# Drug Safety Associate Job Interview Questions And Answers

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# Drug Safety Associate Interview Questions And Answers Guide.

**Question - 1:**
Explain me what is causality?

**Ans:**
Causality is the relationship between a set of factors. In Pharmacovigilance, causality is the relationship between the suspect product and the adverse drug event.
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**Question - 2:**
Explain me what can this type of job lead on to?

**Ans:**
It depends on the company but likely roles are other careers within Medical and Regulatory Affairs, Clinical Research, Training, Compliance and Auditing.
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**Question - 3:**
Explain me what Is The Difference Between An Ade And Adr?

**Ans:**
There may not be a causal relationship between a drug and an ADE, whereas, there is a causal link between a drug and an adverse drug reaction.
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**Question - 4:**
Tell me what is the difference between an ADE and ADR?

**Ans:**
There may not be a causal relationship between a drug and an ADE, whereas, there is a causal link between a drug and an adverse drug reaction.
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**Question - 5:**
What is your greatest strength as Drug Safety Associate?

**Ans:**
This could be a very simple question if you are prepared for it. You just have to talk about the strengths that you know would be of value to the company.
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**Question - 6:**
Tell us what should a narrative consist of?

**Ans:**
A narrative should consist of precise and concise information about the source of report, patient demographics, patient's medical history, concomitant medications, suspect product details and adverse event details in an orderly manner.
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**Question - 7:**
Tell me how did you begin your career in safety?

**Ans:**
When I left university I had a short time working at the MHRA (the UK Regulatory Authority) which was a good introduction to the pharmaceutical industry. From there I went onto work within the safety departments of 2 large pharmaceutical companies.

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**Question - 8:**

Do you know what Is An Adverse Drug Reaction (adr)?

**Ans:**

An adverse drug reaction is a "response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function." Note that there is a causal link between a drug and an adverse drug reaction. In sum, an adverse drug reaction is harm directly caused by the drug at normal doses, during normal use.

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**Question - 9:**

Explain me what Should A Narrative Consist Of?

**Ans:**

A narrative should consist of precise and concise information about the source of report, patient demographics, patient's medical history, concomitant medications, suspect product details and adverse event details in an orderly manner.

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**Question - 10:**

Explain me when do you consider a case to be medically confirmed?

**Ans:**

A case is considered to be medically confirmed if it contains at least one event confirmed or reported by an HCP (Health Care Professional)
Note: HCP can be a physician, nurse, pharmacist, coroner or psychologist (only in Germany).

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**Question - 11:**

Tell me some Data Elements In Icsr?

**Ans:**

Patient demographics: Age, gender and race.
Suspect product details: Drug, dose, dosage form, therapy dates, therapy duration and indication. Adverse event details: Event, event onset date, seriousness criterion, event end date and latency.

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**Question - 12:**

Do you know what Is Pharmacovigilance?

**Ans:**

Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines

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**Question - 13:**

Explain me what is an Adverse Drug Reaction (ADR)?

**Ans:**

An adverse drug reaction is a "response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function." Note that there is a causal link between a drug and an adverse drug reaction. In sum, an adverse drug reaction is harm directly caused by the drug at normal doses, during normal use.

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**Question - 14:**

Explain me what does a Drug Safety Associate do?

**Ans:**

The role varies between companies but typically involves:
* The receipt, processing and reporting of adverse event reports
* Following-up with reporters to obtain further details about a case report
* Providing an information service to healthcare professionals and patients on product safety
* Providing safety expertise to internal cross-functional colleagues

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**Question - 15:**

Explain me what Do You Mean By Causality?

**Ans:**

Causality is the relationship between a set of factors. In Pharmacovigilance, causality is the relationship between the suspect product and the adverse drug event.

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**Question - 16:**

Tell me what is an Adverse Drug Event (ADE)?

**Ans:**

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

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**Question - 17:**

Tell me what is the hardest part of your job?

**Ans:**

Keeping on top of the legislation- safety is highly regulated buy keeping up to date with the legislation and how it is being interpreted by industry and the various regulatory authorities is a challenge.

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**Question - 18:**

Explain me what experience do you have in this field/For drug safety associate?

**Ans:**

Speak about specifics that relate to the position you are applying for. If you do not have specific experience, get as close as you can.
If you are being asked this question from your employer then you can explain your experience. Tell the employer what responsibilities you were performing during your job. You can tell what programs you developed and what modules you worked on. What were your achievements regarding different programs.

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**Question - 19:**

Tell us why did you decide to pursue this career?

**Ans:**

I'm not sure anyone has ever grown up thinking that when they are older they want to work in pharmacovigilance and it was something that I fell into really. However, I enjoyed working within pharmacovigilance and it has progressed from there. The Safety role has evolved over time and working in a culture whereby we are streamlining our processes so that we can focus our energy on using safety data in the smartest, most proactive way to anticipate/identify issues has kept my interest in this area.

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**Question - 20:**

Tell me the regulatory bodies in USA, UK, Japan and India?

**Ans:**

USA: United States Food and drug administration (USFDA).
UK: European Medicines Agency (EMEA).
Japan: Ministry of Health, Labour and Welfare (MHLW).
India: Central Drugs Standard Control Organization (CDSCO)

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**Question - 21:**

Where do you see yourself in 5 years. Or what are your career goals as Drug Safety Associate?

**Ans:**

It is crucial that you discuss your objectives and how you intend to achieve them.
For instance: I would like to be the best in my department or I would love to be the person my colleagues can rely on. I also feel I would be skilled and experienced enough to handle whatever responsibilities might come my way.

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**Question - 22:**

Explain me what is a typical day for you?

**Ans:**

I'm not sure there is one! For me there are two distinct parts of the safety role - the day to day part of the role (which mainly focuses on the handing of safety reports) and the cross-functional part of the role (which mainly focuses on how the safety function can add value in the cross-functional settting).
The day to day part of the role can be routine but the volume and nature of the reports we receive always presents a challenge to ensure that the reports are processed in a timely manner and to the high standards that are expected. At the same time, members of the team can be working on cross-functional projects with our colleagues in the medical affairs or sales and marketing function, or they can be working on cross-industry initiatives.

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**Question - 23:**

Explain me about E2a, E2b and E2c guidelines?

**Ans:**

E2a: E2a guidelines give standard definitions and terminology for key aspects of clinical safety reporting. It also gives guidance on mechanisms for handling expedited (rapid) reporting of adverse drug reactions in the investigational phase of drug development.
E2b: E2b guidelines for the maintenance of clinical safety data management and information about the data elements for transmission of Individual Case Safety Reports.

E2c: E2b guidelines for the maintenance of clinical safety data management and information about the Periodic Safety Update Reports for marketed drugs.

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**Question - 24:**

Tell us what Is The Minimum Criterion Required For A Valid Case?

**Ans:**

* An identifiable reporter
* An identifiable patient
* A suspect product
* An adverse drug event

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**Question - 25:**

Explain me what advice would you give to somebody considering Drug Safety Associate as a career?

**Ans:**

There are a lot of misconceptions about safety. There is part of the role which is relatively routine (e.g. collection and processing of reports) but the key is to think broadly and understand the importance of these activities in protecting patients who receive any given medicine. In addition, the key to being successful in safety is to use your safety expertise to consider how you can add value to your business and improve the understanding of the risk and benefit of a given medicine.

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**Question - 26:**

Explain me as a manager the role typically involves?

**Ans:**

* Having oversight of the day to day pharmacovigilance processes and ensuring they are working correctly
* Attending various safety related meetings (albeit internal or cross-industry)
* Looking at how the safety function can add value to the business
* Providing pharmacovigilance expertise to the management of Patient risk management plans

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**Question - 27:**

Tell me what Are Data Assessments In Pharmacovigilance?

**Ans:**

Data assessments are:
* Individual case report assessment
* Aggregated assessment and interpretation
* Signal detection
* Interactions and risk factors
* Serial study
* Frequency
* Estimation

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**Question - 28:**

What is the hierarchy in MedDRA?

**Ans:**

System Organ Class (SOC)
High Level Group Term (HLGT)
High Level Term (HLT)
Preferred Term (PT)
Lower Level Term (LLT)

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**Question - 29:**

Tell us what is the most difficult situation you have had to face and how did you tackle it as Drug Safety Associate?

**Ans:**

The reason why you are asked this question is to hear what you consider difficult and how you approached the situation. Select a difficult work situation, which was not caused by you and can be explained in a few sentences. You can then show yourself in a positive light by explaining how you handled the situation.

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**Question - 30:**

Please explain what experience do you have in this field or for drug safety associate position?

**Ans:**

If you are being asked this question from your employer then you can explain your experience. Tell the employer what responsibilities you were performing during your job. You can tell what programs you developed and what modules you worked on. What were your achievements regarding different programs.

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**Question - 31:**

Do you know what Are The Types Of Pharmacovigilance (pv)?

**Ans:**

Two types.
1. Active PV and
2. Passive PV
* Active PV: Active (or proactive) safety surveillance means that active measures are taken to detect adverse events. This is managed by active follow-up after treatment and the events may be detected by asking patients directly or screening patient records. The most comprehensive method is cohort event monitoring (CEM)
* Passive PV: Passive surveillance means that no active measures are taken to look for adverse effects other than the encouragement of health professionals and others to report safety concerns. Reporting is dependent on the initiative and motivation of the potential reporters. This is the most common form of pharmacovigilance. It is commonly referred to as "spontaneous" or "voluntary" reporting.

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**Question - 32:**

Tell me when do you consider an event to be serious?

**Ans:**

If an event is associated with any one of the following, it is considered to be serious
* Death
* Life threatening
* Hospitalization or prolongation of hospitalization.
* Congenital anomaly
* Disability
* Medically significant

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**Question - 33:**

Do you know what Is Volume 9a?

**Ans:**

Volume 9A brings together general guidance on the requirements, procedures, roles and activities in the field of pharmacovigilance, for both Marketing Authorisation Holders (MAH) and Competent Authorities of medicinal products for human use; it incorporates international agreements reached within the framework of the International Conference on Harmonisation (ICH).

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**Question - 34:**

Explain me what Is An Adverse Drug Event (ade)?

**Ans:**

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

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**Question - 35:**

Why should we hire you as Drug Safety Associate?

**Ans:**

This is a very common question that is asked in almost every interview. I love this question because it gives you the opportunity to sell yourself. Discuss what makes you standout from the crowd and show them how you can help advance their company. Remember to be specific. This is where all the company research you have done comes into play. You should have an idea as to why the company is hiring or looking to hire someone for that position. What problem do they have that they are looking for people to help them solve. And once you can establish this, you are to show them how you can solve this problem for them.

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**Question - 36:**

Please explain what do you enjoy most about your job?

**Ans:**

Working with the team to develop them - I am keen that my team should be recognised not only for their safety expertise but the other skills and experience that they can bring to the business outside of safety.
I also enjoy looking at how we can make our processes more efficient so that we can create more time for proactive risk management and activities which focus on using safety data to maximise patient safety.

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**Question - 37:**

Tell us what have you done to improve your knowledge for drug safety associate position in the last year?

**Ans:**

Everyone should learn from his mistake. I always try to consult my mistakes with my kith and kin especially with elderly and experienced person.
I enrolled myself into a course useful for the next version of our current project. I attended seminars on personal development and managerial skills improvement.

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