**ELLECOM®**
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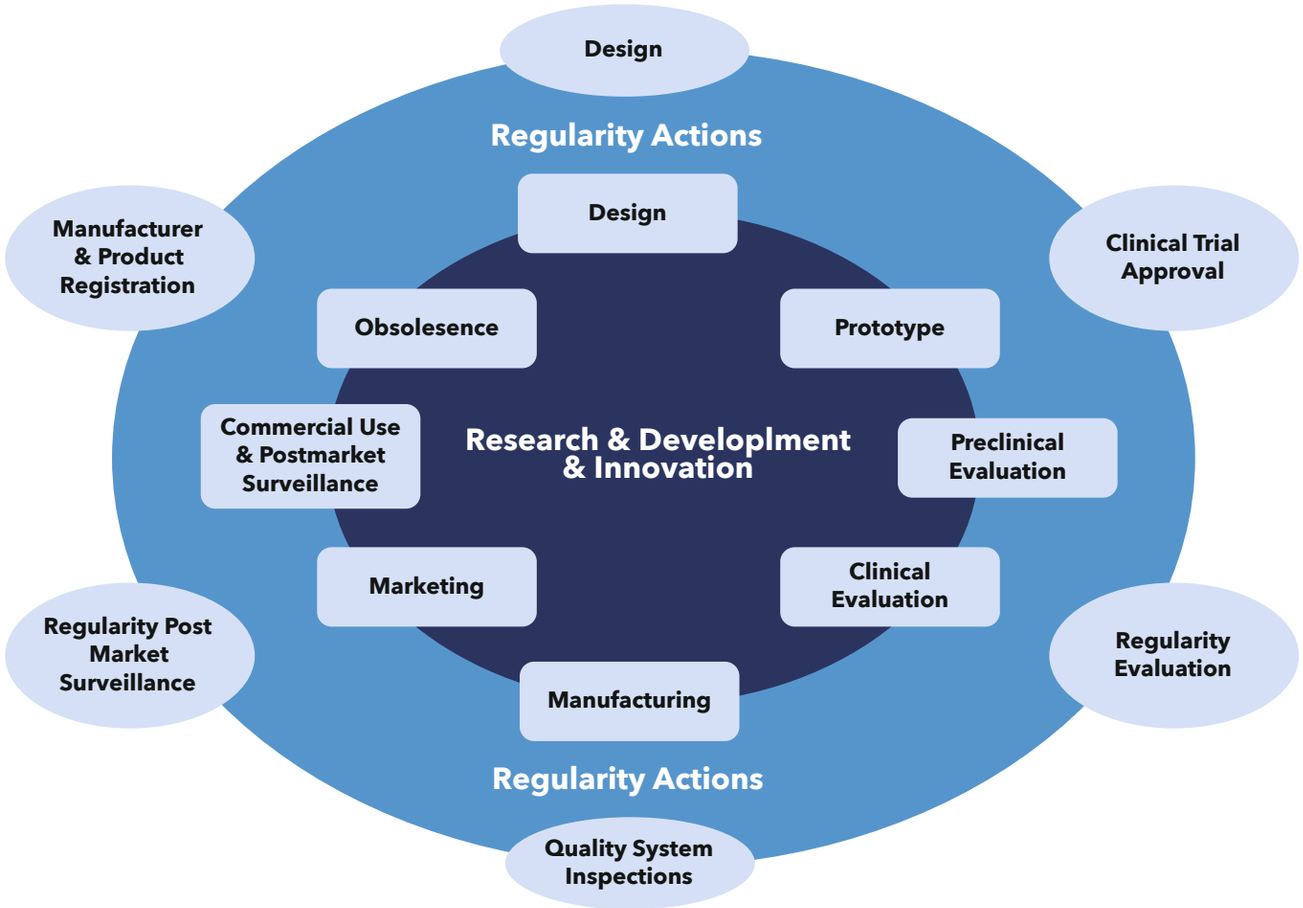
# Solving Trade and Regulatory Problems

# Identification:

## Relationship matrix between R&D, manufacturing, Innovation and Regulatory actions




## International Trade

Ellecom GmbH worked very closely with its logistics partners having impeccable track record in international trade as moving good internationally is operationally a complex process but most importantly Ellecom GmbH invested its resources, in terms of finances and workforce, to work with manufacturers based out of different parts of world specialized in large scale production of Medical Products and In-Vitro Diagnostic products. Expertise in International Trade helped Ellecom to identify existing regulatory barriers in Medical Device sector.

Small and Medium Manufacturers invest their resources in R&D, innovation and manufacturing but marketing their product globally feels like a herculean task for them due the labyrinth of Supranational and National regulations. Working closely with these manufacturers, Ellecom has identified the correlation between R&D, Manufacturing, Innovation and Regulatory actions. Because the regulatory agencies approval is required before the new product can go the market, governmental policies and actions in this field constitute the external framework for medical products manufacturing & Innovation.

## Regulatory Bottleneck

Regulatory issues impact the whole cycle of R&D, Manufacturing, Innovation. For this, the relationship between medical device developers and the national regulations authorities is critical for the innovation and competitiveness in this sector.

Ellecom considers that the regulatory process strongly affects market entry patterns of the small and medium firms and that they are less likely to market their products internationally because of the relatively higher costs of doing so for more financially constrained firms. The knowledge related to regulatory and marketing strategies contributes to the successful results for medical devices entrepreneurs.

Keeping in mind the existing bottleneck, Ellecom developed competency through investing its resources for building an experienced team devoted to research and compliance in the medical device and IVD market and stays on top of emerging trends and requirements in this field.

To overcome the regulatory barriers, Ellecom applies a coordinated effort with critical stakeholders including medical societies, device companies, clinical research organizations and government organizations.

# Solutions:

## International Trade

- International Customer Base: Ellecom offers its large global customer base to the manufacturers who has limited resources to market their product internationally.
- Sales Team: The dedicated sales team of Ellecom understands customer needs and can transfer its knowledge to assist the manufacturer to develop, market and customize their products as per the customer needs.
- Logistic Partners: Moving goods internationally is operationally complex which require in-depth knowledge and experience of logistics. It involves factory pick up & domestic shipment arrangement in the country of origin, shipment security through insurance and transportation.
- International Procurement: Ellecom can offer its expert procurement team to apply due diligent criteria for supplier selection of the raw material and explore such suppliers which can prove cost effective to the manufacturers for developing the final product.
- Marketing Expert: Ellecom understands international market need and guide manufacturers to brand their products to increase their product visibility.
- Product scoping: Ellecom's research team provide scoping studies on product considering supply & demand requirement in different markets.

## Regulatory Solutions

- Market access compliance consulting: Ellecom has regulatory experts to guide manufacturers through the labyrinth of regulatory requirements both at national and supranational level.
- International Registration Services: The business development and regulatory experts of Ellecom can use their network with National Competent Authorities (NCAs) and regulatory bodies to register the product and manufacturer in the different countries and at supranational level.
- Technical compliance support: In terms of process management, production, testing, certification, registration, post market services etc. for successfully listing for the product.
- Quality Management System consultancy: To enhance the corporate image and gain the external trust, establishment, implementation, and third-party certification of the QMS is very important. Ellecom provides quality management system consultancy services for ISO9001 and ISO13485 which corresponds to continuous improvement, customer satisfaction and products meeting the customers and legal requirements, safety, and effectiveness.
- CE MDR: With the implementation of Regulation (EU) 2017/745 on Medical Devices (MDR) on 26th May 2021, the new regulatory framework emphasizing life cycle safety of the device and clinical data support. Ellecom provides facilitation and consulting services for manufacturers to obtain CE under MDR before the end of transition period.
- CE IVDR: For In-vitro diagnostic devices, Regulation (EU) 2017/746 (IVDR) will come into effect on May 26th, 2022, which will put stricter requirements in terms clinical evidence and conformity assessment. Approximately 85% of IVDs need supervision by notified bodies under IVDR. Ellecom provide consulting services on IVDR as the new product classification and conformity assessment path pose higher challenges to diagnostic medical device manufacturers.
- EC REP Services: By following strong compliance protocol as per MDR and IVDR, we keep our clients up to date on the changes in the regulatory framework. In the process of ensuring full compliance with products registrations, we ensure privacy of confidential business information and store safely the copy of technical documentation.
- CH REP Services: Switzerland is now considered a third country to the effects of the EU MDR, Ellecom GmbH with its mother company Infotainment System AG, Switzerland is uniquely positioned to offer Swiss Authorized Representative services.
- Clinical Evaluations and Performance Evaluations: Ellecom works closely with various laboratories based in the EU to provide manufacturers analytical clinical data which is an important aspect of MDR and IVDR.
- Training: Ellecom has established a series of training modules in the field of regulatory affairs targeted at MDR and IVDR. Ellecom training sessions are interactive and driven towards practical implementation and application of MDR and IVDR.

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