RCC-MDR Exam Study Checklist

Instruction:

Use this checklist to track your progress when preparing for the RCC-MDR 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. Train staff to ensure the standard operating procedures (SOPs) are followed in a manner that is proportionate to the risk class. a. Quality management system b. Location of valid SOPs			
2. Ensure that the batch release of a product was produced within the specification of the product and; adheres to quality management systems, and then ensure the issuance of a declaration of conformity to the public. a. Final specification document. b. Check the process of the batch release. c. Content of the declaration of conformity is according to ANNEX IV.			
3. Perform an audit of the release process and document improvements to the process. a. Evaluate if the process was performed accurately.			

RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY

Domain II: Technical Documentation – Exam Weighting Approximately 19%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Compile the technical documentation that contains risk management, labeling information, clinical evaluation, manufacturing process, and a summary of the verification and validation process. a. ANNEX I b. ANNEX II			
2. Create a declaration of conformity and ensure it is up-to-date and submitted to the notified body and/or EU authorized representative. a. ANNEX IV b. Submission process c. EU authorized representative			
3. Obtain confirmation from the EU certification body, submit, and verify that the certification number is active and valid. a. ANNEX II b. ANNEX III c. Conformity assessment routes			
Domain III: Post-marketing Surveillance – Exam Weighting Approximately 28%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Ensure the existence of a procedure (SOP) for a post-market surveillance system of the manufacturer and that it is aligned with requirements. a. ANNEX III b. Quality management system Article 10 (10) c. Location of valid SOPs			
2. Check of presence of released PMS-Plans in proportion to the risk class and appropriate for the type of device. a. Article 83			
3. Check of presence of released PMS-Reports for medical devices of class I; report shall be updated when necessary and made available to the Competent Authority upon request. a. Article 85			

4. Check of presence of released PSUR-Reports for medical devices of class Ilia, class IIb, and class III. a. Periodic safety update report. b. Article 86 c. Manufacturers of class IIb and class III devices shall update the PSUR at least annually. d. Manufacturers of class Ilia devices shall update the PSUR when necessary and at least every two years. e. Submission process with notified body.			
5. Check presence of released SSCPs for implantable devices and for class III devices. a. Article 32 b. Summary of safety and clinical performance (SSCP)			

Domain IV: Vigilance – Exam Weighting Approximately 17%			
Task	**Needs Minimal Review**	**Needs Extensive Review**	**Review Complete**
1. Understand legal obligations to report any serious incident to the Competent Authorities that have the ability to perform and investigate corrective actions. a. Article 15 (D) b. Article 87 through Article 91			
2. Ensure that corrective action report is submitted to the Competent Authorities and ensure its validation. a. Corrective action reporting (Field Safety Corrective Action, FSCA) b. Investigation is performed and a response is submitted to the Competent Authorities. c. Final report is created and submitted to the Competent Authorities.			

Domain V: Clinical Investigation/ Performance Study – Exam Weighting Approximately 15%			
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 investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation. a. ANNEX XV 4.1			
2. Ensure that every precaution has been taken to protect the health and safety of the subject. a. ANNEX XV 4.1 b. Article 10 (16)			