



## RAC (EU) EXAMINATION SUBJECTS & FORMAT

The European RAC Examination is a knowledge-based examination addressing European Union laws, regulations, policies and guidelines affecting medical RAC devices, pharmaceuticals, biologics and biotechnology. The examination consists of 100 items presented in a multiple-choice format. The examination is reviewed and revised annually. The examination content is based on information effective 31 December of the prior year. For example, the examination administered in Fall 2007 includes regulations in effect 31 December 2006. The Spring 2008 examination will also be based on regulations in effect 31 December 2006.

Questions on the RAC (EU) examination fall into three general categories:

- Recall: recognize specific regulatory affairs information;
- Application: comprehend, relate or apply knowledge to new or changing regulatory affairs situations; and
- Analysis: analyze and assemble information, arrive at solutions and/or evaluate usefulness of solutions in regulatory affairs field.

The major subject areas are presented below:

RAC (EU) Examination Content Outline:

### **1. STRATEGIC PLANNING**

#### a. Basic Regulatory Tasks

- i. Evaluate proposed products for jurisdiction/regulatory classification status.
- ii. Evaluate regulatory advantages/disadvantages of non-European market introduction.
- iii. Determine borderline issues (e.g., relative to absorbable devices; drug device combinations; reclassification drug to device or vice versa; devices with viable animal or human materials).
- iv. Assess impact of Member State transpositions of Directives.

#### b. Regulatory Pathways/Regulatory Options

- i. Advise management on requirements and options for regulatory submissions/approvals/conformity assessments (consider the relationship with local, national, international options).
- ii. Analyze legislation for compliance practice needs and interpret to the work situation.
- iii. Develop effective regulatory submission strategies for timely product approval.

- iv. Design/Prepare/Implement global regulatory compliance strategy.
- v. Understand European regulatory background.
- c. Analysis of Other European Regulatory Requirements
  - i. Legislation in other European countries.
  - ii. Obtain approvals in other European countries.
  - iii. Interpret and apply other European legislation.

## **2. DESIGN AND DEVELOPMENT PHASE**

- a. Documentation/Research Permits
  - i. Advise sponsor of regulatory requirements for clinical trials or clinical investigations.
  - ii. Review clinical research study plans.
  - iii. Prepare clinical study procedure in accordance with applicable standards (e.g., EN ISO 14155, GCP, ICH).
  - iv. Determine acceptability of preclinical data/risk analysis to obtain approval to conduct clinical trials.
  - v. Prepare clinical trials submissions to ethics committees and competent authorities.
  - vi. Identify national certification/licensing requirements (e.g., responsible pharmacists for pharmaceuticals manufacturing).
  - vii. Develop Master Records, SOPs and document acceptability of manufacturing change orders.
  - viii. Make reports to competent authorities of adverse events that occurred during clinical trials.
  - ix. Review of clinical results.
- b. Testing Requirements/Compliance (design and development)
  - i. Prepare/review study information such as protocol, case report forms, investigators brochures, patient information letter and informed consent to comply with European regulatory requirements.
  - ii. Ensure research compliance and adequacy of documentation regarding: clinical safety and performance (e.g., EN ISO 14155); human subjects; nonclinical safety; preclinical studies; and product (e.g., GMPs).
  - iii. Assure nonclinical data support initiation of the proposed clinical program.
  - iv. Review relevant biocompatibility assessments for medical devices.
  - v. Maintain license for ongoing clinical trials.
- c. Risk Analysis
  - i. Application of risk analysis techniques (e.g., FMEA, FTA).
  - ii. Preparation of risk analysis documentation and results (e.g., according to EN ISO 14971:2000).

## **3. PREMARKET PHASE**

- a. Liaison with Regulatory Agencies and Subcontractors
  - i. Monitor applications under regulatory review.
  - ii. Negotiate/interact as appropriate, with regulatory authorities and

- notified bodies during the review process.
- iii. Negotiate labeling claims between regulatory authorities, notified bodies and the company.
- iv. Approve/validate vendors to ensure that raw materials, services and subcontracted activities comply with applicable legislation.
- b. Submission/Listing/Registration/Obtaining Approval
  - i. Review the regulatory acceptability of submissions.
  - ii. Document facility/product listings, licenses, approvals, etc.
  - iii. Prepare regulatory submissions.

#### **4. MANUFACTURING PHASE**

- a. Documentation and Quality System Responsibility
  - i. Act as a management representative for the quality system.
  - ii. Establish and ensure development of SOPs necessary for regulatory compliance (e.g., alerts, GMP/facility/quality system, compliance, recalls, etc.).
  - iii. Develop internal audit procedures to ensure regulatory compliance.
  - iv. Develop records retention policies and procedures.
  - v. Select type of quality system to be implemented.
- b. Training
  - i. Develop in-house training programs for company personnel in order to ensure regulatory compliance.
  - ii. Provide trainers with updated information on regulatory requirements to incorporate in ongoing training programs.
- c. Compliance (Manufacturing/Quality Systems)
  - i. Assess whether harmonized standards apply to certain functions/activities.
  - ii. Ensure compliance with quality systems.
  - iii. Direct internal project task groups regarding regulatory compliance.
  - iv. Monitor nonconforming product trends.
  - v. Review documentation supporting proposed changes to products/processes.
  - vi. Review/monitor contractual obligations/agreements to ensure regulatory compliance.
  - vii. Ensure adequacy of validations performed in support of quality systems compliance.
- d. Auditing/Monitoring
  - i. Ensure that all areas are audited per quality systems requirements/regulations.
  - ii. Perform internal audit procedures.
  - iii. Perform reinspection for compliance with inspection findings.
  - iv. Monitor product manufactured for use in clinical trials to determine if it is manufactured in compliance with the appropriate quality systems.
  - v. Review and ensure adequacy of process product specifications.
  - vi. Review and ensure adequacy of organization's quality audit

- program.
- vii. Review internal audit reports and management review reports.
- e. Validation
  - i. Ensure adequacy of overall validation program.
- f. Facilities
  - i. Prepare an application for establishment license.
  - ii. Notify regulatory bodies of pending change in manufacturing facilities.
  - iii. Ensure that facilities are in compliance with applicable legislation.

## **5. MARKETING/POST-APPROVAL PHASE**

- a. Advertising/Promoting/Labeling
  - i. Approve advertising/promotional items for compliance before release.
  - ii. Review labeling for compliance before release.
  - iii. Evaluate advertising and labeling of competitors.
- b. Post-Marketing Surveillance/Pharmaco/Medical Device Vigilance
  - i. Evaluate reports of product failures.
  - ii. Ensure implementation of necessary corrective actions based on results of inspections, audits and failure analysis.
  - iii. Report product failures and/or recalls (field actions) to regulatory agencies as required.
  - iv. Report product safety issues to regulatory agencies as required.
  - v. Review medical device product complaints.
  - vi. Review adverse drug reaction reports.
  - vii. Participate in initiation, strategy and policy of field actions, such as recalls, safety alerts.
  - viii. Assume responsibility for field actions as defined by company procedure.
  - ix. Ensure regulatory compliance of post-approval marketing studies.
  - x. Write field action letters.
  - xi. Implement and monitor effectiveness of alerts/notifications/recalls.
- c. Distribution
  - i. Ensure proper handling and regulatory compliance with import/export of biohazardous material.
  - ii. Ensure compliance with applicable requirements/regulations for distribution of controlled substances for distribution or utilization.
  - iii. Review regulatory aspects of contracts for product distribution (e.g., product complaints, product tracking, etc.).
  - iv. Ensure adequacy of product traceability systems.
- d. Crisis Management
  - i. Advise management regarding the regulatory impact of a crisis event.
  - ii. Advise management on regulatory implications of proposed crisis resolution strategies.
  - iii. Participate in the development and functioning of the crisis management

program.

## **6. INTERFACING**

### **a. Regulatory Agencies**

- i. Communicate directly with various international and local agencies (e.g., CEC, Notified Bodies, Competent Authorities, Standards Bodies) on product regulatory matters.
- ii. Conduct technical presentations to health regulatory advisory committees/agencies.
- iii. Participate in the development of new legislation/guidelines/standards.
- iv. Negotiate industry/regulatory positions.

### **b. Audits/Inspection Teams/Notified Bodies**

- i. Interact with and coordinate use of outside consultants with company personnel (e.g., conduct of clinical studies, preapproval site inspection, response to external audit reports, etc.).
- ii. Negotiate wording of audit findings.
- iii. Participate in acquisition due diligence.
- iv. Accompany/chaperone inspection teams/auditors.
- v. Participate in the identification of necessary corrective actions needed as a result of internal audit reports and communicate to management.
- vi. Communicate corrective follow up actions to management, regarding audits/inspections.

### **c. Government and Public Relations**

- i. Maintain records on relevant EU legislation.
- ii. Review public communications, press releases, etc.

### **d. Interdepartmental Guidance**

- i. Advise marketing regarding claims that can/cannot be made.
- ii. Advise management on proposed and newly finalized legislation.
- iii. Advise appropriate company personnel when a regulatory body exceeds its authority.
- iv. Communicate regulatory agency/industry positions within the organization.
- v. Develop “early warning system” to identify potential regulatory problems affecting the organization.
- vi. Notify/consult/brief legal counsel when necessary or appropriate.
- vii. Participate in medical review committees.

### **e. Standards Organizations**

- i. Identify the standards developing organizations appropriate for the company’s products.
- ii. Negotiate/interact as appropriate, with standards developing organizations.
- iii. Review draft documents when routed for comment.