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Sample Question **Regulatory Affairs Certification (RAC) 101**

NEW QUESTION # 29
Following the introduction of a new regulation, an evaluation of the company's products by the regulatory affairs professional indicates that 10 percent do not comply with the regulation. What should the regulatory affairs professional do PAST to meet the new requirement?

- A. Request a permanent waiver from the new regulation.
- B. Contact the trade association for advice.
- C. Review documents for the field.
- D. Communicate with the relevant internal department.

Answer: A

NEW QUESTION # 30
A company has submitted a pre-market application of a new product to a major regulatory authority for review and approval. The regulatory authority issues the company a written commitment that the studies are complete and an estimate of the period and the results in the review process. The company has not yet received the pre-market application. During the time period of the review of the pre-market application, which has been set at 120 days, the company receives a letter from the regulatory authority stating that it no longer believes that the product will be approved based on a recall withdrawal of a similar product in another country. What is the BEST response?

- A. Contact a legal counsel in a regulatory authority to discuss the exception.
- B. Review the regulatory guidance to determine how to proceed.
- C. Consult with the legal department to discuss the best course of action.
- D. Contact the regulatory authority regarding its obligation to honor the commitment to approve the application.

Answer: A

NEW QUESTION # 32
During new drug development, a new impurity in the drug substance is detected at a level of 0.12%. The intended maximum daily dose is less than 2 g/day, and the drug is known generally not to be toxic. What should be done in response to identifying the impurity?

- A. Perform a new clinical qualification study, wait until the review is available, and then... (after performing an identification study)
- B. Perform both identification and a new clinical qualification studies concurrently.

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SAP Certified Professional - Solution Architect - SAP BTP Sample Questions (Q28-Q33):

NEW QUESTION # 28

A company is struggling with organizing and managing the immense amount of data generated by the business. They have been told about several possible solutions that SAP BTP offers; however, they are confused about which solutions they should use. A large amount of their historical and current data is in comma-separated values (CSV) and JavaScript Object Notation (JSON) documents. These documents need to be stored for reporting purposes. The client prefers to use the latest SAP solutions. Which SAP BTP solution would you recommend?

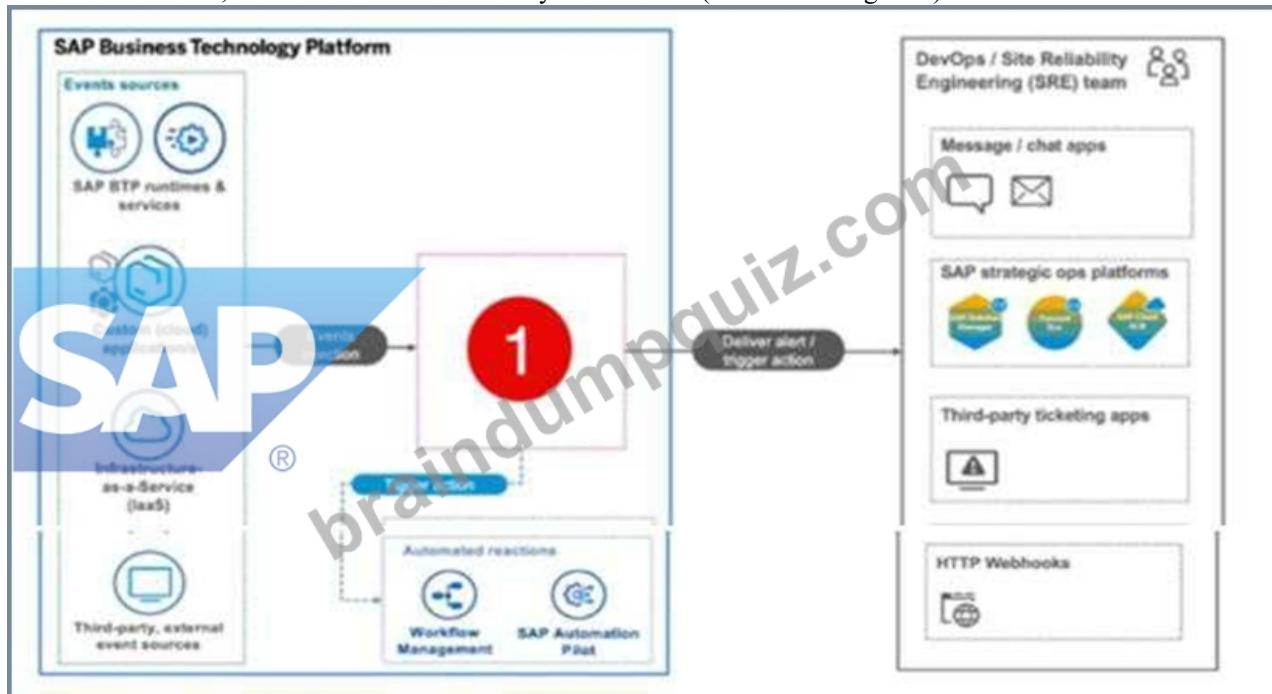
- A. SAP HANA Cloud, data lake
- B. SAP HANA Cloud
- C. SAP Datasphere
- D. SAP Data Warehouse Cloud

Answer: A

NEW QUESTION # 29

The DevOps / Site Reliability Team has a Question: for you. Over the course of the last month, several trust certificates have expired for several SAP BTP destinations, which has in turn occupied a significant portion of their time reinstalling. They wish to be informed before the certificate expires and to have a workflow triggered automatically.

As a solution architect, which SAP BTP service would you recommend (see attached diagram>)?



- A. SAP Monitoring service for SAP BTP
- B. SAP Alert Notification service for SAP BTP
- C. SAP Solution Manager
- D. SAP Solution Lifecycle Management service for SAP BTP

Answer: B

NEW QUESTION # 30

The customer is looking to use an SAP BTP service to replicate master data objects across connected business applications. The service should be based off of the process integration style and the integration use case pattern as defined in the SAP Integration Solution Advisory Methodology.

The customer wants to use an SAP BTP service to synchronize the workforce person master data object between SAP S/4HANA Cloud and SAP SuccessFactors HXM Suite as part of the Hire to Retire process (for cloud deployment). They prefer a service that uses a "hub and spoke" model to enable the synchronization.

Which of the following SAP solution should the customer use as the "Placeholder Icon" (see attached diagram)?



- A. SAP Cloud Integration
- B. SAP Master Data Governance
- C. SAP NetWeaver Master Data Management
- D. SAP Master Data Integration

Answer: D

NEW QUESTION # 31

Company XYZ, a global firm with 25K+ employees across the geographic locations Europe (headquarters), the USA (manufacturing), and South America (procurement), is migrating to SAP S/4HANA using SAP BTP. Each geographic location has dedicated IT staff managing access, authorizations, and SAP BTP resource quotas. For cost control, the company aims to analyze and optimize the usage and cost of SAP BTP resources both globally and by geographic location, intending to enhance their SAP BTP Account model structure.

Which of the following SAP BTP account models are appropriate? Note: There are 2 correct answers to this question.

- A. One global account with one directory for each region
- B. One global account with one subaccount for each region
- C. One global account for each business function with a corresponding subaccount for that region
- D. One global account for each business function with a corresponding directory for that region

Answer: A,B

NEW QUESTION # 32

The finance department is creating a series of reports for their line of business (LOB) users and would like to integrate the reports in a front-end portal. They would like the LOB users to maintain the portal, as opposed to IT. As a solution architect, they come to you to recommend which SAP BTP service best fits their needs.

Which service would you recommend?

- A. SAP Launchpad Service
- B. SAP Fiori Launchpad
- C. SAP Build Work Zone, advanced edition
- D. SAP Build Work Zone, standard edition

Answer: C

NEW QUESTION # 33

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