Growth partnership for a self-care centric lifestyle

Innovation | Acceleration | Growth

Regulatory CoE – Service offerings

Regulatory CoE – Service offerings

Regulatory service throughout product lifecycle

Regulatory strategy | Design for compliance | Tech file preparation

50+ global regulations

Supports for global regulatory compliance | 250 + localization

EU MDR / UKCA MHRA

Track global regulations | Work stream | Process framework for remediation

Working relationship

NB like BSI, TUV SUD/ Rheinland, DEKRA, Intertek | NRTL/GLP accredited labs for safety and materials testing

Track standards and regulations

Global matrix | Track new/changes | Impact assessment | Remediation strategy | 1200+ std assessed

Compliance management

Remediate QMS and tech file for latest standards and regulations like MDSAP, MDR, IVDR

Support for agency/NB findings

For NC, #483, warning letter investigation from RA perspective | Propose and implementation of CAPA

Competent team

Working experience in regulatory environment | 350+ Core RA FTE | 2500+ trained resources

Design for compliance

Global regulatory strategy

Considering the country-specific agency, the complexity of regulation, process, dura-tion, the similarity of regulations, acceptance of other country approval, etc. HCL grouped countries as below:

Group A: European Union

Countries covered under European regulation (MDR/IVDR):
Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Norway, Hungary, Italy, Lithuania, Netherlands, Poland, Portugal, Romania, Spain, Sweden, Turkey, Ireland, United Kingdom.

Group B: Separate approval

Countries where specific regulations and regulatory agency exists for device approval.

Example:
Brazil, Canada, China, India, Japan, Republic of Korea, Russian Federation, and the USA

Group C: Apply with other RA approval

Countries less processing effort with CE Marking/ USFDA approval. Apply for registration with necessary documents.
Example:
Australia, Belarus, Columbia, Egypt, Hong Kong, Indonesia, Israel, Kazakhstan, Malaysia, Mexico, Philippines, South Africa, Taiwan, Thailand, and UAE.

Group D: No/Limited regulation

Countries where there is no/limited regulation for medical devices as of now.

Example:

Pakistan, Sri Lanka

Example:

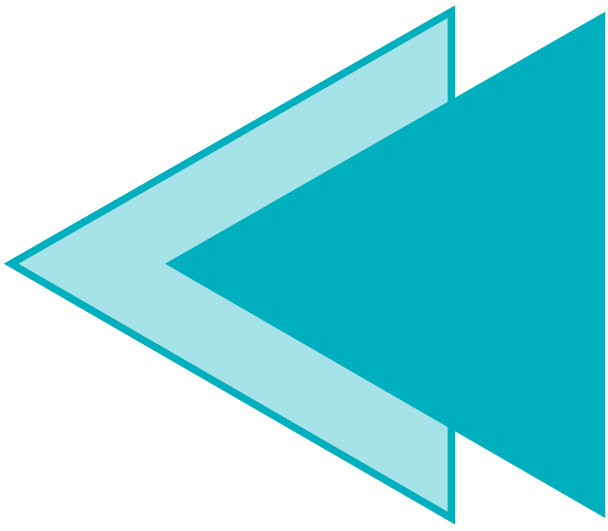
Below is the suggested way of implementing this regulatory affairs strategy:

- Prepare **regulatory plan**, identifying regulatory requirements, approach and schedule;
- Register and market in **USFDA** and Health **Canada** (Group B);
- Register and market in China, Japan, Korea, and Russia (**Group B**)
- Register and market in countries (**Group C**) where USFDA approval is accepted;
- Register and market in **Group D**.

List of countries HCL supports for regulatory submission

S. No:	Region	Technical documentation + Regulatory submission	Tech Doc. + Joint ownership for Reg. submission	Joint ownership for Tech doc. +Regulatory submission
1	APAC	6	16	27
2	EMEA	20	36	62
3	ASEAN	5	6	0
4	LATAM	3	5	23
5	USA	1	0	0
6	Canada	1	0	0

- **Technical documentation + Regulatory submission:** Preparation of all regulatory documentation (technical file, Declaration of Conformity, etc.) and submission to regulatory authority will be fully owned by HCL.
- **Tech Doc. + Joint Ownership for Reg. Submission:** Preparation of regulatory documentation will be owned by HCL and submission to regulatory authority will be jointly owned along with the customer.
- **Joint Ownership for Tech Doc. + Regulatory Submission:** Preparation of regulatory documentation and submission to regulatory will be jointly owned along with the customer.



Standard tracking / Watch-Input-Task- approach

Inputs

- List of products and launch details
- Device descriptions with details of intended use
- Access to standards (log in account)
- Access to regulatory requirements for each

Task

Regulatory/standards matrix:

- For each product and country it was placed, identify the latest and applicable standards and regulations
- Prepare regulations/standards matrix
- Get the regulations/standards matrix reviewed and approved by stakeholders

Track regulatory/standards matrix:

- Subscribe to respective standards developing organization (SDO)
- Monitor respective SDO and country-specific office site for any new/revised standards and regulations

Review new/reviewed regulations/standard:

- For any new/revised standards and regulations, review the standards for applicability/changes
- Notify outcome of the review to stakeholders - process and/or product owners

Regulations/standard impact assessment:

- Conduct impact assessment due to new/revised standards and regulations
- The impact may include QMS and product level
- Notify outcome of the assessment to stakeholders – process and/or product owners

Action plan:

- Based on the impact assessment, prepare an action/remediation plan, if applicable
- Share the action/remediation plan with stakeholders for further actions

Maintain updated regulations/standards matrix:

- Maintain updated standards matrix for any new/revised standards and regulations and for any new geo launch

Output

- Regulation/standards matrix
- Regulation/standard review report
- Regulations/standard impact assessment
- Action plan

Case study - Global standards database maintenance and impact assessment

Business objective

- Assess regulatory compliance for a range of medical devices
- Maintain updated standards database
- Conduct impact analysis for new/changed standards

HCL solution

- Establish and maintain standards matrix for each product families with geo-specific latest and applicable standards and regulations
- Complete impact assessment for any new or revised standards and regulations

Scope of work

- Standards' applicability **assessment** (clause-wise assessment)
- Identification of **labeling** requirements – IFU and label (which includes symbols)
- **Compliance level assessment** based on design and test reports

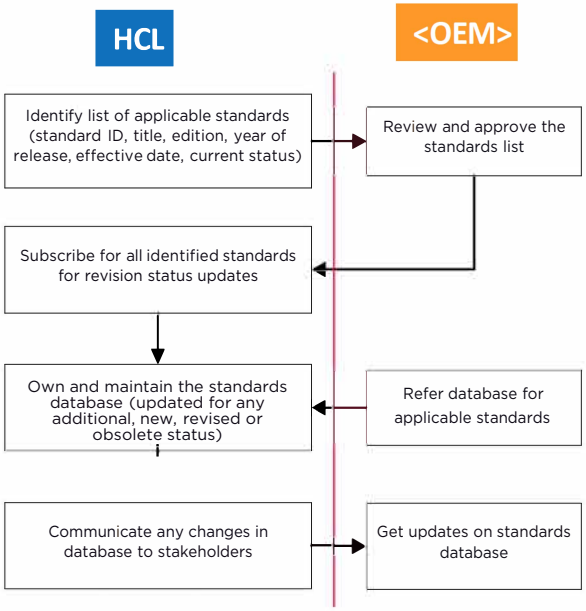
Target market

- **15+** countries, including USA, EU, China, Japan, Canada.

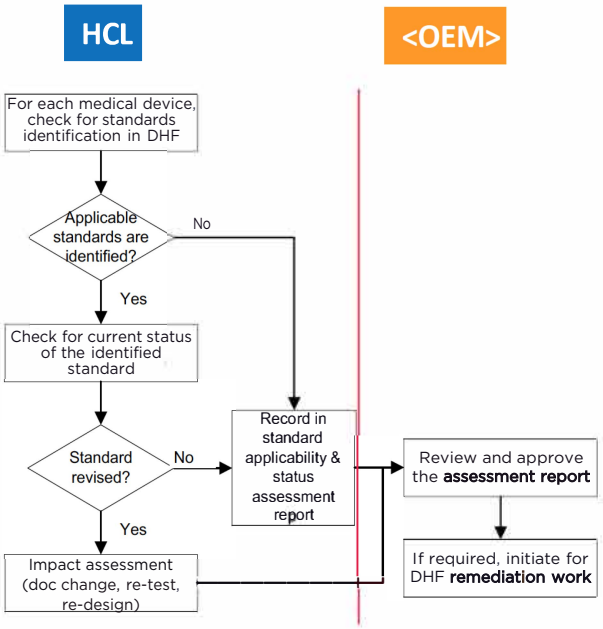
Outputs

- List of applicable standards
- Standards assessment report
- Compliance assessment report
- Labeling requirements

Global standards identification



Standards' assessment



Case study - regulatory compliance - standard management system

Scope:

- **Monitoring** standards database
- **Assessment** of the change between the existing and the new version of the standards
- Assessing the **implication** of the change with the product compliance
- Proposing the **action plan** for complying with the revised standard

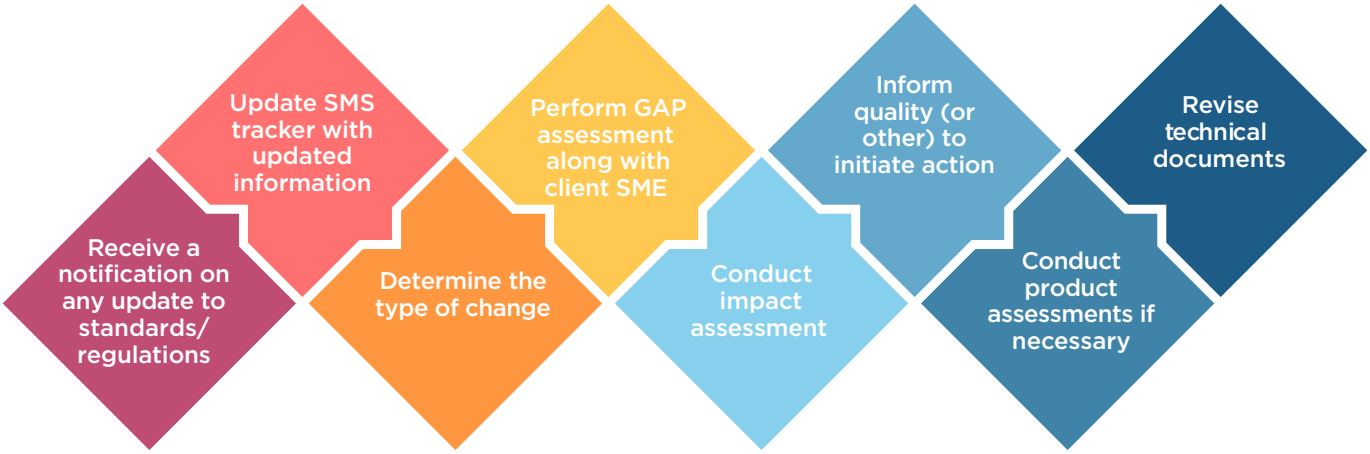
Global standards database:

- Number of products: **150+**
- Number of standards: **1000+**

Duration and resource:

- 1 regulatory consultant

Process:



FOR MORE INFORMATION, PLEASE CONTACT

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