CYIENT

ENSURING IVDR COMPLIANCE FOR OVER 300 PRODUCTS OF A US BASED IN-VITRO DIAGNOSTICS MAJOR

Client Name: A top in-vitro diagnostics major specializing in immunodiagnostics and clinical chemistry analyzers

Client Since: 2015

Industry: In-vitro diagnostics

Location: United States

Client Challenge: Ensuring compliance of over 300 products to IVDR within the May 2022 deadline

Cyient's Solution: Backed by in-depth domain understanding, Cyient team developed a highly structured approach to IVDR implementation. With the use of process automation and re-usable templates, the team was able to save significant time for IVDR transition.

Summary of Results: Cyient team ensured timely compliance to IVDR so that the client could maintain its market leading position in the IVD space.

Overview

Cyient's client, a market leader in in-vitro diagnostics, has a broad portfolio of devices in immunodiagnostics, transfusion medicine and clinical chemistry analyzers. To maintain its leadership position in the EU region, the client needed to ensure that all its product lines are IVDR compliant within the May 2022 deadline. Through a highly structured approach to remediation, process automation and in-depth understanding of the new regulations, we developed technical documents in accordance to Annex I, Annex II and Annex III of IVDR. Our solution helped the client to ensure IVDR readiness for multiple products within a period of 18 months, way ahead of the May 2022 deadline.

Client Business Challenge

The EU In-Vitro Diagnostics Regulations (IVDR) modernize the decades old In Vitro Diagnostics Directive (IVDD) with an aim to increase focus on safety and quality of devices. This entails stringent documentation establishing risk-based classification, clinical evidence, analytical tests, performance evaluation and regular post-market surveillance.

The major challenges that the client faced in ensuring IVDR compliance were:

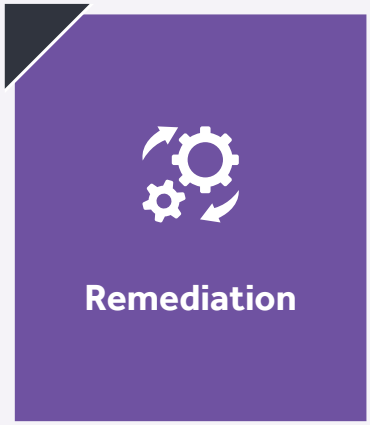
- Most of the legacy device documentation was over 10-15 years old. For a lot of the products, many versions of performance evaluation reports and analytical test reports were archived, making it difficult to conclude the product claim
- For products that had documentation, the data was provided in incompatible formats with multiple document management systems and across different business units
- A lack of structured standard operating procedure/process for technical file remediation led to delays in compliant documentation
- The quantum of work was massive as there were over 300 products including
  - Clinical Chemistry Analyzers, Assays and Reagent
  - Immunodiagnostics Assays and Equipment
  - Transfusion Medicine Reagents and Equipment

Such challenges threatened the market position of over 300 products involving total revenue of $500 million.

The Cyient Solution

Cyient adopted a four-phased approach for this project

Cyient's team selected a representative sample list of 5 products across immunodiagnostics, transfusion medicine and clinical chemistry analyzers to identify the existing evidences and compile the Technical File. This involved interacting with cross functional teams and taking inputs from different product owners. The team developed a robust process to take dynamic inputs and remediate all the files in different product families without hampering the integrity of the technical file.



Cyient developed an integrated approach to review more than 300 technical documentations to complete the remediation effectively. This was accomplished through:

- An integrated approach to identify gaps in the existing documentation, compiling new file with review from product owners
- A process flow to identify data from existing pool of resources relevant to manufacturer claims and compile it
- An SOP to distinguish misleading information and wrong claims in the existing documentation and develop documentation to support actual claims

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This phase involved submission of IVDR technical file updated with new requirements and QMS to the notified body for review. Any observation received from notified body was duly investigated and Cyient took care of Corrective Action Preventive Action (CAPA).

Maintenance

Cyient manages the technical file in the existing document management system, updates it with ongoing changes in the products, and supports document management system migration.

The Results

Established Regulatory Center of Excellence:

Successful execution of the IVDR project helped us gain client confidence resulting in establishment of a Regulatory Center of Excellence with over 15 regulatory experts, domain specialists and engineers. The hybrid offshore-onsite model delivers around 25% cost benefits to our client.

Reduced Lead Times:

Where applicable, Cyient team leveraged reusable templates and established a process flow that led to si`gnificant lead-time reduction. Application of these methods resulted in shorter lead-time for subsequent remediation efforts.

Maintain Market Position:

A total of 300 products were remediated as part of the project resulting in revenue protection of $500 Mn+. Client could successfully comply with IVDR and sell its products in the EU market.

DESIGNING TOMORROW TOGETHER

At Cyient, we always work on making sure that our clients keep pace with disruptive changes in their respective industries. By ensuring IVDR compliance for over 300 products we supported our client in maintaining their industry leading position while also becoming future-ready.

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Cyient (Estd: 1991, NSE: CYIENT) is a global engineering and technology solutions company. As a design, build, operate & maintain partner for leading organizations worldwide, we take solution ownership across the value chain and leverage the power of digital technologies and advanced analytics, along with domain knowledge and technical expertise, to solve complex business problems. With more than 15,000 employees in 20 countries, our industry focus includes aerospace and defense, medical, telecommunications, rail transportation, semiconductor, industrial, and energy.

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