Oracle Argus Safety Suite 6 Essentials
Exam Study Guide

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Objective & Audience

Objective
Help you prepare to take Oracle Argus Safety Suite 6 Essentials (1Z0-551) Exam by providing pointers to resources that you can use in your preparation.

Targeted Audience

• Implementers, System Integrators
• Candidates should be familiar with Safety Installation and Configuration, Insight Installation and Configuration, Data Migration approaches, Architecture and Schema supporting Argus Safety Suite, Integration and Go Live tasks and Reporting on regulatory requirements
• Oracle’s Argus Safety Suite Specialization is for individuals focused on selling and implementing an advanced drug safety management solution.
• It is a proven and highly scalable system in use at global pharmaceutical companies, medical device manufacturers, biotech. companies, and CROs of all sizes.
• The Argus Safety Suite is a fully integrated platform designed to ensure regulatory compliance and comprehensive product stewardship, from clinical development all the way through post-marketing surveillance
• Up-to-date training and field experience are recommended.
Exam Topics & Objectives

Exam Topics
The Oracle Argus Safety Suite 6 Essentials (1Z0-551) Exam consists of 8 topics:

1. Argus Safety and Insight Installation and Configuration Overview
2. Project management track
3. Business track
4. Technology track
5. Data migration track
6. Configuration track
7. Integration track
8. Go-live track

Exam Objectives
The exam objectives are defined by learner or practitioner level of knowledge:

- **Learner-level**: questions require the candidate to recall information to determine the correct answer.
- **Practitioner-level**: questions require the candidate to derive the correct answer from the application of their knowledge, which can only be attained by extensive experience with the product.
Training Options

For each exam topic there have been identified alternative training options that are available at Oracle. The training options are divided into three categories:

• **Boot Camps**
  The Boot Camps are designed as a "jump start" training to enhance your skills by providing role-based training on industry-leading Oracle solutions and services. The boot camps are built as concise, intensive, and real-time training to give partners a competitive advantage as they prepare to build powerful solutions for their own customer base. Partners can choose to attend these boot camps in class or in a live virtual class format to maximize the effectiveness and the time allocated to training.

• **Instructor-Led Training**
  Partners can take any publicly-scheduled OPN and Oracle University courses. Benefit from hands on experience to gain real working skill and work toward Oracle certifications.

• **Online Training**
  Oracle Partners are entitled free access to the Oracle Knowledge Center (OUKC), a vast library of recorded product courses. New courses are regularly added to the library, providing partners with the latest information and training to master new products or to increase proficiency on the new releases.

A Guided Learning Path for the Oracle Argus Safety Suite 6 Implementation Specialization has also been provided through the OPN Competency Center, and features independent learning modules on various Argus Safety Suite 6 Implementation topics.
Reference Materials

We recommend that partners preparing for the exam should also review the Oracle Argus Safety Suite 6 Guided Learning Paths (GLPs) in preparation to take Oracle Argus Safety Suite 6 Essentials (1Z0-551) Exam:

- Oracle Argus Safety Suite 6 Sales Specialist
- Oracle Argus Safety Suite 6 PreSales Specialist
- Oracle Argus Safety Suite 6 Support Specialist
- Oracle Argus Safety Suite 6 Implementation Specialist
- Oracle Argus Safety Implementation Boot Camp

The following would be particularly useful as reference materials to be used as well:

- **Oracle eDelivery**
  Provides copies of software and current documentation found at: http://edelivery.oracle.com/

- **Oracle University**
  Provides an on-line courses and information on available courses found at: http://education.oracle.com/

- **My Oracle Support**
  Provides access to patch sets and enables logging of technical system requests found at: https://support.oracle.com

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Topic 1: Argus Safety and Insight Installation and Configuration Overview

Objectives:

• Describe the typical steps for Argus Safety and Insight installation

• Describe the key configuration elements for Argus Safety and Insight

Level
Practitioner
Learner

Training Options:

• Online Training:
Oracle Argus Safety Suite 6 Implementation Specialist

• Implementation Boot Camp:
Oracle Argus Safety Implementation Boot Camp

Sample Questions:

• Which two options are used to determine company size with regards to determining Argus Safety Suite’s sizing requirements? (Choose two)

A. Number of concurrent users
B. Number of databases supported by IT
C. Number of enterprise applications hosted in datacenter
D. Number of new cases reported each month
E. Number of workstations connected to the network

• Which option is the required web server software for Argus Safety Web Server?

A. Apache 2.2
B. IIS 5.1
C. IIS 6.0
D. Oracle iPlanet Web Server
E. Weblogic Server 11g
Topic 2: Project management track

Objectives:
- Explain the key factors that need to be considered to drive a successful implementation of Argus Safety
- Explain the typical project components that shape the approach and associated planning activities

Level: Learner

Training Options:
- Online Training:
  Oracle Argus Safety Suite 6 Implementation Specialist
- Implementation Boot Camp:
  Oracle Argus Safety Implementation Boot Camp

Sample Question:
- A company is currently using Argus 5.1 and decides to upgrade to Argus 5.2. Which type of migration tool is best suited for this scenario?
  
  A. An ETL tool
  B. Excel spreadsheets
  C. Oracle's migration tool for upgrades
  D. A custom developed migration tool
  E. Oracle Import / Export Utility.

- Which information is NOT required during the Requirements Gathering and collection phase of a migration project?
  
  A. Project timeline
  B. Scope of the migration
  C. Client resources available to support the migration
  D. Location of databases to support the migration
  E. Downstream applications impacted by the migration
Topic 3: Business track

Objectives:
- Create a basic business process and workflow within Argus
- Explain reporting regulatory requirements
- Explain reporting capabilities of the Argus Safety Suite
- Explain the need for signal detection
- Describe the reconciliation process

Training Options:
- Online Training:
  Oracle Argus Safety Suite 6 Implementation Specialist
- Implementation Boot Camp:
  Oracle Argus Safety Implementation Boot Camp

Sample Question:
- Pharmaceutical companies are required to submit expedited reports. How can an expedited report be defined?
  A. All safety reports that are submitted by a Healthcare Professional;
  B. All serious cases.
  C. All cases reported as a result of a drug-drug interaction.
  D. It will depend on the local reporting requirements.
  E. A report that requires reporting in a given number of days.
Topic 4: Technology track

Objectives:
- Describe the Architecture Influencers
- Describe the Architectural components needed to support the Argus Safety Suite
- Explain the schema that supports Argus Safety
- Explain the frequently queried Argus Safety tables and relationships

Level
- Learner
- Learner
- Practitioner
- Practitioner

Training Options:
- Online Training:
  Oracle Argus Safety Suite 6 Implementation Specialist
- Implementation Boot Camp:
  Oracle Argus Safety Implementation Boot Camp

Sample Question:
1. Which table would you refer to for information about a case that was reported as a result of a journal review.
   A. CASE_BFARM_DATA
   B. CASE_MASTER
   C. CASE_LITERATURE
   D. CASE_HOSP
   E. LM_STUDY_PRODUCTS
Topic 5: Data migration track

Objectives:

- Describe the different migration approaches
  Level: Learner
- Explain the types of information needed during requirements gathering and collection
  Level: Learner
- Perform a data mapping activity
  Level: Practitioner

Training Options:

- Online Training:
  Oracle Argus Safety Suite 6 Implementation Specialist

- Implementation Boot Camp:
  Oracle Argus Safety Implementation Boot Camp

Sample Question:

- Which three Argus functions need to be assessed as part of the cut over activities?

  A. Audit Log
  B. Audit Readiness
  C. Case Assessment
  D. Case Triage List
  E. Case Work list
  F. Medical Assessment

- Post go-live, which two tasks are key tasks of Argus Administrators?

  A. Case Triage
  B. Decide on which studies can be unblended
  C. Define Licensing Agreements
  D. Develop Cutover Plan
  E. Manage System Maintenance
  F. Support Business Users
Topic 6: Configuration track

Objectives:
- Configure Argus Safety
- Configure Argus Interchange
- Configure Argus Dossier
- Configure Argus Insight
- Configure Argus Reconciliation
- Configure Argus Affiliate

Training Options:
- Online Training:
  Oracle Argus Safety Suite 6 Implementation Specialist
- Implementation Boot Camp:
  Oracle Argus Safety Implementation Boot Camp

Sample Question:
- Which two statements are true about the Argus Safety Workflow configuration?.
  A. Workflow states must be selected from a set of predefined workflow states in Argus Safety.
  B. **Workflow rules can be defined to link any two defined Argus Safety workflow states.**
  C. It is possible to have one workflow state be linked with more than one workflow rule.
  D. It is not possible to add logic to a workflow rule involving the product attributes.
Topic 7: Integration track

Objectives:
- Describe the key integration points for the Argus Safety Suite modules

Training Options:
- Online Training:
  Oracle Argus Safety Suite 6 Implementation Specialist
- Implementation Boot Camp:
  Oracle Argus Safety Implementation Boot Camp

Sample Question:
- Which dictionaries can be used for Coding concomitant medication products within Argus

  A. WHO Drug Dictionary
  B. MedDRA
  C. TMS
  D. WHO ART
  E. MedDRA J
Topic 8: Go-live track

Objectives:
• Perform the key tasks for go-live preparation
• Perform the Argus functions that need to be executed for cutover
• Perform the key tasks for ongoing support post go-live

Level
Learner
Practitioner
Learner

Training Options:
• Online Training:
  Oracle Argus Safety Suite 6 Implementation Specialist

• Implementation Boot Camp:
  Oracle Argus Safety Implementation Boot Camp

Sample Question:
• What could be carried out as part of a Roll Back Plan?
  A. Which steps of data migration need to be repeated in which circumstances.
  B. Defining User Profiles.
  C. Training.
  D. Workflow decisions.
  E. Who should be contacted in case of technical failures.
Exam Registration

- **How to register for the exam?**
  You can register for all Oracle certification exams with Pearson VUE
  Before a registration can be submitted, a Pearson VUE profile must be created
  using your Company ID. Your Company ID can be obtained by contacting your
  local Oracle Partner Business Center or by signing in to your OPN account. Your
  Company ID is located in the section on the right under “Company information”.

  Please follow these instructions in order to properly set-up your Pearson VUE
  account for the first time.

- **Have you completed an Oracle Certification Exam in the past?**
  Due to systems enhancements, each partner who has completed an Oracle
  Certification Exam will need to update their Pearson VUE profile in order to
  receive credit and for those records to appear in the [OPN Competency Center](http://www.oracle.com/certification).

- **How to get full recognition as Certified Implementation Specialist?**
  To get full recognition as a Certified Implementation Specialist you need to:
  A. Update your Pearson VUE profile with your Company ID
  B. Activate your Certview Account

  Please follow these instructions and your records will be properly recorded.