RCC-IVDR Exam Study Checklist

Instruction:

Use this checklist to track your progress when preparing for the RCC-IVDR certification exam.

1. When you begin your studying, review each task statement and place a checkmark in the box that best describes your study needs for each task. The associated knowledge areas are listed below the checklist.
2. If you are not familiar with or do not regularly perform the content in the listed task, you most likely need extensive review and should check the 'needs extensive review' box.
3. If the content listed is a task that you perform regularly as part of your job, you most likely need less review and should check the 'need minimal review' box.
4. Once you complete your review of the content in the listed task, check the 'review complete' box.

Domain I: Conformity of the Devices – Exam Weighting Approximately 21%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Ensure all devices placed on the market have a valid declaration of conformity. a. ANNEX I b. ANNEX II c. ANNEX III d. ANNEX IV e. Article 17 f. Article 7 through			
2. Ensure, where applicable, the devices have a valid European Conformity (CE) notified body certificate. a. Notified body website or EUDAMED to check the validity of the CE certificate (scope, valid dates, authenticity) b. ANNEX XII c. Article 51			
3. Ensure that a management system for packaging material is in place or the device is properly CE marked. a. Article 18 b. ANNEX V			

4. Ensure the manufacturer or the authorized representative complies with the requirements of the IVDR. a. Article 10, 11, 12 b. MDCG 2022-16 Guidance on Authorized Representatives Regulation			
5. Review audit reports of the devices' realization and release processor perform these audits to ensure corrective and preventive actions are applied. a. Article 10 b. Article 16 c. ANNEX I d. ANNEX IX e. ANNEX XI f. ISO 13485 awareness, specific requirements for IVDs			
6. Ensure the design team is trained and understands the requirements that are outlined in the IVDR. a. Article 47 through 50 b. Chapter VI c. ANNEX I d. ANNEX II e. ANNEX XIII f. ANNEX XIV			
Domain II: Technical Documentation – Exam Weighting Approximately 24%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Ensure that the technical documentation is in place and is in accordance with IVDR. a. ANNEX I b. ANNEX II c. ANNEX III			
Domain III: Post-marketing Surveillance – Exam Weighting Approximately 19%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Establish, implement, and maintain a post-marketing surveillance system. a. Article 78 through 85			

2. Communicate with Competent Authorities, notified bodies, other economic operators, customers and/ or other stake holders. a. Article 78 a. Article 82 through 84 a. Article 87			
3. Ensure processes exist for reporting of serious incidents and field safety corrective actions in the context of vigilance. a. Article 78 b. Article 82 through 87			
4. Know and understand the documentation requirements regarding post marketing surveillance. a. Article 79 through 81 b. ANNEX III			

Domain IV: Vigilance – Exam Weighting Approximately 17%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Ensure there is a process and procedures in place to manage field safety corrective actions and responsibilities for the process. a. Article 82			
2. Ensure there is a process for Trend Reporting. a. Article 83			
3. Ensure required communications with Competent Authority are fulfilled i.e., providing documents, and answering questions related to event/FSCA as applicable. a. Article 84			
4. Ensure there is a process to manage investigations into adverse events and CAPAs related to safety issues. a. Generic			
5. Ensure there are processes in place to facilitate feedback from field (HCP, patients, and users) to Manufacturer. a. ANNEX I § 20.4.1 (A through F)			
6. Report any serious adverse events or concerns related to the vigilance process to the Competent Authority. a. Article 82			

Domain V: Clinical Investigation/ Performance Study – Exam Weighting Approximately 19%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Ensure that a signed statement by the natural or legal person responsible for the manufacture of the performance study device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical performance study. a. Chapter VI b. ANNEX I c. ANNEX XIV			
2. Ensure that the performance study is planned in order to protect the health and safety of the subject(s). a. ANNEX I b. ANNEX XIV			

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