National School of Healthcare Science

NHS England

IACC 2023 Case-based discussion (CBD) scenario

Specialty:	Clinical Pharmaceutical Science

CBD Scenario

CBD Scenario Title	Replacement of Isolator									
CBD Scenario Aim	The aim of this scenario is to identify all the procurement and validations steps needed to replace a piece of equipment in compliance with regulation									
CBD Focus (please provide the codes of the module(s) this scenario addresses)	Quality Assurance and Quality Control 1 (SPE200)		Quality Assurance and Quality Control 2 (SPE222)							
GSP Domains covered (enter X to indicate all that apply)	**GSP 1**	X	**GSP 2**	X	**GSP 3**		**GSP 4**		**GSP 5**	
CBD Scenario description	You have been given funding to replace your isolator for the preparation of cytotoxics. Please describe how you would go about this.									
CBD Scenario model answer/ assessor guidance Detailed guidance that will be available for the assessors. Include guidance on what kinds of behaviours, actions, comments should secure a pass. What should the assessor expect to see? Assessors will be asked to plan questions in advance including links to trainee's IACC submission.	Pass indicators: Some or all of the following should be discussed: 1. Development of a User Requirement Specification (URS), including Health and Safety concerns relating to siting of isolator 2. Tender process / send to suppliers 3. Review responses; go and see different isolators in situ 4. Complete the Design Qualification (DQ) and risk assessment (as required) 5. Describe Factory Acceptance Test (provided by the company but may be observed) 6. Describe the Instruction Qualification (IQ) process 7. Describe the Operation Qualification (OQ) process 8. Describe the Performance Qualification (PQ) process 9. Write the validation report Fail indicators: Trainee doesn't include reference to URS, DQ, IQ, OQ and PQ									

Trainee instructions Please include any specific information to be provided to the trainee as part of the CBD scenario	No specific trainee instructions

Criteria being assessed by this CBD scenario

Aspect	**Please indicate if this criterion is being assessed**
1. Understands the clinical context of the scenario, including priority setting and testing strategies	
2. Understands scientific principles of scenario	X
3. Can discuss the relevant procedures involved in the scenario and associated health and safety issues	X
4. Understands and applies the appropriate test validation, IQC, EQA, relevant professional/clinical guidelines	
5. Understands and applies associated IT/bioinformatics and other appropriate resources	
6. Is able to interpret and report patient results and provide appropriate clinical advice	
7. Can discuss the significance of patient results within the clinical context of the referral	
8. Understands the ethical, legal and social implications of the scenario	X
9. Is aware of the importance of audit and can use this tool effectively	
10. Output meets accepted laboratory/professional standards	X
11. Demonstrates awareness of the limits of responsibility and when to seek advice	
12. Consideration of patient/professionalism	
13. Overall ability to perform	X