# OVERVIEW

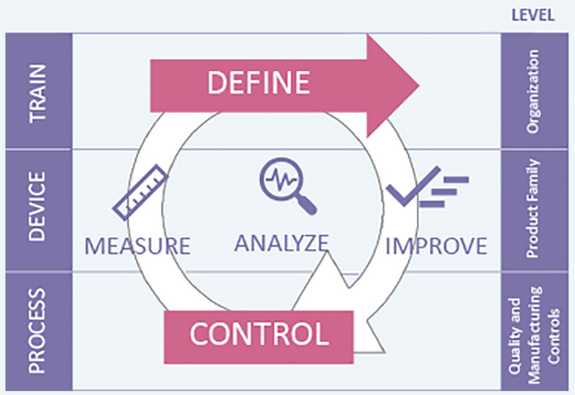
**PROJECT TYPE** REGULATORY COMPLIANCE

**CHALLENGE** Bring all EU market products to European Union Medical Device Regulation 2017/745 (EU-MDR) compliance. The intent of this case study is to provide a high-level road-map to remediate and submit for approval, devices/processes that are currently in the EU market under MDD (Medical Device Directive).

**SCOPE** Quality Management System, Clinical Evaluations, Pre and Post Market Surveillance, Global Supply Chain, Human Factors, Biocompatibility, Materials of Concern, Packaging, Operations, Regulatory, Reliability, RPE, Safety, Manufacturing.

# APPROACH

Using the DMAIC (Define, Measure, Analyze, Improve, Control) methodology figure 1, MEC (Medical Engineering Consultants) divided the roadmap to EU-MDR regulatory compliance into three stages:



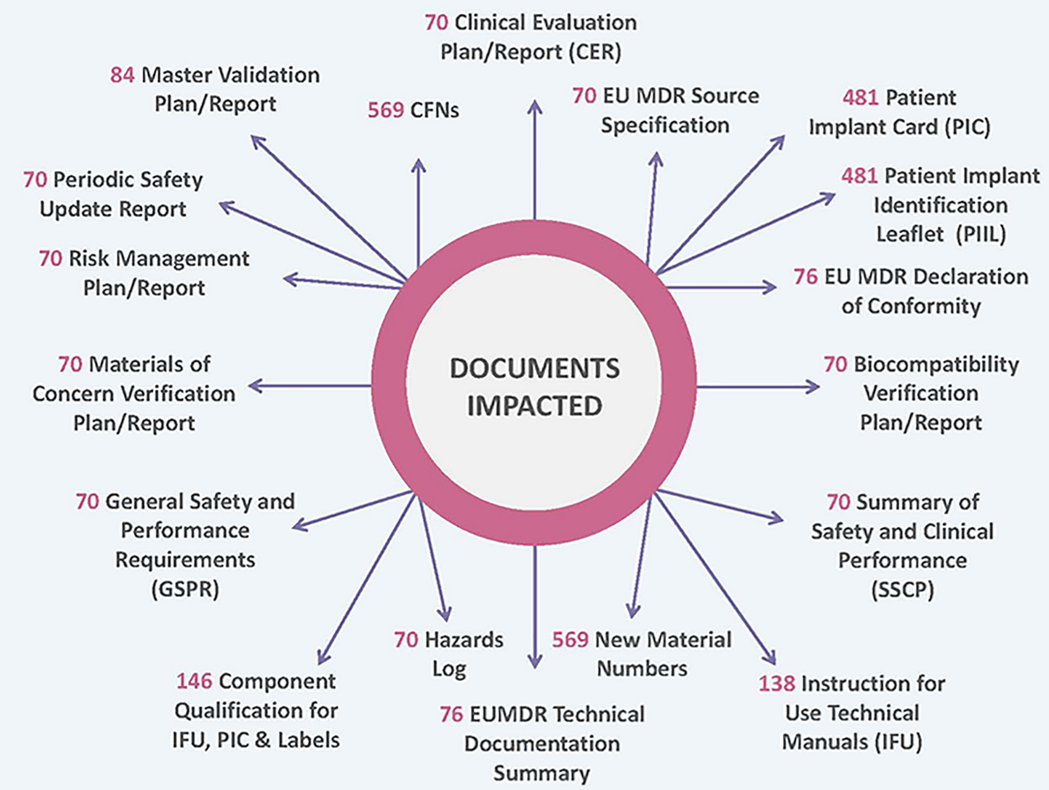

** Figure 1*

**DEFINE** Provides the organization with understanding of the regulation and how it applies specifically to the marketed product (e.g., based on the device classification). As such MEC defines this stage as translation; how does the organization translate the regulations to the organization's language.

**MEASURE / ANALYZE / IMPROVE** Relates specifically to the technical file of the device and/or product family that is to be remediated and consequently submitted for EU-MDR approval. Once the current state is measured, the organization along with MEC consultants, analyze the gaps and ensure all compliance elements, as noted in figure 2, are added to the remediation plan.

**CONTROL** At this stage the org's QMS and Device's technical documentation are compliant with regulations; however, the device's performance in the field and the organization continuous compliance must be controlled. In addition, as the applicable standards are revised, the organization must have a process that evaluates the changes and assesses how the org's QMS is affected by the change.

# RESULTS




** Figure 2*

# CONCLUSION

As the primary function of the regulation is to maintain Patient Safety, the MEC methodology ensures that the Organization and the Device adheres to such function, while maintaining product availability in the EU Market.

Figure 2 shows the number of elements that were required to be remediated in a large Organization. The outcome of this case study, with the use of the MEC methodology, was for the client to understand and quantify the business endeavor and thus to keep product available in the EU market. In this example the org's devices' certifications, under MDD (Medical Device Directive), were to expire thus immediate action was deployed across impacted areas. Proper and strategic planning allowed the team to manage the remediation workload, leverage testing and minimize deficiency questions, by the Notified body, and target a 12-month timeframe between submission and approval.



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