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Value | Acceleration | Compliance

IVDR

THE COUNTDOWN IS ON! ARE YOU READY?

The new In Vitro Diagnostics Regulations(EU-IVDR) brings a number of significant changes, putting pressure on all In Vitro Devcies Companies to closely examine the Regulation, assess the impact it will have on their own organization, and implement compliant processes and procedures accordingly. With limited time until 2022, it is critical to swiftly go around devising new regulatory strategies in order to move forward efficiently and in time.

HCL is the one-stop answer to all your IVDR needs - assessment, prioritization, transformation

IVDR MDR COMPLIANCE CHALLENGES

TRANSITION STRATEGY

- Create efficiency by grouping products based on intended use & risk class
- Prioritization of the products on the basis of revenue forecast and effort estimated for compliance
- Evaluate the option of “Do-It-Yourself” vs managed services
- Select the right partner for your journey

PRIORITIZATION OF PRODUCT PORTFOLIO

- **Product remediation planning** based on business criticality of the product, validity of existing Certificates, optimal use of the grace period, and availability of robust performance data

MASSIVE DOCUMENTATION AND LABELLING UPDATES

- IVDR requires re-writing of all chapters of Technical Files, creation of new documents such as PERs, PMS and PMPF Reports, PSURs, GSPR compliance checklist reports, updating of existing documents such as RMRs and updates of all labels and IFUs
- Manufacturers have historically underemphasized generation of sufficient clinical evidence and Post-Market Surveillance,, necessitating additional activities in this area

READINESS & AVAILABILITY OF NOTIFIED BODIES BREXIT IMPACT

- Currently, Notified Bodies are focused on Medical Device related changes that have a shorter time-line to meet compliance
- Only a limited number of Notified Bodies is planning for IVDR designation

INTERPRETATION OF REQUIREMENTS

- EU Commission guidance
- Report templates not yet available
- Different interpretations from Notified Bodies
- EUDAMED data requirements not yet to be finalized

IVDR IMPACTS ALL AREAS OF THE BUSINESS

REGULATORY

- All Technical Files need a new DOC, updating to the new format, include new chapters such as a Post Market Surveillance Plan, new performance and on-market safety related reports
- Introduction of risk-based classification of IVDs
- The new GSPR introduce additional requirements related to scientific validity, performance characteristics, risk-benefit analysis and labelling

R&D

- State of the art compliance to latest version of standards
- Analytical studies to be compliant with CLSI guidelines
- Stability Programs for Specimens, Reagents, Controls and Calibrators
- Technical documentation
- No grandfathering!

CLINICAL

- Clinical utility needs to be defined for IVDs, additional clinical studies may be required to demonstrate clinical utility
- Scientific Literature data can be used to support the requirement for clinical evidence
- SSP for Class C and D devices

LABELING

- All labelling needs updating to include UDI, hazardous substances
- Language requirements increase the need for translations
- IFUs, package inserts need to include more information related to safety, warnings, residual risks, performance, clinical benefits etc.
- Kits that include third party devices will need specific labeling

MEDICAL SAFETY

- Enforced post market surveillance with feedback into risk management and labelling
- Post Market Surveillance Plan required for all IVDs
- Implementation of trend reporting
- Periodic Safety Update Reports to be published annually (Class C and D IVD devices)
- Timeline for reporting of adverse events reduced from 30 to 15 days.

SUPPLY CHAIN

- Supply chain has to be mapped out to identify the economic operators: Importer, Distributor, Authorized Representative
- Contracts need to be in place to ensure obligations of the different players are met
- Master data for EUDAMED SKU registration (approximately 60 data points) need to be captured and maintained
- Person responsible for Regulatory Compliance to be Identified from Manufacturer and Authorized Representative organizations

QMS

- QMS needs significant updates
- Planning & managing recertification audits
- Building relationship with a Notified Body

HCL CAPABILITY IN IVD SPACE

REGULATORY

- 200+ member Regulatory Center of Excellence with average domain experience of 10+ years
- Experience across in vitro diagnostic devices and implantable devices
- Established relationship with global Notified Bodies including TUV, UL, BSI

CLINICAL

- 150+ Medical Writers with experience in developing search strategies, literature-based clinical evidence and Performance Evaluation Reports (for IVDs), Clinical Evaluation Reports (for Medical Devices)
- Worked with top 10 medical device and IVD companies on submissions in the USA, Europe and Australia
- Access to a network of clinicians throughout India and USA

Product Development

- 42 years of product engineering experience, 18+ yrs in Medical Device and IVD space
- Experience across all risk classes of IVD devices
- DHF remediation experience with MD/IVD customers

Quality

- Best-in class Medical Quality Management Systems and Processes, compliant to ISO 13485, ISO 14971, 21 CFR Part 820
- Definition of QMS process, build a QMS system
- Ability to conduct independent QMS audit

IVDR TRANSITION PROGRAM – HCL APPROACH

PHASE 1

Assessment

- Collect List of impacted Products (IVDs placed on EU Market)
- Assess QMS, existing Technical File, Product DHF, DMR, RMR, Product Labelling, Performance and Stability data => map against IVDR requirements, identify gaps
- Ensure compliance to latest versions of applicable standards, identify gaps.

Pilot & Planning

- Pilot Remediation of representative Technical File(s) => rewrite chapters, generate new reports
- Validation with NB,
- Plan for Implementation Phase

PHASE 2

PHASE 3

Remediation and CE Marking

- Implement the Remediation plan
- Update the QMS, DHF, DMR, Technical File chapters including PER, labeling, and RMR
- Creation of PSUR,PMS Plan and Report, PMPF, SSCP)
- Supply chain mapping and economic operators remediation
- Data gathering & submission to EUDAMED
- Audit preparation and planning

Lifecycle Management

- Maintain DHF, Technical File
- Post-market Surveillance activities including periodic updates to PMPF, PSUR
- EUDAMED data maintenance

PHASE 4

HCL IVDR PROGRAM SETUP AND DELIVERABLES

PROGRAM GOVERNANCE

Program planning, establish meeting cadence with client, align on periodic dashboard updates, KPI reporting, coordination between functional workstreams

Proposed Program Workstreams (Engaging Cross-functional Client Team Members)

Regulatory

- Technical file gap assessment across all chapters
- IVD classification
- Basic UDI-DI strategy

R&D

- DHF review
- GSPR compliance
- Standards assessment
- Analytical studies per CLSI guidelines
- Stability of Specimens, Reagents, Controls and Calibrators

Clinical

- Clinical Validation per CLSI guidelines
- Post Market Performance Follow Up Plan and Report
- Summary of Safety and Performance
- Literature search to establish scientific validity of analytes/assay parameters and generate clinical evidence for product

Labeling

- Label and IFU assessment and updates
- UDI Implementation

Technical Support

- Post Market Surveillance Plan and Report
- Periodic Safety Update Report
- Trend reporting SOP and template
- Assessment of Complaint handling process, Field Safety Corrective Action, CAPA process

Supply Chain

- Supply chain mapping
- Contract templates for economic operators
- EUDAMED UDI master data identification
- RACI matrix to ensure Regulatory Compliance

Quality

- QMS assessment, SOP updates, new SOP creation
- Notified Body (NB) recertification, audit preparation and NB reviews

HCL TOOLS AND TEMPLATES FOR SEAMLESS EXECUTION

CHECKLIST AND TEMPLATES

- Technical File assessment checklist
- General Safety and Performance Requirements (GSPR) checklist
- Labelling assessment checklist
- IFU assessment checklist
- Checklist for Performance Evaluation
- Risk management checklist
- Performance Evaluation Report template
- Scientific Validity Report template
- PMS-Plan and Report templates
- Post Market Performance Follow Up (PMPF) templates
- Periodic Safety Update Report (PSUR) template
- Summary of Safety and Performance (SSP) template

IVDR RELATED EXPERIENCE

- Developed and refined gap assessment templates, defined gap types, scoring matrix based on projected remediation effort
- Completed Pilot gap assessment of ~ 75 Technical Files (reagents, calibrators, controls, accessories, instruments or platforms) with multiple clients
- Generated templates and content of various reports as a part of Technical File transformation
- Led IVDR Technical File gap assessment/remediation related working sessions, involving cross-functional team members from Regulatory, Clinical, Quality, Technical Product Development, Medical Affairs & Biostatistics

FOR MORE INFORMATION, PLEASE CONTACT

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