How to Prepare for IVDR

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greenlight guru

Rook Quality Systems

MAKE EVERY MOVE COUNT

MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

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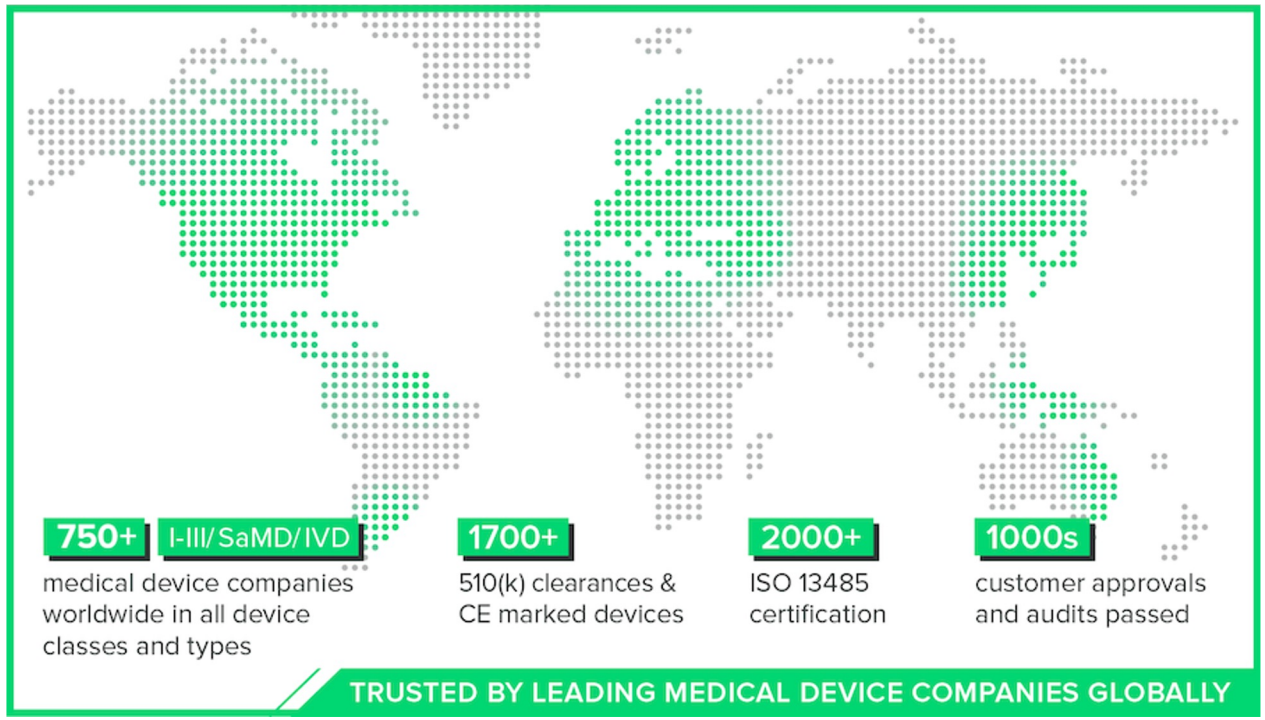

"Best eQMS I have ever used..."

This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry. ***It is simple, intuitive and easy to use...*** We are successfully implementing a Quality Culture.

- Director of Regulatory Affairs & Quality Assurance

"Modern QMS Software and Outstanding Customer Service."
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"Demystifying QMS and Regulatory Requirements"
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"Makes your QMS Simple and Effective"
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Rook Quality Systems is a consulting firm dedicated to helping startup to mid-sized medical device companies develop and maintain effective and efficient quality systems.

Experience

A decade working with class I-III devices, SaMD, and IVDs. Supporting companies in the very early stages of QMS and device creation, from design through commercialization and post-market monitoring.

Expertise

Rook's team of thirty one quality engineers and certified auditors are experts in FDA regulations, MDSAP audits, ISO 13485:2016 compliance, and MDR conformity and provide support during an external or regulatory audit.

Efficiency

We leverage experience and best practices to help build the QMS so that clients can get their devices to market faster than standard methods, and use these systems to continue producing effective, quality devices.

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We provide specialized and custom consulting services for all classes of medical devices, including medical software and combination devices.

- Quality System Design
- DHF/ TF Creation
- Audit Support
- Software Validation
- Design Control
- Risk Management
- Regulatory Submission Support (Int'l)
- Quality System Training

Outline of Webinar

- Overview of the IVDR 2017/746 Regulations
- Timeline for IVDR Implementation
- Breakdown of different classifications for IVDR
- QMS Requirements for IVDR Compliance
- Technical File Requirements for IVDR
- Post Market Requirements
- Diagnostic Software
- Q&A

History of IVD Regulations in EU

- The previous regulations, IVDD is over twenty years old (98/79/EC)
- MEDDEV guidance's have been continually updated for specific types of devices
- The majority of IVD products in the EU were able to self certify under the IVDD meaning that **80-90% of companies did not require Notified Body review and audits!**
- **This is a big jump from no compliance to requiring NB review and auditing!**
- Current process is similar to EUA in the USA where design, QMS, risk and V&V are looked at as optional my many manufacturers and there will be major gaps moving to IVDR.

IVDR Compliance Timelines

- May 26, 2025 for Class D
- May 26, 2026 for Class C
- May 26, 2027 for Class B
- May 26, 2027 for Class A sterile devices
- May 26, 2022 for all new devices
- Certifications that are self certified will remain valid until May 27, 2025 for Class A, B that do not need a NB review

- Still time for current devices on the market but all new devices need to comply now to meet IVDR regulations similar to MDR transition timelines

IVD Definition under IVDR

- in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
- (a) concerning a physiological or pathological process or state;
- (b) concerning congenital physical or mental impairments;
- (c) concerning the predisposition to a medical condition or a disease; (d) to determine the safety and compatibility with potential recipients;
- (e) to predict treatment response or reactions;
- (f) to define or monitoring therapeutic measures.
- Specimen receptacles shall also be deemed to be in vitro diagnostic medical

IVDR Classification Examples

- Class D – Highest Risk
  - Examples - IVDs exposed to high-risk diseases or agents. **COVID tests**, HIV diagnostics, blood donor screenings
- Class C – Medium Risk
  - Examples - Blood glucose self screening, PSA screening, genetic tests, cancer markers
- Class B – Moderate Risk
  - Examples – Pregnancy tests, urine test strips, clinical chemistry
- Class A – Low Risk
  - Examples – specimen receptacles, buffer solutions, culture media

IVDR Classification Rules

- The IVDR Classification rules are outlined in Annex VIII

- Provides an overview of how each device is classified and rules to help manufactures properly define the class of each type of device
- Seven rules in total
- Rule 1 – Class D
- Rule 2,3,4 – Class C
- Rule 5 – Class A
- Rule 6,7 – Class B
- Some exceptions listed in the specific rules

How to start the process

- Identify the classification of your IVD product and determine when your deadline is for IVDR compliance
- Begin to prepare the necessary QMS documents if you do not have them
- Begin to prepare the necessary Technical File and performance records for the specific IVD product
- Secure a notified body that will provide your IVDR certification
- Currently there are only seven NBs
  - BSI
  - Dekra x 2
  - GMED
  - TUV SUD, TUV Rheinland
  - 3EC International

How to start the process - NB

- Reach out to a Notified Body to determine if they are taking new clients and the timeline for the IVDR certification based on the class of your device
- Begin the quoting process with the IVDR NB
- Confirm and schedule audits and technical documentation review
- **All performance data must be complete including clinical trials before you can start the technical documentation review**
- In some cases, companies can become ISO certified first before moving to IVDR so that they are clients of the NB and given higher priority for the audits and documentation review
- Be aware this is very expensive, and prices are going up!

How to Prepare your QMS

- Start with ISO 13485:2016 as a backbone for your QMS
- Update procedures and forms to comply specifically with the QMS requirements outlined in **Annex IX**
- Key SOPs that are required for IVDR Compliance
  - General Safety and Performance Requirements Template
  - Usability SOP
  - Clinical Performance Evaluation SOP
  - EUDAMED/UDI SOP
  - Distribution/Economic Operators SOP
  - Post Market Performance Follow-up Plan / Procedure
  - Post Market Surveillance
  - Regulatory Compliance SOP
  - Vigilance/Recall/Adverse Event Handling SOPs

Ongoing QMS Compliance

- Start with ISO 13485:2016 as a backbone for your QMS, need to fulfil requirements of 13485 for ongoing compliance
- Continue to monitor Quality Objectives, analysis of quality data, post market feedback and performance
- Conduct annual internal audits and management review
- Ensure any design changes are properly verified and validated including software
- Maintain UDI compliance and EUDAMED upload requirements
- Document all suppliers, economic operators, distributors with necessary QMS records
- NB will conduct annual audits of QMS and technical documentation, as well as one **unannounced audit every 5 years at the manufacturing site**

Technical Documentation

- Class B, C, and D require technical documentation assessment by the notified body prior to IVDR Certification
- This process is typically conducted off site outside of the audit timeline and can take anywhere from a few weeks to a few months
- Technical documentation review covers all aspects of the device performance, labeling, usability, state of the art, software, and V&V records related to the IVD.
- Technical reviewer will provide feedback and any gaps must be addressed with formal responses and or CAPAs
- Test data must include clinical data for each indication or claim related to the IVD product to ensure your certification meets the full scope of your intended use

Technical Documentation – IVDR

- The application shall enable the design of the device characteristics and performance(s) to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed.
- It shall include:
- (i) test reports, including results of studies carried out with intended users;
- (ii) where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment;
- (iii) data showing the suitability of the device in view of its intended purpose for self-testing or near patient testing;
- (iv) the information to be provided with the device on its label and its instructions for use.

Post Market Reqs - Article 78

- **General PMS for all products under IVDR**
- Each device manufacturer shall maintain and update PMS in a manner proportionate to the risk class of the device
- Data shall be used to update the following items
  - Benefit-risk determination of the IVD
  - Performance evaluation
  - General Safety and Performance requirements
  - Need for any CAPAs or field safety actions
  - Usability improvements
  - Detect and report trends related to the device

Post Market Reqs - Article 79

- **Post Market Surveillance Plan**
- Each device manufacture shall maintain and update PMSP that identifies how the company will meet the requirements of Article 78 (previous slide)
- This should include details on how data will be collected, analyzed, and the frequency of the review
- Risk should be incorporated in the PMSP based on the class of the device and any previous PMS data
- The PMSP will be part of the technical documentation and reviewed by the NB for your initial certification and ongoing compliance.

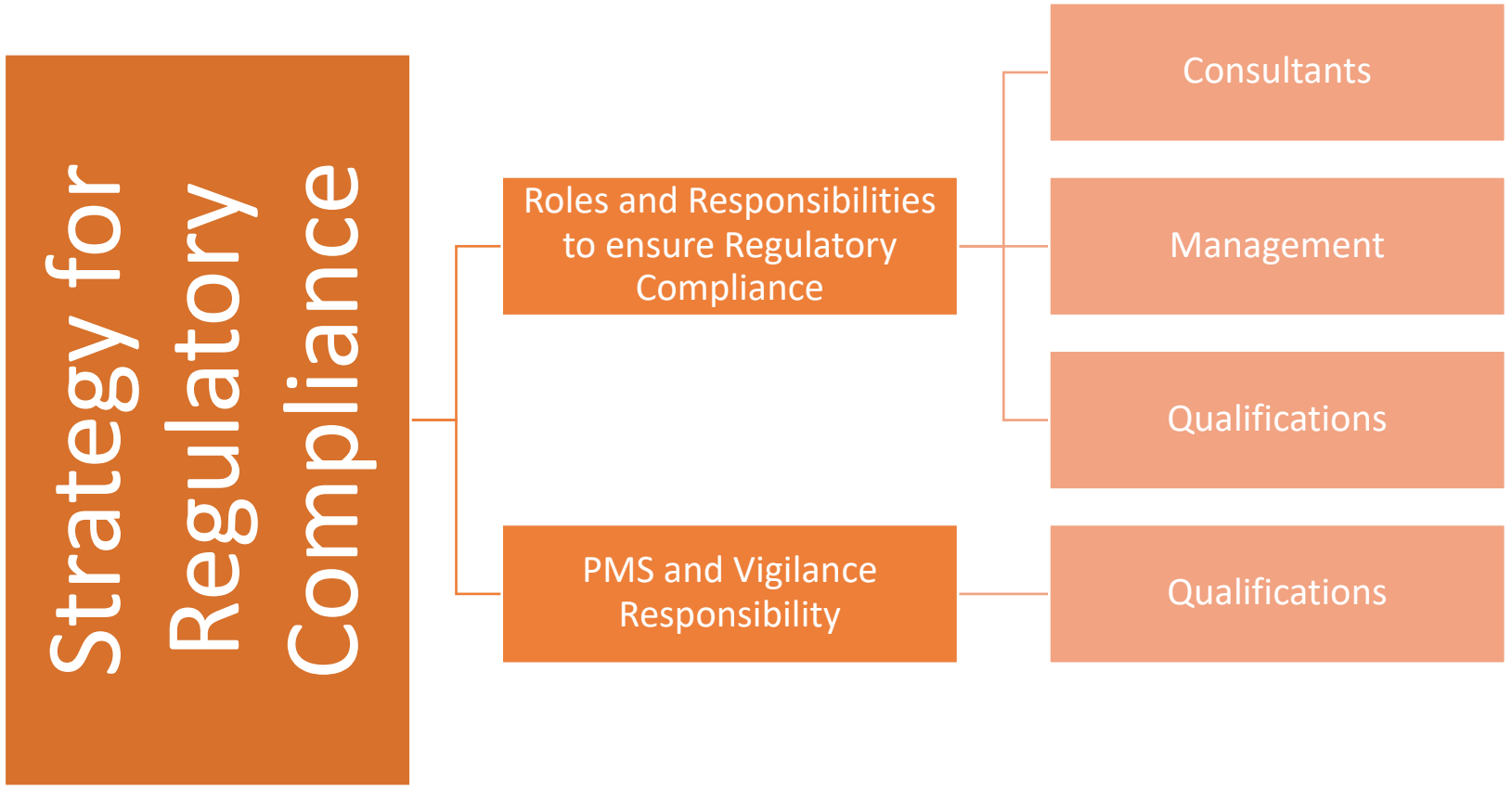
Post Market Reqs - Article 80

- **Post Market Surveillance Report**
- Each device manufacture shall maintain and update PMSR that identifies how the company will meet the requirements of Article 78,79 (previous slide)
- PMSR is required only for Class A and B
- The report should include any CAPAs or design changes (including software) that were conducted as a result of the PMS data collected for the IVD product
- The PMSR will be part of the technical documentation and reviewed by the NB for ongoing compliance.

Post Market Reqs - Article 81

- **Periodic Safety Update Report**
- Each device manufacture shall maintain and update PSUR that identifies how the company will meet the requirements of Article 78,79 (previous slide)
- PSUR is required only for Class C and D
- The report should include conclusions of the benefit-risk determination taking into account new PMS data and performance data
- Main findings of the Post Market Performance Follow-up Plan (PMPF)
- Volume of sales of the device, usage frequency
- The PSUR should be updated annually
- Class D manufactures must submit the PSUR electronically per Article 48

Regulatory Compliance - Article 15



Articles 82-85 Incidents and FSCAs

- **Ensure SOP outlines new requirements for reporting Incidents and FSCAs per IVDR**
  - **Detailing timeline requirements for Vigilance, Incidents, and FSCAs**
  - **SOP outlines statistical analysis of incidents and when to report to EUDAMED**
  - **SOP incorporates risk into the investigation of the Incident/FSCA**
- **Templates or Forms for the reporting of serious incidents**

Performance Studies Article 66-76

- **Articles 66-76 Detail the requirements for applying, conducting, and completing performance studies for IVD products under IVDR**
- Sections highlight the following requirements that must be met for new IVD manufacturers as well as manufactures that already have CE for their IVD
- Article 66 outlines how to apply for a performance study with the specific Member State
- Article 68 defines how to conduct the study as well as the performance study plan requirements
- Articles 71-73 identify how to handle any changes to the performance study, corrective actions, and handling the termination of a study.
- Article 76 defines the process for recording and reporting AEs from the study

Diagnostic Software under IVDR

- Some SaMD products or products containing software may fall under IVDR discretion instead of MDR
- The IVDR classification rules should be reviewed with the intended use of the software to determine if the software product is classified as a diagnostic or medical device.
- MDCG 2019-11 Provides guidance on the classification and qualification of software under MDR and IVDR
- Examples of software that would be classified under IVDR
  - Software that uses output of various parameters to identify risks for a disease
  - Software that analyses output from diagnostic devices to provide a screening or diagnostic result
  - Software that automates cytology screening to classify results

Diagnostic Software under IVDR

- Decision Step 1: Does the Medical Device Software (MDSW) provide information within the scope of the in vitro diagnostic medical device definition? (f) should qualify as In Vitro Diagnostic Medical Device Software (IVD MDSW)
- (a) concerning a physiological or pathological process or state (by investigation of this process or state); or
- (b) concerning congenital physical or mental impairments
- (c) concerning the predisposition to a medical condition or a disease;
- (d) to determine the safety and compatibility with potential recipients;
- (e) to predict treatment response or reactions;
- (f) to define or monitoring therapeutic measures.

Diagnostic Software under IVDR

- Decision Step 2: Does the MDSW create information based on data obtained by in vitro diagnostic medical devices only? If the information provided is based on data obtained solely from in vitro diagnostic medical devices, then the software is an in vitro diagnostic medical device and is therefore an IVD MDSW. If the data analysed is obtained from a combination of both in vitro diagnostic medical devices and medical devices, proceed to step 3.
- Decision Step 3: Is the intended purpose substantially driven by data sources coming from in vitro diagnostic medical devices? If yes, then the applicable legislation is Regulation (EU) 2017/746. If the intended purpose is substantially driven by data sources coming from medical devices, then the applicable legislation is Regulation (EU) 2017/745. In the condition where the intended purpose of the MDSW output data fulfils both the medical device and in vitro diagnostic medical device definitions set out in the MDR and IVDR (refer to Decision Step 2), a weighting of the data sources based on the significance of the information21 in relation to fulfilling the intended purpose should be conducted to aid the manufacturer in determining which regulation to apply.

Closing Remarks

- There is a lot of work to do to comply with IVDR over the next few years for companies that are currently self certified
- 80-90% of IVD manufacturers in the EU currently have never been evaluated or audited by a NB
- The gap between self certification and IVDR compliance is greater than any other regulatory change in the past 30 years including MDR
- Tools like greenlight.guru, smart trial, and consultants like RookQS will greatly improve your chances of success with IVDR compliance
- Notified bodies are busy and companies should look to establish a relationship asap to ensure they meet their IVDR deadlines

Questions?

www.RookQS.com
Make sure to visit our website to learn more about our services and consulting team.

Contact **info@rookqs.com** for more questions, comments, or to set up a meeting. One of our consultants will be sure to reach out to assist!