive 98/79/EC on In Vitro Diagnostic (IVD) Medical Devices

In Vitro Diagnostic Regulations 2017/746

3 Years, 26 May 2020 | Transition Period | 5 Years, 26 May 2022

MDR/IVDR IMPACT

Classification Rules	Conformity Assessment	Identification and Traceability	Clinical Evaluation, PMS	GSPR General Safety & Performance Requirement
• New classification system MDR-22/IVDR -7 • Rules modified and added for classification • Specific rule for software classification	• Commission Assessment (MDCG) for High Risk Device	• Unique Device Identification (UDI) introduced with mandatory implementation as per defined timeline for various class of products • Product registration , review and safety reporting through EUDAMED after a decided time • Summary reports availability to public for specific products	• Post market clinical/ performance follow up enforced • Trending of adverse event and updating of risk files accordingly enforced • Reporting of adverse event, field safety corrections	• Conformity with new GSPR • New requirements related to Material compatibility , IT network, Cybersecurity, Mobile platforms, Usability, Home healthcare • Emphasis on pre launch and post launch risk management activities

PROPOSED APPROACH FOR MDR/IVDR COMPLIANCE

Consolidate List of Products impacted (Devices placed in EU Market)	**Review and confirm the impacted product list**	**Obtain access to Tech File, DHF, Risk Management File, QMS documents**	**Assess Product Tech File & Risk Management File for MDR requirements**	**Assess QMS for revisions to address MDR requirements**
Submit TechFile to Notified Body for new certification	**Review and Approve updated documents**	**Implement the Remediation plan** **e.g. Update QMS, DHF, TechFile, labeling, DMR**	**Review and Approve the Remediation plan**	**Estimate and propose Remediation plan to address additional requirements**
Address findings if any from Notified body	**Maintain CE Marking certificate and TechFile**	**Perform PMS, Trend Analysis, PMCF**		

BUSINESS BENEFITS OF WORKING WITH HCL

- On time compliance with
  - Re-usable components
  - Best practices across accounts
  - India Time zone advantages
  - Swift team scale up
- Cost savings with India offshore team
- Potential Process improvements

HCL DIFFERENTIATORS

- Dedicated Regulatory Centre of Excellence(COE) with relevant skills sets
- 10 plus years of proven experience in Tech File & DHF Remediation
- We bring our deep understanding of US FDA Regulations to MDR which it closely mirrors in requirements.
- Hands-on experience helping our customers through other regulatory changes for eg. ISO 13485, ISO 14971, IEC 60601x, IEC 62304, UDI, Cybersecurity, Mobile Medical Apps (MMA) et al.

Hello, I'm from HCL's Engineering and R&D Services. We enable technology led organizations to go to market with innovative products and solutions. We partner with our customers in building world class products and creating associated solution delivery ecosystems to help bring market leadership. We develop engineering products, solutions and platforms across Aerospace and Defense, Automotive, Consumer Electronics, Software, Online, Industrial Manufacturing, Medical Devices, Networking and Telecom, Office Automation, Semiconductor and Servers & Storage for our customers.

For more details contact: rmakesh@hcl.com
Follow us on twitter: http://twitter.com/hclers and our blog http://www.hcltech.com/blogs/engineering-and-rd-services
Visit our website: http://www.hcltech.com/engineering-services/

HCL

BI-103224313770689-EN00GL