Growth partnership for a self-care centric lifestyle

Innovation | Acceleration | Growth

Regulatory CoE – Service offerings

Regulatory CoE – Service offerings

Regulatory feasibility → Regulatory planning → Standards' assessment → Regulatory reviews → Safety and compliance test → Regulatory dossier and submission support → Regulatory monitoring and compliance sustenance

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.
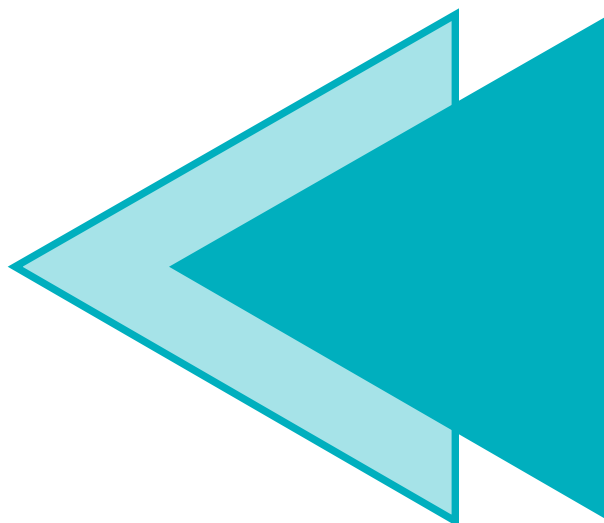
Standard tracking / Watch-Input-Task- approach

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)
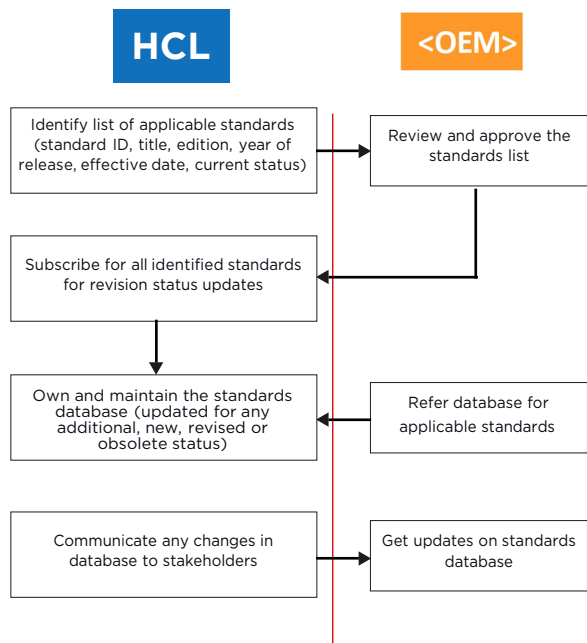- **Compliance level assessment** based on design and test reports

Target market

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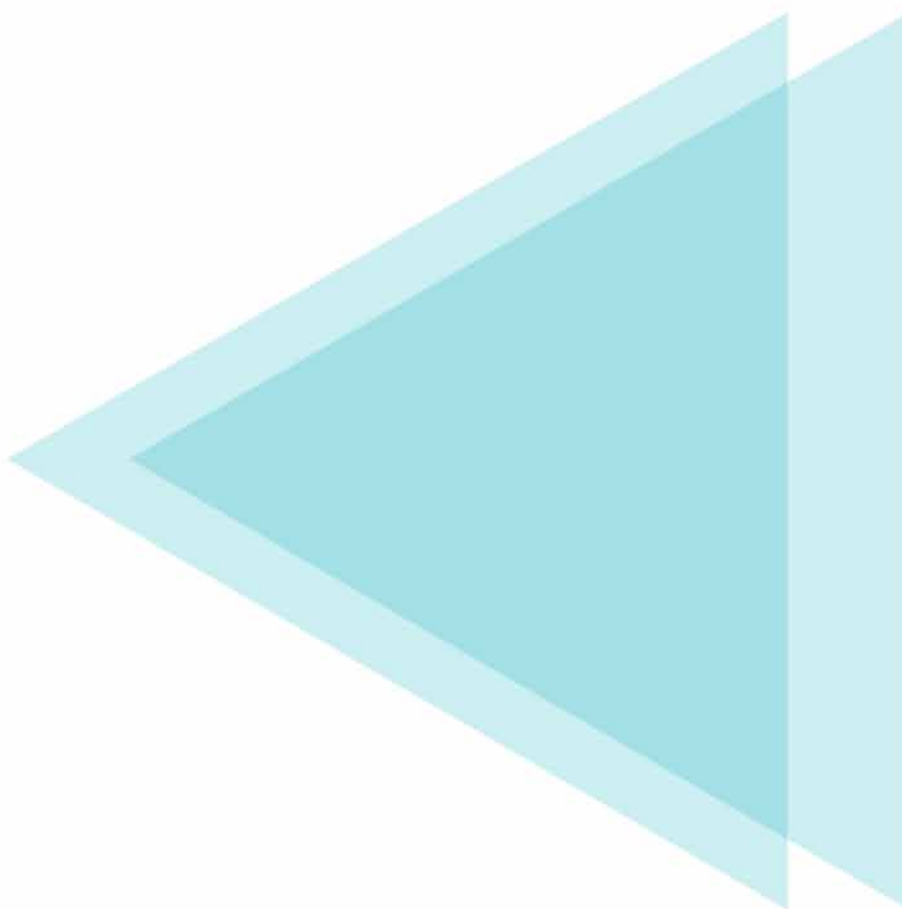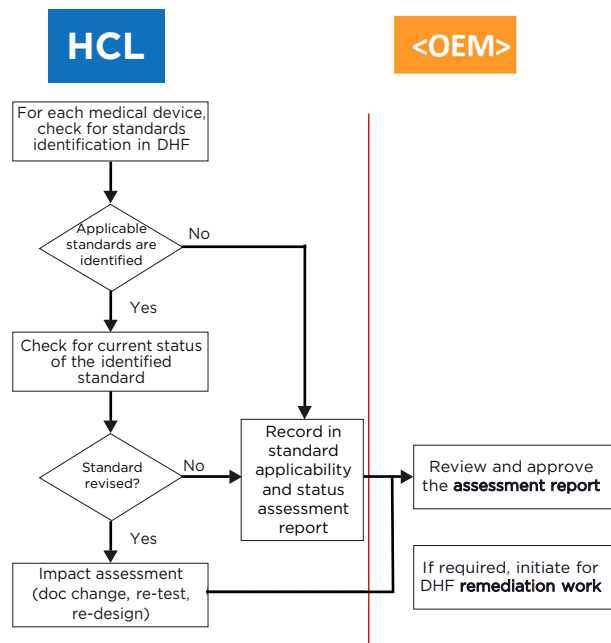
Outputs

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

Global standards identification

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<OEM>

Identify list of applicable standards (standard ID, title, edition, year of release, effective date, current status)

Review and approve the standards list

Subscribe for all identified standards for revision status updates

Own and maintain the standards database (updated for any additional, new, revised or obsolete status)

Refer database for applicable standards

Communicate any changes in database to stakeholders

Get updates on standards database

Standards' assessment

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For each medical device, check for standards identification in DHF

Applicable standards are identified — No

Yes

Check for current status of the identified standard

Standard revised? — No

Yes

Record in standard applicability and status assessment report

Impact assessment (doc change, re-test, re-design)

Review and approve the **assessment report**

If required, initiate for DHF **remediation work**

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
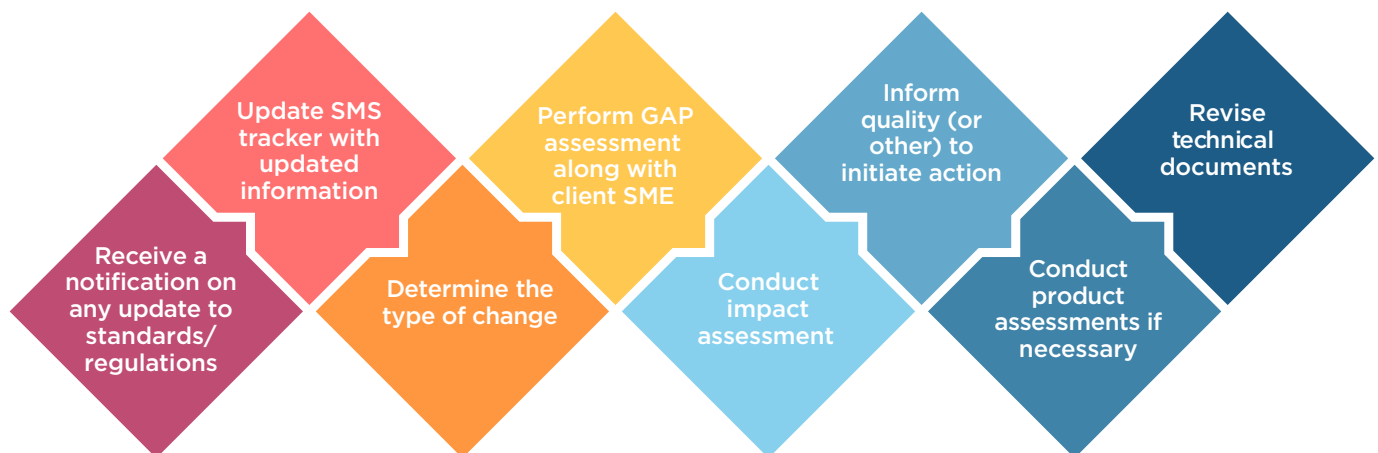- Proposing the **action plan** for complying with the revised standard

Global standards database:

- Number of products: **150+**
- Number of standards: **1000+**
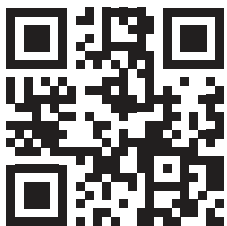
Duration and resource:

- 1 regulatory consultant

Process:

- Receive a notification on any update to standards/regulations
- Update SMS tracker with updated information
- Determine the type of change
- Perform GAP assessment along with client SME
- Conduct impact assessment
- Inform quality (or other) to initiate action
- Conduct product assessments if necessary
- Revise technical documents

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