RAC (US) Examination
Study Checklist

Instructions: Use this checklist to track your progress when preparing for the RAC (US) 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 28% of exam)			
Task	**Needs extensive review**	**Needs minimal review**	**Review complete**
1. Evaluate proposed products for regulatory classification (drug/device/biologic/combination/OTC etc.) /jurisdiction (CDER/CDRH/CBER etc.)			
2. Monitor and assess the regulatory environment (product specific guidances, competitor products etc.) to propose regulatory path forward (generic/OTC/predicate device etc.)			
3. Evaluate US regulatory implications for non-US (global) development and marketing			
4. Provide input to FDA, industry (PhRMA, AdvaMed etc.) and standards (USP, ASTM, ICH etc.) organizations to influence the US regulatory environment (legislation, regulations, guidance documents, standards etc.)			
5. Determine requirements (local, national, international) and options for regulatory submissions (NDA/BLA/PMA/510k, electronic/paper, 505(b)(2), etc.), approvals (priority review, user fees, etc.), and compliance activities (registration, listings, etc.).			
6. Advise management on timelines, benefits/risk assessment and financial implications of the proposed regulatory strategy			
7. Investigate and communicate the availability of incentives (pediatric, orphan, fast track, HDE etc.) to support product development			
8. Develop optimal strategy for Agency interactions during product development and life cycle management			
9. Advise internal stakeholders (marketing, manufacturing, R&D etc.) regarding current/pending guidances, regulations, Agency/industry initiatives etc. to ensure regulatory strategy is in alignment with company objectives.			
10. Consult with marketing/project team to develop intended use and claims (target product profile)			

11. Assess quality systems (e.g., CE marking, ICH, GMP/QSR, ISO, etc.) by performing audits to determine compliance to Quality System Regulations (QSR) and Drug GMP, assuring compliance to established SOPs for QSR and drug GMPs [e.g., failure investigations, etc], and making recommendations for improvement of quality systems, based on audit findings and QSR or GMP requirements.			
12. Develop/deliver/assure in-house training programs for all company personnel for regulatory compliance (Refers to GXP).			
13. Assure implementation and documentation of training programs including identification of training needs (job-specific and general GMP training) and training schedules.			
14. Provide trainers with updated information on regulatory requirements to incorporate in on-going training programs.			
15. Conduct regulatory due diligence and advise senior management during product or company acquisitions and collaborations			
16. Ensure regulatory obligations are met for In- and Out-licensing of products			
17. Ensure regulatory obligations are met for contract activities (manufacturing, complaint handling, regulatory operations etc.)			
Domain II: Pre-Approval (approximately 25% of exam)			
Task	**Needs extensive review**	**Needs minimal review**	**Review complete**
1. Determine test requirements (GLP/non-GLP, biocompatibility, carcinogenicity studies specific to drug/biologic/device, etc.) and identify applicable guidances			
2. Ensure compliance with nonclinical safety (GLPs) and applicable performance standards (ISO, ASTM, ANSI, ICH etc.)			
3. Determine adequacy of nonclinical data and risk analysis to support initiation of clinical trials including any appropriate risk management			
4. Assess quality systems (e.g., CE marking, ICH, GMP/QSR, ISO, etc.) by performing audits to determine compliance to Quality System Regulations (QSR) and Drug GMP, assuring compliance to established SOPs for QSR and drug GMPs [e.g., failure investigations, etc], and making recommendations for improvement of quality systems, based on audit findings and QSR or GMP requirements.			
5. Determine requirements with regard to clinical safety and efficacy (GCPs)			
6. Ensure compliance with all clinical standards (GCPs, (clinical trial monitoring and auditing), IRBs, safety reporting, informed consent, financial disclosure, etc.)			

7. Advise project team of regulatory recommendations for ongoing aspects of clinical trials/investigations (amendments to protocol etc.)			
8. Identify non-US country specific requirements for impact to US submissions (IND/IDE, annual report etc.)			
9. Prepare and/or review information included in IND/IDE submission such as: label, clinical investigation plan/protocol, case report form, investigators brochure, informed consent etc.			
10. Ensure that any identified safety risks have been appropriately addressed with the clinical development program			
11. Ensure that CFR requirements for adverse event reporting are established and being followed			
12. Evaluate need for and contribute to the development of Pediatric Development Plan and/or waivers/deferrals, Orphan Designation Applications etc.			
13. Determine regulatory requirements for manufacturing /quality system certifications (clinical trial supplies, manufacture, dosage forms, device classification, DMFs, etc.)			
14. Ensure compliance with cGMPs and QSR (SOPs, record retention, calibration etc.)			
15. Verify device Design History File complies with regulatory requirements including risk management			
16. Ensure regulatory compliance of manufacture and release of investigational products for clinical use			
17. Review completeness of documentation to support IND/IDE submissions			
18. Ensure specifications for testing of API/drug substance/drug product and documentation of raw materials (novel excipients, animal derived materials etc.) comply with regulatory requirements			
19. Ensure specifications for device components, manufacturing process, and product have been defined and meet regulatory requirements (including product and quality system software)			
20. Evaluate manufacturing changes for compliance with appropriate change control systems/process and determine regulatory filing strategy			
21. Review and monitor regulatory compliance for suppliers (contract manufacturers, CROs etc.)			
22. Prepare pre-market submissions (IDE/IND) and masterfiles for drugs/biologics/devices including investigational labeling			
23. Guide project regarding submission format (CTD/eCTD etc.)			
24. Review application for completeness according to “refuse-to-file” guidelines			

25. Negotiate/interact as appropriate with Agency during development/submission process (Pre-IDE/IND, End of Phase 2, Meetings, Respond to Agency comments etc.)			
26. Monitor and maintain ongoing IDE/IND applications (e.g., amendments, annual reports, updates)			
27. Determine requirements for export/import of investigational products (customs, USDA, etc)			
28. Ensure that the identified risks have been appropriately flagged and monitored			
29. Initiate process to obtain non proprietary (USAN) and proprietary names			
Domain III: Approval (approximately 24% of exam)			
Task	**Needs extensive review**	**Needs minimal review**	**Review complete**
1. Assess and verify adequacy of nonclinical data to support approval			
2. Assemble nonclinical reports and prepare nonclinical summary documentation as appropriate			
3. Assess the adequacy of clinical safety and efficacy data to support approval and desired label claims			
4. Assemble clinical reports submission and prepare summary documentation as appropriate			
5. Ensure clinical trial monitoring and clinical trial audits are performed			
6. Assess and verify the adequacy of data to support submission approval and desired label claims/product specifications			
7. Assess and verify the readiness of the drug/device manufacturing facility for PAI (Ensure compliance with GMP and QSR)			
8. Assemble CMC documentation submission and prepare summary documentation as appropriate			
9. Prepare and schedule pre-submission meetings with the Agency at the appropriate stage of the submission (e.g., pre-IND/IDE, end of Phase 2, etc.) to reach agreement on content, format, and other issues/proposals.			
10. Guide project regarding submission format (CTD/eCTD, paper etc.)			
11. Negotiate/interact as appropriate with Agency during the submission process (120 Day Safety Report, Respond to Agency comments, 100 Day Review etc.)			
12. Prepare for and participate in Advisory Committee Meeting/Advisory Panel Meeting if requested			
13. Drive the creation of draft labeling that meets regulatory requirements and negotiate final labeling with FDA at end of review period (SPL)			

14. Develop post approval regulatory plans and negotiate agreement with FDA (eg risk evaluation and mitigation strategy (REMS) and post market clinical follow up plan)			
15. Provide guidance on FDA review practices and current thinking (refusal to file, priority review assignment, FDAs Best Review Practices, etc.)			
Domain IV: Post-Approval (approximately 23% of exam)			
Task	**Needs extensive review**	**Needs minimal review**	**Review complete**
1. Submit required licensing fees, drug listings, periodic reports and updates (e.g., PSURS, masterfiles, etc.)			
2. Comply with product post-marketing approval requirements/condition of approval studies (Phase IV Studies)			
3. Prepare, implement and monitor strategy for alerts/notifications/recalls/market withdrawal			
4. Advise management on alerts/notifications/recalls			
5. Provide regulatory input on post approval change management			
6. Assess documentation to support product and process changes and determine regulatory category of change (PAS, CBE, Annual Reports etc)			
7. Prepare and submit supplements/design change applications and notifications to NDA, BLA, PMA			
8. Maintain and record changes to the technical file/design dossier or NDA/BLA.			
9. Ensure compliance with Risk Evaluation and Mitigation Strategy (REMS).			
10. Evaluate reports of product complaints			
11. Ensure that appropriate systems are in place to document and track product complaints and ADR reports			
12. Ensure implementation of necessary corrective actions based on results of inspections, audits, failure analysis, and consent decrees			
13. Report product safety issues/failures to regulatory agencies as required [e.g. ADEs]			
14. Review adverse drug reaction reports and medical device reports			
15. Review and approve revised labeling and claims, public communications, press releases, advertising, and promotional items for regulatory compliance			
16. Evaluate data to support comparative claims in advertising and implications of off-label use			
17. Ensure compliance with regulatory requirements for supply, handling, distribution, import and export of materials.			
18. Ensure compliance with applicable requirements/regulations for distribution of controlled			

substances			
19. Review regulatory aspects of contracts for product distribution (e.g., product complaints, product tracking, etc.)			
20. Advise on the issues related to drug/product/lot releases (Annual Product Review, Device History Record)			
21. Advise management regarding the regulatory impact of a crisis event			
22. Develop regulatory plan to address the crisis event.			
23. Advise management on regulatory implications of proposed crisis resolution strategies			
24. Facilitate coordination of outside consultants and company personnel in response to Agency comments (PAI, 483 responses, conduct of clinical studies etc.)			
25. Negotiate with Agency wording of inspection findings			
26. Manage/accompany/chaperone inspection teams or auditors			
27. Advise internal functional groups regarding regulatory compliance (e.g., FDA 483's, warning letters, and consent decrees) and communicate corrective follow-up actions to management			
28. Prepare strategy/briefing documents for panel hearings and informational meetings (Advisory Committee)			
29. Communicate/refer external requests for information			
30. Develop Freedom of Information Act strategy regarding confidentiality and protection of proprietary information and document requests			