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Regulatory Affairs Certification (RAC) Global Scope

RAPS RAC-GS

Version Demo

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Topic Break Down

Topic	No. of Questions
Topic 1, Strategic Planning	22
Topic 2, Pre-Marketing	39
Topic 3, Post-Marketing	31
Total	92

QUESTION NO: 1

At the last internal audit, a regulatory affairs professional identified a need for a corrective action for the manufacturing process. Which of the following stakeholders should be notified FIRST?

A. Quality improvement

B. Quality assurance

C. Clinical affairs

D. Regulatory agency

ANSWER: B

Explanation:

Quality assurance should be notified first because the finding concerns a manufacturing-process corrective action and therefore must enter the organization's controlled quality-system processes. Quality assurance is responsible for ensuring that audit findings are assessed, documented, investigated as appropriate, and managed through the corrective and preventive action process. This includes ensuring the issue is appropriately risk assessed, that responsibilities and timelines are assigned, that the corrective action addresses the identified cause, and that effectiveness is verified before closure. Prompt quality assurance involvement also preserves the independence, traceability, and documentation needed to demonstrate that the manufacturer has handled the audit finding in accordance with its quality management system. For medical-device manufacturers, corrective action is a core quality-system requirement: the U.S. FDA's Quality Management System Regulation requires manufacturers to establish procedures for implementing corrective and preventive action, including investigating causes and verifying that actions are effective. Similarly, ISO 13485 requires organizations to take action to eliminate causes of nonconformities and evaluate the effectiveness of those actions. These principles make quality assurance the appropriate initial stakeholder for formal oversight and coordination of the corrective-action process. See the FDA's Quality System Regulation overview and ISO 13485:2016.

QUESTION NO: 2

Which of the following statements regarding export regulations for an approved product is CORRECT?

A. The product must not be in accord with the specifications of the foreign purchaser.

B. The product must not be in conflict with the laws of the country to which it is intended for export.

C. The product must not be labeled on the outside of the shipping package that it is intended for export.

D. The product must not be sold or offered for sale in domestic commerce.

ANSWER: B

Explanation:

The product must not be in conflict with the laws of the country to which it is intended for export. This accurately reflects a fundamental condition for exportation under the U.S. Federal Food, Drug, and Cosmetic Act. A product exported from the United States must comply with the importing country's applicable laws; an exporter cannot rely on U.S. export provisions to send a product into a foreign market where that product would violate the destination country's legal requirements. In practice, this requires the manufacturer or exporter to understand the destination market's requirements, which may include product authorization or registration, technical documentation, labeling language and content, importer responsibilities, and any country-specific restrictions. The requirement is especially important because U.S. marketing authorization does not itself establish that a product may legally be placed on another country's market. Regulatory professionals should therefore confirm and document that the proposed export is consistent with the laws of each intended importing country before shipment. The statutory export provisions are set out in section 802 of the FD&C Act, including conditions related to compliance with the laws of the importing country. See 21 U.S.C. § 382 and the FDA's Exporting FDA-Regulated Products resource.

QUESTION NO: 3

A regulation change is imminent and may require further non-clinical testing on a product currently in Phase III clinical trials. What is the most appropriate action to take FIRST?

A. Obtain a copy of the proposed regulation and analyze the impact.

B. Inform the company's senior management and arrange an emergency meeting

C. Consult with the company's legal department regarding options.

D. Arrange for additional testing of the product at the testing facility.

ANSWER: A

Explanation:

Obtain a copy of the proposed regulation and analyze the impact. is the appropriate first action because regulatory affairs decisions should begin with a clear, evidence-based understanding of the actual proposed requirement, its scope, effective date, transition provisions, and the product categories to which it applies. “Imminent” does not itself establish that additional non-clinical testing will be required for this specific product or that testing must begin immediately. Reviewing the authoritative proposal enables the regulatory professional to perform a structured gap and impact assessment against the existing non-clinical package, ongoing Phase III program, development timeline, and planned marketing-application strategy. That assessment creates the factual basis for a proportionate internal escalation, targeted legal or scientific consultation, interaction with regulators where appropriate, and any later protocol or resource decisions. For US products, proposed rules and associated materials are published through the Federal Register, which provides the official text and rulemaking record; see the Federal Register. FDA also explains that guidance documents represent the agency’s current thinking and do not themselves establish legally enforceable responsibilities, reinforcing the importance of identifying the precise regulatory instrument and its status before acting: FDA Guidance Documents.

QUESTION NO: 4

In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?

A. Product stability

B. Product registration

C. Product formulation

D. Product requirements

ANSWER: A

Explanation:

Product stability is correct because the environmental conditions in the intended country of use directly determine whether a medicine will retain its identity, strength, quality, purity, and performance throughout its labelled shelf life. In global development, the relevant environmental consideration is chiefly the local climate, particularly expected temperature and humidity during distribution, storage, and patient use. These conditions can accelerate degradation, alter physical properties, affect moisture-sensitive dosage forms, or compromise packaging protection. Consequently, the development program must generate stability data under appropriate long-term and accelerated conditions and select a formulation, container-closure system, storage statement, and expiry period that remain suitable for the intended markets.

The International Council for Harmonisation stability guideline establishes that stability testing should be performed with consideration of the climatic conditions in the regions where the product will be marketed. Its framework supports evidence-based assignment of retest periods and shelf lives, as well as appropriate labelled storage conditions. Considering product stability early is therefore essential to a globally viable product strategy, because it links country-specific environmental exposure to product quality across the full lifecycle. See the ICH stability testing guideline and the WHO stability-testing guidance.

QUESTION NO: 5

A sponsor is preparing a clinical trial in several countries. One country requires that compensation arrangements for trial-related injury be described in the informed-consent materials, while the other participating countries do not have this requirement.

Which approach is MOST appropriate?

A. Prepare a country-specific informed-consent document that includes the required compensation information.

B. Use one global informed-consent document because the protocol is identical in all countries.

C. Describe compensation arrangements only in the clinical trial agreement with the investigational site.

D. Exclude the country from the trial unless all other countries adopt the same consent language.

ANSWER: A

Explanation:

Prepare a country-specific informed-consent document that includes the required compensation information. is correct because informed-consent materials must meet the applicable ethical and regulatory requirements of each country in which the trial is conducted. The sponsor should retain the core protocol-consistent information across all sites while adapting the consent form, where necessary, to address local requirements such as compensation, insurance, privacy, language, and contact information. Using one global form without the required local information could prevent ethics committee approval or result in inadequate participant information in that country.

QUESTION NO: 6

A company is considering use of a reliance pathway in a country that may consider assessments completed by a reference regulatory authority. The product proposed for reliance has a different manufacturing site and a narrower indication than the product authorized by the reference authority.

What is the BEST regulatory approach?

A. Confirm whether the local reliance pathway permits the proposed product differences and submit the required bridging information.

B. Submit the reference authority's approval letter as the only required evidence.

C. Market the product because the indication is narrower than that authorized by the reference authority.

D. Exclude all reference-authority information and submit a full independent dossier in every case.

ANSWER: A

Explanation:

Confirm whether the local reliance pathway permits the proposed product differences and submit the required bridging information. Reliance pathways can reduce unnecessary duplication of assessment, but they do not automatically apply where the product, manufacturing site, indication, labeling, or conditions of use differ from the reference authorization. The local authority must be able to determine whether the reference assessment remains relevant to the product proposed for its market.

The company should identify the local eligibility criteria, compare the proposed product against the reference product, and provide justified evidence addressing the differences. Assuming that the reference approval automatically authorizes the local product ignores country-specific legal requirements. Submitting an entirely independent full dossier may be unnecessary if the local authority accepts reliance with appropriate bridging data.

QUESTION NO: 7

According to WHO, what are the temperature and humidity conditions for a Zone IVb long-term stability study?

A. 25: C and 60% RH

B. 30° C and 35% RH

C. 30c C and 65% RH

D. 30: C and 75% RH

ANSWER: D

Explanation:

The correct long-term stability-storage condition for climatic Zone IVb is **30: C and 75% RH**, conventionally written as 30 °C ± 2 °C and 75% RH ± 5% RH. Zone IVb represents hot and very humid climatic conditions and is used to establish whether an active pharmaceutical ingredient or finished pharmaceutical product remains within its approved quality specifications throughout its proposed shelf life when distributed or stored in such markets. WHO stability guidance specifies the long-term testing conditions by climatic zone so that studies reflect the environmental stresses likely to be encountered in the intended region of supply. For Zone IVb, both the elevated temperature and high relative humidity are essential aspects of the prescribed condition; the result supports assignment of a shelf life and labelled storage statement appropriate to hot, very humid regions. WHO presents these conditions in its guideline tables for long-term stability studies of drug substances and finished pharmaceutical products. See the WHO publication WHO Technical Report Series No. 1010, Annex 10 and the associated WHO Technical Report Series No. 1010 PDF.

QUESTION NO: 8

According to ICH, how many stability time points are normally required to establish a two-year shelf life for a product?

A. 3

B. 5

C. 7

D. 9

ANSWER: C

Explanation:

7 is correct because ICH Q1A(R2) specifies that long-term stability testing should normally be conducted every three months during the first year, every six months during the second year, and annually thereafter. For a proposed two-year shelf life, this produces testing at the initial time point and at 3, 6, 9, 12, 18, and 24 months. Thus, the complete data set contains seven stability time points, including the zero-month (initial) result. These data are used to evaluate how the product's quality attributes change over time under the proposed long-term storage condition and to support assignment of the labelled shelf life. The word "normally" is important: ICH recognizes that the design should be scientifically appropriate to the product and the study, but the stated schedule is the standard expectation for long-term studies. This frequency provides sufficient observations across the proposed two-year period to identify trends and support a scientifically justified shelf-life assessment. The requirement is described in ICH's Q1A(R2): Stability Testing of New Drug Substances and Products, within the ICH Quality Guidelines.

QUESTION NO: 9

A company plans to transfer manufacture of a marketed drug product to a new site in order to improve supply continuity. The proposed site will use the same formulation and approved manufacturing instructions, but has different equipment and environmental controls.

Which activity is MOST important before the transfer is implemented?

A. Assume that no further action is needed because the formulation is unchanged.

B. Perform a documented comparability and regulatory impact assessment.

C. Notify all regulatory authorities immediately without completing a technical assessment.

D. Begin commercial manufacture at the new site and generate validation evidence afterward.

ANSWER: B

Explanation:

Perform a documented comparability and regulatory impact assessment. Even where formulation and written instructions are unchanged, differences in equipment, facility design, utilities, environmental controls, personnel practices, and process capability can affect critical quality attributes and process performance. The company must determine the validation, stability, quality, and postapproval reporting requirements before manufacture at the new site is used for commercial supply.

Assuming that the transfer requires no further action because the formula is unchanged overlooks the potential impact of the manufacturing environment. Filing an immediate global notification without first defining the change and its evidence package may result in incomplete submissions. Conducting commercial manufacture first and generating evidence afterward may be unacceptable if prior regulatory approval is required.