September 2018

Regulatory Affairs Certification (US)

CANDIDATE GUIDE

RAPS.org/RAC

CONTENTS

WELCOME

Introduction

Congratulations on your decision to pursue Regulatory Affairs Certification (RAC). We commend your commitment to your career and the regulatory profession.

This guide contains information about:

- RAC examination eligibility requirements
- Guidelines for submitting an examination application
- Preparing for the examination
- How to schedule your examination and what to expect at the testing center
- What to expect after the examination

Regulatory Affairs Certification (RAC), is the only post-academic professional credential for regulatory professionals in the healthcare product sector. It is intended for individuals employed in regulatory agencies, industry, consultancies and other settings involved with the regulation of healthcare products. The RAC is a professional credential that denotes commitment to excellence, pursuit of knowledge and career advancement. Success on the RAC examinations requires knowledge of the appropriate regulations and the ability to think critically about the regulatory issues and challenges that occur throughout the healthcare product lifecycle.

RAC-credentialed professionals are among the current and rising leaders in the regulatory profession. To date, more than 8,000 individuals have earned the RAC, some holding multiple credentials.

Value of the RAC

The RAC demonstrates to employers, clients and colleagues that a regulatory professional has the essential knowledge, skills, critical thinking abilities and commitment to advancing professional knowledge and abilities. As the demand for competent regulatory professionals increases globally, RAC-credentialed professionals are well positioned to be effective team members and contributors in every work setting. Recognition of the RAC continues to grow around the world and RAC-credentialed professionals earn higher salaries than those who do not hold the credential.*

In RAPS' *2018 Scope of Practice & Compensation survey for the Regulatory Profession*, RAC holders in North America reported earning an average of 18% more than their counterparts who do not hold the credential.*

*Based on data from the *2018 RAPS Scope of Practice & Compensation Survey of the Regulatory Profession*

About Certification

The primary purpose of any professional certification program is to provide an independent assessment of the knowledge, skills and/or competencies required for competent performance of a professional role. This assessment is typically accomplished by the successful completion of an examination.[1]

[1] Defining Features of Quality Certification and Assessment-Based Certificate Programs. (2010) The Institute for Credentialing Excellence.

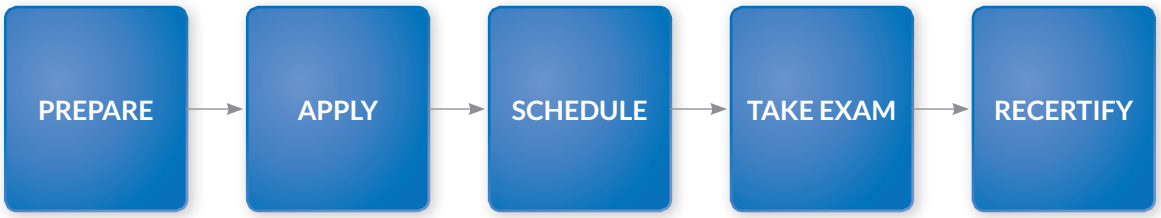
Eligibility Requirements

To be eligible for the RAC examination you need to meet one of the following educational and professional experience requirement combinations:

- Baccalaureate or equivalent first university degree and a minimum of three years of regulatory or regulatory-related work experience*
- Master's degree and a minimum of two years of regulatory or regulatory-related work experience*
- Doctorate degree and a minimum of one year of regulatory or regulatory-related work experience*

**Regulatory-related experience may include quality assurance, quality control, clinical research related to the approval of health products or health product project management.*

Your Journey



Nondiscrimination Policy

The RAC program does not discriminate among candidates on the basis of age, gender, race, religion, national origin, disability, sexual orientation or marital status.

PREPARING FOR THE EXAM

Preparing for the Examination

The RAC examinations are challenging so it is important to develop a study plan to prepare for the examination. Your plan should be based on your knowledge, experience and preferred approach to learning. Here are some things to consider:

Review the examination content outline (see p. 16). The examination content outline contains the content domains, competency statements and number of questions in each domain. Examination questions are based on guidelines and regulations effective 31 July of the prior year.

Assess the scope and depth of your knowledge and experience. Use the test content outline as a checklist and evaluate your areas of strength and weakness. This will help focus your study on the areas you need most.

Build and implement your plan. Allow sufficient time to build your knowledge base in areas where you have limited experience and to expand your knowledge in areas more familiar to you. Use reference materials to supplement your knowledge.

Question Types

The examinations consist of 100 multiple-choice questions, answered in a two-hour time limit. There are three question types which may be used in the RAC Exams.

Recall	Application	Analysis
Recall questions ask for specific information, typically about regulations and guidance that are important aspects of the regulatory process. These questions may relate to any stage of product development and may relate to regulations specific for product types.	Application questions require relating specific knowledge to a situation that may be encountered in the scope of practice of a regulatory professional.	Analysis questions may be described as a small case or example requiring the candidate to read and assemble information in order to identify and evaluate various solutions.

Computer-Based Testing

The RAC examinations are computer-based and administered only at testing centers selected and confirmed by the testing vendor. RAC examinations will not be stored or accessible through the internet and will not be offered at facilities that are not pre-selected and qualified for security measures.

RAC Examination Overview

Each examination is based on a survey of the scope of practice and specific roles and responsibilities of regulatory professionals in the workplace with at least three years of regulatory experience. Each examination is reviewed and revised annually and content is updated for the October/November exam cycle. Examination content for RAC US exam is based on regulations and guidelines in

	RAC (US)
Knowledge required and regulatory basis	• Thorough knowledge of regulatory functions throughout product lifecycle for medical devices, IVDs, pharmaceuticals and biologics • FDA regulations • Critical thinking and analytical skills

The RAC (US) examination is accredited by the National Commission for Certifying Agencies (NCCA)

Check the RAPS website at RAPS.org/rac/prepare for additional resources that may be helpful to you. Some resources are free of charge and others are available for purchase. Resources are not required to be RAPS produced.

APPLYING FOR THE EXAMINATION

RAC Application Process

You may apply for the RAC online or submit the printable application form available on the RAC exam schedules webpage.

Testing Windows and Application Deadlines

Application Deadline	Testing Window
21 March 2019	22 April–31 May 2019
24 September 2019	21 October–30 November 2019

Applications and payment must be received by 11:59 pm (US Eastern Time) on the application deadline dates listed above. Applications received after the deadline will not be processed.

Examination Fees

- RAPS Member $465 (US)
- List $585 (US)

The RAPS member rate applies only if you are a member at the time you submit your application. If you apply for RAPS membership prior to submitting an RAC application, please be sure you receive confirmation of your RAPS membership before you submit your RAC application. If you apply for RAPS membership after you submit an RAC application, RAPS will not refund the difference.

Get information about RAPS membership online at RAPS.org/join-raps.

General Application Instructions

Include your name on the application as it appears on your government-issued photo identification (ID). If your name on your application does not match the government id, you will not be allowed to sit for the exam at the testing venue.

Provide an email address. All communications about your RAC examination, including information about scheduling your examination and examination results, are electronic. Please contact the RAC program office at certification@raps.org if there is any change in your email address after you have submitted your application.

Complete the RAC examination application fully. As part of the application process, you must attest that you have met the eligibility requirements, have read and agree to abide by the policies outlined in this Candidate Guide, and have read and accept the Code of Ethics for Regulatory Professionals. Incomplete applications will delay processing and may cause your application to be rejected if not completed by the application deadline.

Submitting Payment

The correct payment must accompany your application. You may submit your application and payment in the following ways:

Payment type	Application submission method
Credit card	Apply online, by fax or postal mail to: Regulatory Affairs Professionals Society Attn: RAC Program Office 5635 Fishers Lane Suite 550 Rockville, MD 20852 USA
Check or money order	Postal mail only to: Regulatory Affairs Professionals Society RAC 5635 Fishers Lane, Suite 550 Rockville, MD 20852 USA
International wire transfer	Fax a completed application form and copy of bank wire confirmation to confirm your application to: RAPS Account #1000043228997; ABA #061000104 Swift Code SNTRUS3A; Suntrust Bank, Richmond, VA. Must reference name of candidate. All bank charges are the responsibility of the payer. For all wire payments: fax (+1 301 770 2924) or email (certification@raps.org) a completed form and copy of bank wire confirmation to confirm your registration.

Application Receipt Confirmation

You will receive an email notification thanking you for your order, which signifies that your application has been received. If there are any questions about your application or your application is selected for audit, you will be contacted by the RAC program office.

Application Audit

RAPS may audit a percentage of applications for completeness and accuracy. If your application is selected for audit, you will receive email notification of the audit, what types of documentation must be submitted and the deadline for submission of requested documentation. If you do not comply with the terms of the audit by the stated deadline, you will not be allowed to take the test and your examination fee will be refunded minus a $100 processing fee.

Incomplete Applications

If your application is incomplete, you will be notified by the RAC program office, and the application deficiencies must be corrected by the application deadline. Failure to submit required information prior to the deadline will lead to rejection of your application and you will be issued a refund of the examination fee, minus a $100 processing fee.

Application Rejection

Applications for RAC examinations will be rejected for failure to meet eligibility requirements or falsification of application information. Rejected applicants will be refunded the examination fee, minus a $100 processing fee.

Application Withdrawal/Cancellation and Refunds

An application may only be withdrawn or cancelled before the application deadline. Requests to withdraw or cancel an application will not be accepted after this deadline. To withdraw or cancel an RAC application, you must submit a written request to the RAC program office at certification@raps.org. There is a $100 processing fee for withdrawn or cancelled applications.

Transferring to Another Testing Cycle

A request to transfer to the next testing cycle may be made without charge before the application deadline. Requests to transfer to the next testing cycle after the application deadline but before the end of the testing window will incur a transfer fee of $250. Transfers will be allowed up to 10 days after the end of the testing window. After this period transfers will not be allowed and applicants will be required to pay a new application fee at full price. For individuals who require a transfer due to an unavoidable emergency please see the 'Emergency Situations' section.

Appeals Process

Candidates have the right to appeal any adverse decision made by the RAC program office. An appeal must be submitted in writing not more than 30 days following the date of notification of the adverse decision. Appeals should be sent to the RAC program office at certification@raps.org or via US mail to RAPS headquarters. All appeals will be addressed by the RACB. Decisions about appeals made by the RACB will be final.

EXAMINATION SCHEDULING

Scheduling Your Examination

You will schedule your examination online directly with RAPS' contracted testing vendor, Castle Worldwide. You will receive a "Notice to Schedule" email from Castle Worldwide approximately 15 days prior to the start of the testing cycle with instructions about how to schedule your examination. Please be sure that your email address can accept emails from testing@castleworldwide.com. This email will contain a website link, unique login ID and password. You will use this site to schedule a testing center location, test date and time.

Testing in the US and Canada

When scheduling your examination at a testing center in the US or Canada, once you log into the Castle Worldwide scheduling site, you will be shown the available dates and times at your selected testing center and you will select your preferred testing date and time. Once you submit your selection you will receive a confirmation email.

International Testing

When scheduling your examination at a testing center outside of the US or Canada, you will select your preferred testing center location, date and time. You may submit up to three preferred international testing centers, dates and times. Once you have submitted your preferences, Castle Worldwide will send a confirmation email within five business days. Submission of your preferences does not confirm that you are scheduled to test on your selected date or time. Castle Worldwide cannot guarantee availability of any international testing center or date during the designated testing cycle. If none of your preferred selections are available, Castle Worldwide will contact you to offer an alternate date/location for approval. Upon approval, Castle Worldwide will issue you a confirmation email.

You should schedule your examination as soon as possible for the best chance of receiving your preferred testing date and location. You must submit your test scheduling request at least seven days prior to your preferred testing date. All examinations must be scheduled five days prior to the close of the testing cycle. Once you have scheduled your examination, you will receive a confirmation email from Castle Worldwide. You must bring a copy of the confirmation email with you to the testing center on test day.

Castle Worldwide reserves the right to cancel any testing site. In the event of a cancelled site, you will be notified by Castle Worldwide and instructed about how to reschedule your testing location and appointment without additional fees.

Changing Your Examination Appointment Within the Same Testing Window

If you wish to change the date, time or location of a scheduled examination, you will need to go to the link on your appointment confirmation email. If you have difficulty rescheduling online, you can contact Castle Worldwide by telephone at +1 919 572 6880. A fee of $50 (US) for each change is required, payable to Castle Worldwide. Changes may not be made less than five business days before your scheduled examination date. You may only reschedule to another date within the current testing cycle. If you wish to reschedule to another testing window, please see 'Transferring to Another Testing Cycle.'

Emergency Situations

Under certain circumstances, as outlined below, the RAC program may, at its discretion, transfer an applicant's test to the next testing window and waive the transfer fee.

If an applicant cannot take the RAC exam for one of the following reasons:

- A documented, personal medical emergency
- A death in your immediate family
- Unexpected military deployment

The applicant may request to transfer to the next testing cycle. In such circumstances the applicant must contact the RAC program office no more than five days after the scheduled examination date (if a date has already been scheduled through the testing vendor).

A personal medical emergency means that the candidate has experienced a medical issue. Transfer requests are not applicable for medical issues affecting family members. To apply for a transfer waiver the appropriate documentation must be submitted to the RAC program office no later than 30 days of your scheduled examination date. Only one emergency transfer will be allowed and candidates will not be eligible for a refund following a transfer. Work-related emergencies do not qualify for this exception.

Failure to Schedule an Examination or Appear for Your Examination Appointment

If you do not schedule an examination appointment or you fail to appear for your scheduled examination appointment, you will be considered a 'no-show' and will forfeit all examination fees. The following are situations in which you will be considered a 'no-show':

- Failure to schedule an examination appointment during the testing cycle
- Failure to appear at your scheduled appointment
- Arriving at the testing site more than 15 minutes after your scheduled appointment time
- Failure to have appropriate photo identification at the examination appointment

If you fail to schedule or appear, you may reapply to take an RAC examination in the future and will be required to pay full application fees.

Special Accommodations for the Examination

Candidates who require special accommodations under the Americans with Disabilities Act (ADA) and ADA Amendments Act (ADAAA) should send the completed Special Accommodations Request Form with the Documentation of Disability-Related Needs form (see Appendices B and C) completed by a qualified professional, to the RAC program office at certification@raps.org or RAPS headquarters at the time of application. The request must indicate the nature of the disability and specific testing accommodations requested. Candidates will be notified in writing if their request is approved.

ON EXAMINATION DAY

What to Bring to the Testing Center

You should arrive at the testing center at least 30 minutes before your scheduled appointment for check in. You must bring a copy of the examination appointment confirmation email with you.

To be admitted to the testing center you must bring current, valid government-issued identification (ID). Your identification must include your name (in English characters or translation to compare with your RAC application information), photograph and signature.

Your identification must match your name exactly as it appears on the examination appointment confirmation notification provided by Castle Worldwide. If you do not provide appropriate and/or matching identification, you will not be permitted to take the examination and will forfeit all examination fees.

The following are acceptable forms of government-issued identification:

- driver's license
- military ID
- passport
- national identification card

Items Prohibited at the Testing Center

Candidates are expressly prohibited from bringing the following items to the test center:

- cameras, cell phones, optical readers or other electronic devices that include the ability to photograph, photocopy or otherwise copy test materials
- notes, books, dictionaries or language dictionaries
- book bags,luggage, purses or handbags
- iPods, mp3 players, tablets, headphones or pagers
- calculators, computers, PDAs or other electronic devices with one or more memories
- personal writing utensils (i.e., pencils, pens and highlighters)
- watches
- food and beverages
- coats and jackets
- Hats, hoods or other headwear are not permitted in the examination room unless required for religious purposes. All items are subject to inspection by the proctor if suspicious behavior is detected.
- Please note that sweaters and sweatshirts without pockets or hoods are permitted.

You will be provided with:

1. paper and pencil or erasable noteboards and markers at the test center
2. have an abbreviations table

Please note that Castle Worldwide testing centers administer examinations for multiple organizations. Individuals in the testing room with you may be taking different examinations and have different rules for their examination including time and what is allowed at their testing station.

Other Considerations

- Smoking is prohibited.
- You may not ask questions about examination content.
- All examinations are monitored and may be recorded in both audio and video format.
- No breaks are scheduled during the examination. If you need to leave the testing room to take a break, you will not be given extra time to finish the examination. You may be required to present your ID when returning to the testing room.

Cancellation Due to Inclement Weather

In the event of bad weather, a natural disaster or other emergency, Castle Worldwide will post the information on their website. Candidates scheduled at a site operating on a delay will receive an email from Castle Worldwide. Should the site be closed entirely, Castle Worldwide will contact the candidates to reschedule.

Examination Security and Confidentiality

The RAC examinations are the sole and exclusive property of the RAC program. These materials are confidential and not available for review by any person or organization other than the RACB and the examination committees. Copying, publishing or disclosing examination content in any form is considered a violation of the RAC Security and Confidentiality policy and will be subjected to disciplinary action which may include termination of a testing session, invalidation of test results and/or\ revocation of an RAC credential.

Termination of Examination Administration/Dismissal From the Testing Center

You are expected to conduct yourself in a professional manner at all times at the testing center. The test center administrator or proctor is authorized to dismiss you from an examination and/or request that a test score be cancelled if you engage in any of the following:

- using or attempting to use someone else to take the examination
- using notes or other study materials during the testing process
- creating a disturbance. Disruptive behavior in any form is not tolerated. The test administrator has sole discretion to determine what constitutes disruptive behavior.
- communicating in any manner with anyone other than the administrator or proctor during the testing process
- leaving the testing room without permission
- tampering with a computer
- removing or attempting to remove any material from the testing room
- failing to follow any examination policies or requirement explained in this Candidate Guide

Problems at the Testing Center

The RAC program and Castle Worldwide take steps to assure that the RAC examination process is effective. However, irregularities may sometimes occur. If you encounter technical difficulties during the examination, please contact the proctor immediately. If a delay exceeds 30 minutes, you may request to reschedule your examination to another date if you are unable to wait any longer.

AFTER THE EXAMINATION

Examination Scoring

RAC examinations are scored by Castle Worldwide after the close of the testing cycle. Examinations are not scored at testing centers. A statistical report of scoring is reviewed by a statistician and the examination committee to assure ongoing quality of the examinations.

All scores are reported on a scale of 0 to 99 with 75 being the passing score. The scaled score is neither the number of questions answered correctly nor the percent of questions answered incorrectly. You cannot look at the scaled score and determine the number of correctly answered questions needed to pass the examination.

Notification of Examination Results

Examination results are typically available four to six weeks after the close of the testing cycle. The spring testing cycle closes on 31 May and the autumn testing cycle on 30 November. You will receive an email notification with your pass or fail results. Approximately four to eight weeks following the close of the testing cycle, you will receive a confirmation of your scaled score. Results are released only to candidates. No results will be reported over the telephone or by fax.

RAC Recognition

A list of all active RAC-credentialed professionals is available online at RAPS.org/RAC. Newly credentialed professionals are added after all candidates are notified of their status. If you do not wish to be included in the online listing, please contact the RAC program office.

Use of the RAC Designation

When you pass an RAC examination you may use the RAC designation after your name as a professional credential. You should list your RAC and specific RAC credentials on your resume, curriculum vitae, employment or other professional records. The RAC designation cannot be used by individuals who fail to maintain the RAC credential by meeting recertification requirements.

Retaking the Examination

Candidates who do not pass the RAC examination are eligible to retake the examination. To apply for re-examination, candidates must submit a new application. There is no limit on the number of times a candidate can take an examination. Candidates can retake the exam as soon as the next testing window.

Release of Information

The RAC program maintains strict procedures for ensuring the confidentiality of all candidate records. Information about candidates is released only to the candidates themselves. Scores are only released to the candidate and are not released by telephone or fax even to the candidate.

RECERTIFY

Maintaining Your RAC Credential

Continual learning, knowledge enhancement and professional development are vital to regulatory professionals. Once certified, you maintain your RAC through continued learning and involvement in professional activities. You are required to renew your RAC every three years by earning 36 RAC recertification credits. Credits may be accumulated in many ways, including participation in continuing education, public speaking on regulatory topics, professional writing and involvement with professional organizations.

Individuals who hold more than one RAC designation are only required to submit a single recertification application with a total of 36 credits. The recertification cycle is based on the initial RAC certification and the related recertification cycle. You can find detailed information about maintaining and renewing your RAC in the RAC Recertification Guide.

Contact Information
Regulatory Affairs Professionals Society
Attention: RAC Program Office
5635 Fishers Lane, Suite 550
Rockville, MD 20852
USA
Tel +1 301 770 2920, ext. 200
Fax +1 301 770 2924
Email: certification@raps.org

Castle Worldwide Inc.
900 Perimeter Park Drive, Suite G
Morrisville, NC 27560
+1 919 572 6880
email: testing@castleworldwide.com

APPENDIX A: RAC (US) DETAILED EXAMINATION CONTENT OUTLINE

The RAC (US) examination is organized into four major domains, with associated tasks and responsibilities typically undertaken by a regulatory professional. The approximate distribution of types of questions for each domain is shown in the following outline. Questions on the examination will address the tasks and activities presented in this outline.

Domain I: Strategic Planning

Approximately 28 questions for a 100-question examination (percent of items on examination: 28%)

Regulatory Framework

- Evaluate proposed products for regulatory classification (drug/device/biologic/combination/OTC/predicate devices, etc.) and jurisdiction (CDER/CDRH/CBER, etc.).
- Monitor and assess the regulatory environment (product specific guidances, competitor products, etc.) to propose regulatory path forward (generic/OTC/predicate device, etc.).
- Evaluate US regulatory implications for non-US (global) development and marketing.
- Provide input to FDA and industry (PhRMA, AdvaMed, etc.) and standards (USP, ASTM, ICH, etc.) organizations to influence the US regulatory environment (legislation, regulations, guidance documents, standards, etc.).

Regulatory Pathways and Options

- 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.).
- Advise management on timelines, benefits/risk assessment and financial implications of the proposed regulatory strategy.
- Investigate and communicate to management the availability of incentives (pediatric, orphan, fast track, HDE, etc.) to support product development.
- Develop optimal strategy for Agency interactions during product development and life cycle management.
- 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.
- Consult with marketing/project team to develop intended use and claims (target product profile).
- 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.
- Develop/deliver/assure in-house training programs for all company personnel for regulatory compliance (Refers to GXP).
- Assure implementation and documentation of training programs including identification of training needs (job-specific and general GMP training) and training schedules.
- Provide trainers with updated information on regulatory requirements to incorporate in on-going training programs.

Interaction With Other Companies

- Conduct regulatory due diligence and advise senior management during product or company acquisitions and collaborations.
- Ensure regulatory obligations are met for in- and out-licensing of products.
- Ensure regulatory obligations are met for contract activities (manufacturing, complaint handling, regulatory operations, consultants, etc.).

Domain II: Preapproval

Approximately 25 questions for a 100-question examination (percent of items on examination: 25%)

Nonclinical Development

- Determine test requirements (GLP/non-GLP, biocompatibility, carcinogenicity studies specific to drug/biologic/device, etc.) and identify applicable guidances and resources for such requirements.
- Ensure compliance with nonclinical safety requirements (GLPs) and applicable performance standards (ISO, ASTM, ANSI, ICH, etc.).
- Determine adequacy of nonclinical data and risk analysis to support initiation of clinical trials including any appropriate risk management.
- 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.

Clinical Development

- Determine requirements with regard to clinical safety and efficacy (GCPs).
- Ensure compliance with all clinical standards (GCPs, clinical trial monitoring and auditing), IRBs, safety reporting, informed consent, financial disclosure, etc.).
- Advise project team of regulatory recommendations for ongoing aspects of clinical trials/investigations (amendments to protocol, etc.).
- Identify non-US country specific requirements for impact to US submissions (IND/IDE, annual report, etc.).
- 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.
- Ensure that any identified safety risks have been appropriately addressed with the clinical development program.
- Ensure that CFR requirements for adverse event reporting are established and being followed.
- Evaluate need for and contribute to the development of Pediatric Development Plan and/or waivers/deferrals, Orphan Designation Applications, etc.

CMC/Device Design and Manufacturing

- Determine regulatory requirements for manufacturing /quality system certifications (clinical trial supplies, manufacture, dosage forms, device classification, DMFs, etc.).
- Ensure compliance with cGMPs and QSR (SOPs, record retention, calibration, etc.).
- Verify device Design History File complies with regulatory requirements including risk management.
- Ensure regulatory compliance of manufacture and release of investigational products for clinical use.
- Review completeness of documentation to support IND/IDE submissions.

- 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.
- Ensure specifications for device components, manufacturing process and product have been defined and meet regulatory requirements (including product and quality system software).
- Evaluate manufacturing changes for compliance with appropriate change control systems/process and determine regulatory filing strategy.
- Review and monitor regulatory compliance for suppliers (contract manufacturers, CROs, etc.).

Agency Interaction

- Prepare premarket submissions (IDE/IND) and master files for drugs/biologics/devices including investigational labeling.
- Ensure that the project is in compliance regarding submission format (CTD/eCTD, etc.).
- Review application for completeness according to "refuse-to-file" guidelines.
- Negotiate/interact as appropriate with Agency during development/submission process (Pre-IDE/IND, End of Phase 2, Meetings, Respond to Agency comments, etc.).
- Monitor and maintain ongoing IDE/IND applications (e.g., amendments, annual reports, updates).
- Determine requirements for export/import of investigational products (customs, USDA, etc.).
- Ensure that the identified risks have been appropriately flagged and monitored.
- Initiate process to obtain nonproprietary (USAN) and proprietary names.

Domain III: Approval

Approximately 24 questions for a 100-question examination (percent of items on examination: 24%)

Nonclinical Section

- Assess and verify adequacy of nonclinical data to support approval.
- Assemble non-clinical reports and prepare nonclinical summary documentation as appropriate.

Clinical Section

- Assess and verify the adequacy of clinical safety and efficacy data to support approval and desired label claims.
- Assemble clinical reports submission and prepare summary documentation as appropriate.
- Ensure clinical trial monitoring and clinical trial audits are performed and documented.

CMC/Device Design and Manufacturing

- Assess and verify the adequacy of data to support submission approval and desired label claims/product specifications.
- Assess and verify the readiness of the drug/device manufacturing facility for PAI (Ensure compliance with GMP and QSR).
- Assemble CMC documentation for submission and prepare summary documentation as appropriate.

Submission and Review Process

- Prepare and schedule presubmission 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.
- Guide project regarding submission format (CTD/eCTD, paper, etc.).
- Negotiate/interact as appropriate with Agency during the submission process (120 Day Safety Report, Respond to Agency comments, 100 Day Review, etc.).

- Prepare for and participate in Advisory Committee Meeting/Advisory Panel Meeting if requested.
- Drive the creation of draft labeling that meets regulatory requirements and negotiate final labeling with FDA at end of review period (SPL).
- Develop postapproval regulatory plans and negotiate agreement with FDA (e.g., risk evaluation and mitigation strategy (REMS) and postmarket clinical follow up plan).
- Provide guidance to project teams on FDA review practices and current thinking (refusal to file, priority review assignment, FDA's Best Review Practices, etc.).

Domain IV: Postapproval

Approximately 23 questions for a 100-question examination (percent of items on examination: 23%)

Postmarketing/Maintenance

- Submit required licensing fees, drug and device listings, periodic reports and updates (e.g., PSURS, master files, etc.).
- Comply with product postmarketing approval requirements/condition of approval studies (Phase IV Studies).
- Prepare, implement and monitor strategy for alerts/notifications/recalls/market withdrawal.
- Advise management on alerts/notifications/recalls.
- Provide regulatory input on postapproval change management.
- Assess documentation to support product and process changes and determine regulatory category of change (PAS, CBE, Annual Reports, etc).
- Prepare and submit supplements/design change applications and notifications to NDA, BLA, PMA.
- Maintain and record changes to the technical file/design dossier or NDA/BLA.
- Ensure compliance with Risk Evaluation and Mitigation Strategy (REMS).

Postmarketing Surveillance/Vigilance

- Evaluate reports of product complaints.
- Ensure that appropriate systems are in place to document and track product complaints and ADR reports.
- Ensure implementation of necessary corrective actions based on results of inspections, audits, failure analysis and consent decrees.
- Report product safety issues/failures to regulatory agencies as required [e.g., ADEs].
- Review adverse drug reaction reports and medical device reports.

Advertising/Promoting/Labeling

- Review and approve revised labeling and claims, public communications, press releases, advertising and promotional items for regulatory compliance.
- Evaluate data to support comparative claims in advertising and implications of off-label use.

Distribution

- Ensure compliance with regulatory requirements for supply, handling, storage, distribution, import and export of materials.
- Ensure compliance with applicable requirements/regulations for distribution of controlled substances.
- Review regulatory aspects of contracts for product distribution (e.g., product complaints, product tracking, etc.).
- Advise on the issues related to drug/product/lot releases (Annual Product Review, Device History Record).

Crisis Management

- Advise management regarding the regulatory impact of a crisis event.
- Develop regulatory plan to address the crisis event.
- Advise management on regulatory implications of proposed crisis resolution strategies.

Agency Interaction

- Facilitate coordination of outside consultants and company personnel in response to Agency comments (PAI, 483 responses, conduct of clinical studies, etc.).
- Negotiate with Agency wording of inspection findings.
- Manage/accompany/chaperone inspection teams or auditors.
- 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.
- Prepare strategy/briefing documents for panel hearings and informational meetings (Advisory Committee).
- Communicate/refer external requests for information.
- Develop Freedom of Information Act strategy regarding confidentiality and protection of proprietary information and document requests.

APPENDIX B: SPECIAL ACCOMMODATIONS REQUEST

The Regulatory Affairs Certification Board (RACB) may provide accommodations to candidates with a disability as defined by the *Americans with Disabilities Act* (*ADA*). Please review the RAC Candidate Guide before submitting this form to be sure you quality for special accommodations.

Please type or print

Name _____
First Last MI

Address _____
Street Mail Stop/Suite/Apt

_____
City State/Province Zip

Country _____

Phone (with area/country code) _____

Email address _____

For which of the following examinations are you requesting accommodations?

❑ RAC (US)
❑ RAC (EU)
❑ RAC (CAN)
❑ RAC (Global)
❑ RAC (Devices)
❑ RAC (Drugs)

Type of accommodation you are requesting _____

_____

Have you previously received accommodations in any educational or testing situation?
❑ Yes
❑ No

If yes, please describe the accommodations received _____

_____

I certify that the above information is true and accurate.

Signature _____ Date _____

APPENDIX C: DOCUMENTATION OF DISABILITY-RELATED NEEDS

To the Professional: The individual identified below is requesting accommodations for the Regulatory Affairs Certification (RAC) examination. The Regulatory Affairs Professionals Society requires that candidates requesting testing accommodations provide documentation of the disability from a person qualified to assess the disability.

By completing and signing this form, you are verifying that the individual named below has been diagnosed with the stated disability and the recommended accommodation is required to fairly demonstrate the candidate's ability on the examination.

Candidate Name _____
First Last MI

Please include the following:

1. Diagnosis (note: mental and emotional disabilities must include a diagnosis from the DSM-IV)

_____

_____

_____

2. Description of the candidate's disability and how the disability affects the candidate's major life activities (e.g., hearing, seeing, walking, talking, performing manual tasks)

_____

_____

_____

3. Recommended Accommodations:

_____

_____

_____

Signature _____ Date _____

Title _____

5635 Fishers Lane
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Rockville, MD 20852
USA

RAPS.org/RAC