GLOBAL

REGULATORY WRITING & CONSULTING

CASE STUDY

Mid-Size Genetic Testing Firm seeking support implementing the new EU IVDR standards.

Manufacturer / Device Type: Mid, Class C

Services: Writing, Training, Project Management, Consulting

EU IVDR Documents: Templates, SOPs, PEP, PER, SSP

We build and train teams to maximize efficiency and quality.

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GLOBAL'S IVD CAPABILITIES

Project Management including schedule creation and full-service project management for EU IVDR deliverables

Training including our IVDR bootcamp and custom training programs

Regulatory & Technical Consulting including PER strategy, SSP strategy, SOP review, and template review

Medical & Regulatory Writing including PEP/PERs, SSPs, and Literature Reviews

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ABOUT THE CLIENT

A mid-size genetic testing firm, Client V, faced the challenge of implementing the new European In Vitro Diagnostic Regulation (EU-IVDR) standards. The company lacked experience with IVDR and needed assistance in developing a Performance Evaluation Report (PER) template and establishing robust internal processes to ensure compliance. Recognizing their limitations, they approached a recruiting firm, which in turn sought GLOBAL's specialized expertise.

ABOUT THE PROJECT

Unfamiliarity with IVDR: Client V's internal regulatory team had no prior experience with IVDR requirements and lacked templates, SOPs, and a clear understanding of the regulation's nuances.

Need for Training and Templates: The team required both educational resources and practical tools to navigate IVDR compliance effectively.

GLOBAL SOLUTIONS

To address Client V's challenges, GLOBAL executed a comprehensive, multi-pronged approach:

1. **Strategy Consulting:**
- GLOBAL engaged a leading authority on IVDR to collaborate with Client V and confirm their regulatory strategy, ensuring it aligned with IVDR requirements for a specific diagnostic device.
- GLOBAL's consultant partnered with the regulatory writing team to design a customized PER template and develop SOPs and work instructions for ongoing and future IVDR projects.

2. **Internal Training:**
- GLOBAL's consultant delivered a multi-day training program tailored to Client V's needs.
- The training covered IVDR's regulatory requirements, the team's new responsibilities, and best practices for preparing compliant submissions.

3. **Regulatory Writing and Review:**
- Using the templates created during the engagement, GLOBAL's regulatory writing team drafted key deliverables, including the Performance Evaluation Plan (PEP), PER, and Summary of Safety and Performance (SSP) for one of Client V's flagship devices.
- The team coordinated closely with Client V and GLOBAL's consultant to gather stakeholder input, ensure accuracy, and confirm that all deliverables met regulatory requirements.

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OUTCOME

1. **Enhanced Compliance Readiness:**
   - Client V's regulatory team gained a clear understanding of IVDR and the ability to manage future compliance efforts.
   - The training program increased team efficiency and confidence in preparing regulatory submissions.
2. **Streamlined Processes:**
   - GLOBAL's SOPs and work instructions established a sustainable framework for future IVDR projects.
   - The customized templates significantly reduced document preparation time.
3. **High-Quality Deliverables:**
   - GLOBAL's writing team produced regulatory submissions that met all IVDR requirements, ensuring Client V's diagnostic device was fully compliant.

Future Implications: With GLOBAL's support, Client V has established a scalable and robust approach to IVDR compliance. The tools and training provided by GLOBAL will enable Client V to:

- Efficiently adapt to future regulatory changes.
- Leverage the templates and processes for other diagnostic devices, ensuring long-term operational success.

CONCLUSIONS

This case study highlights GLOBAL's ability to deliver tailored solutions that address complex regulatory challenges. By combining expert consulting, training, and high-quality writing services, GLOBAL ensured Client V's success in achieving IVDR compliance while setting them up for sustained growth.

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