RAC (EU) Examination
Study Checklist

Instructions: Use this checklist to track your progress when preparing for the RAC (EU) certification examination. 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.

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. 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. Once you complete your review of the content in the listed task, check the 'Review complete' box.

Domain I: Strategic Planning (approximately 31% of exam)			
Task	**Needs minimal review**	**Needs extensive review**	**Review complete**
Regulatory Framework			
1. Determine the regulatory classification status in European Union markets where the product may be launched.			
2. Monitor and assess the regulatory environment in European Union markets where the product may be launched (including additional national requirements such as legal status) and initiate changes within the company.			
3. Investigate and communicate when it is necessary to request technical and scientific guidance from relevant organisations.			
4. Evaluate regulatory requirements for markets outside of the European Union that recognize EU requirements.			
5. Provide input to trade associations and standards organizations to influence the European regulatory environment (legislation, guidance documents, and standards).			
6. Perform Competitor Surveillance (e.g., EPAR, SmPCs, claims, indications) to evaluate potential changes, is-sues, and strategies.			
7. Contribute to in-house training programmes for company personnel to ensure regulatory and quality compliance.			
Regulatory Pathways and Options			
8. Advise management on requirements and options for regulatory submissions, approvals, and conformity assessments (e.g., local, national, international options).			
9. Advise management on timelines, risks and financial implications of the proposed regulatory strategy.			
10. Investigate and communicate the availability of incentives (e.g., financial, data/market exclusivity) to support product development.			

11. Develop effective regulatory submission strategies for timely product approval.			
12. Advise colleagues on compliance with relevant regulatory legislation, guidelines, standards, etc.			
Health Economics			
13. Provide input to and advise senior management regarding Comparative Effectiveness/Health Technology Assessment.			
14. Advise senior management regarding pricing and reimbursement issues.			
Interaction with Other Companies			
15. Advise senior management during product or company acquisitions and collaborations.			
16. Conduct regulatory due diligence during acquisitions and collaborations.			
17. In- and out-licensing of products from/to a third party.			
Crisis Management			
18. Advise management regarding the regulatory impact of a crisis event (e.g., plant shut down) and propose a resolution strategy.			
19. Participate in the development and functioning of the crisis management programme.			
Domain II: Designs and Development (approximately 36% of exam)			
Task	**Needs minimal review**	**Needs extensive review**	**Review complete**
Manufacturing/Quality (CMC)			
1. Define and communicate regulatory requirements for the scope of manufacturing authorisations/quality system certifications (e.g., clinical trial supplies, operations allowed, pharmaceutical forms, design, manufacture, device types).			
2. Review completeness of production documentation to support CTA/MAA submissions/manufacturing transfer.			
3. Ensure that available stability data supports intended shelf-life of product.			
Nonclinical and Clinical Development			
4. Advise sponsor of regulatory requirements for clinical trials/investigations.			
5. Determine adequacy of nonclinical data and risk analysis to support approval to conduct clinical trials/investigations.			
6. Identify national/local requirements and prepare clinical trials/investigations submissions to CA/EC.			
7. Prepare or review study information such as IMPD/technical file/design dossier, label, clinical investigation plan/protocol, case report form, investigators brochure, patient information letter, and informed consent to comply with local, regional, national, European, and international			

regulatory requirements.			
8. Interact with and coordinate the use of CROs, subcontractors, test facilities, and consultants.			
9. Respond to questions/comments from CA/EC.			
10. Ensure regulatory compliance of manufacture and release of investigational products for clinical use.			
11. Ensure that reporting procedures are in place to report adverse events that occur during clinical trials/investigations to CA/EC.			
12. Review clinical data from literature and other sources.			
13. Report trial/investigation results to CA/EC.			
14. Maintain authorisation for on-going clinical trials/investigations (e.g., amendments, annual reports, updates).			
15. Evaluate need for and contribute to the development of Paediatric Investigation Plans/waivers/deferrals.			
Preregistration/CE Marking Interfacing			
16. Evaluate need for and coordinate Protocol Assistance/Scientific Advice Meetings with CAs.			
17. Liaise with project team to develop project plans including submission timelines, deliverables, etc.			
18. Liaise with marketing/project team to develop target product profile and determine the claims that can and cannot be made based on available data.			
19. Participate in audits/inspections by NBs/CAs and contribute to responses to audit findings as required.			
20. Evaluate and communicate relevant legislation and guidelines (e.g., EMA, scientific, harmonized standards, and essential requirements).			
Registration/CE Marking			
21. Ensure adequate documentation to support MAA/Technical File/Design dossier. (see test content outline for details)			
22. Prepare MAA/Design Dossier/Technical File.			
23. Submit MAA (incl. eCTD requirements)/Design Dossier to CA/NB.			
24. Monitor /track submission progress (procedural timelines).			
25. Respond to questions/comments from CA/NB.			
26. Meet with CA/NB to negotiate during review process.			
27. Coordinate product information (i.e. label, carton, and leaflet/IFU) translations.			
28. Review approval documents/certificates.			
Domain III: Postapproval (approximately 33% of exam)			
Task	**Needs minimal review**	**Needs extensive review**	**Review complete**

Advertising/Promoting/Labelling			
1. Review and approve revised labelling and claims, public communications, press releases, advertising, and promotional items for regulatory compliance.			
2. Provide regulatory input to commercial and marketing strategies.			
3. Review and evaluate advertising, labelling, and claims of competitors.			
4. Provide regulatory input to tender applications (e.g., overview of licensing status, product quality, product shelf life, declaration of conformance).			
5. Evaluate and communicate to management the implications of off-label use.			
Postmarketing Surveillance and Vigilance			
6. Evaluate reports of product failures and complaints.			
7. Write field safety notices and report product failures and recalls /field safety corrective actions to CAs.			
8. Maintain vigilance and ensure post-market surveillance activities are conducted.			
9. Ensure that Periodic Safety Update Reports (PSUR) are compiled and submitted to CAs according to regulatory timelines.			
10. Ensure regulatory compliance of post-approval clinical studies.			
11. Ensure implementation and monitor effectiveness of safety alerts, notifications, field safety corrective actions, and recalls.			
12. Consider use of information gained in the post-market phase for broadening product indications.			
Supply Chain			
13. Ensure compliance with regulatory requirements for supply, handling, distribution, import and export of materials.			
14. Review regulatory aspects of supplier and distributor contracts (e.g., complaints, traceability, changes, etc.).			
Product-specific Crisis Management			
15. Advise management regarding the regulatory impact of a crisis event (e.g., batch failure)			
16. Advise management on regulatory implications of proposed crisis resolution strategies.			
Postapproval Regulatory Compliance			
17. Advise the Management Representative/Qualified Person regarding regulatory requirements.			
18. Ensure quality system SOPs meet regulatory requirements			
19. Assess whether new or revised legislation, guidelines, monographs and harmonized standards affect certain functions, activities, or products			
20. Initiate, monitor, document and submit changes where			

applicable to ensure compliance with new or revised legislation, guidelines, monographs, and harmonised standards.			
21. Review and monitor contractual obligations and agreements with NBs to ensure regulatory compliance.			
22. Negotiate wording of audit findings.			