

Company A Lecture Bureau
Product and Packaging Complaints
Module X, Section Y

Production Script

First submission (v1)
xx/xx/xx

Description

This document is a draft submission of the script for **Product Quality Complaints** e-learning program.

Notes

Text in brackets does not appear in the copy [This does not appear]

The “Buttons” field only refers to those buttons that are not part of the standard navigation.

History

First submission XX-XX-XX

Type: Content Screen		Event #	00-000
Text	Audio	Graphic/Video	
[Lesson Title]: Product Quality Complaints policy			
Introduction			
<ul style="list-style-type: none"> Welcome to the training for Product Quality Complaints. <p>Two categories of complaints</p> <p>Confidentiality policy</p>	<p>[Narrator]: In our final lesson entitle Product Quality Complaints.</p> <p>Company A has two categories of complaints and a confidentiality policy on the handling of these complaints that are essential for a REP to know.</p>		
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: LO Screen		Event #	01-020
Text	Audio	Graphic/Video	
[Lesson Title]: Product and Packaging Complaints: Section 3			
Learning Objectives			
<p>At the end of this section, you will be able to:</p> <ul style="list-style-type: none"> • Describe the Product and Packaging Complaint policy. • Identify a manufacturing/packaging emergency. • Identify a non-emergency complaint. • Describe the confidentiality policy on handling complaints. • Describe the follow-up process to the complainant. 	<p>[Narrator]:</p> <p>At the end of this section, you will be able to describe the Product and Packaging Complaint policy, identify a manufacturing/packaging emergency and a non-emergency complaint.</p> <p>You will also be able to describe the confidentiality policy for handling complaints and the follow-up process to the complainant.</p>	<p>Collage of images depicting packages with no product in it, or two different products, or a package with two different strengths of the same product or an image of a bottle with a label with a certain dosage, but the drug within is another drug dosage level. Broken tablets or damaged packages could be part of the collage as well.</p>	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: Content Screen		Event #	01-030
Text	Audio	Graphic/Animation/Video	
[Page Title]: Policy			
<p>Policy</p> <p>Product and packaging complaints are classified as:</p> <ul style="list-style-type: none"> • Emergencies • Non-emergencies. <p>XX Marketing and sales personnel must be familiar with the reporting requirements for each type of complaint, and must follow the reporting procedures outlined in this policy.</p> <p>All reports must be made promptly and accurately.</p>	<p>[Narrator]: Company A is dedicated to ensuring that Company A and its employees comply with all applicable reporting requirements relating to Company A product and packaging complaints.</p> <p>Product and packaging complaints are classified as either emergencies, or non-emergencies.</p> <p>XX Marketing and sales personnel must be familiar with the reporting requirements for each type of complaint, and must follow the reporting procedures outlined in this policy.</p> <p>All reports must be made promptly and accurately.</p>	<p>Image or two of the two different types of complaints. (Use images from collage on learning objectives page.)</p>	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Navigation			
Main navigation panel			
Notes			

Type: Content Screen		Event #	01-040
Text	Audio	Graphic/Video	
[Page Title]: Manufacturing/Packaging Emergencies			
Manufacturing/Packaging Emergencies: <ul style="list-style-type: none"> • Mislabeling or product mix-up • Empty or under filled capsules • Extraneous material in a parenteral • Possible microbial contamination in a parenteral • Alleged tampering • Child-resistant closure has a defect that might cause it not to work • Inhaler mouthpiece is inhaled 	<p>[Narrator]:</p> <p>A manufacturing or packaging complaint (Product Quality Complaint) is an emergency when:</p> <p>Mislabeling or product mix-up occurs. Examples of this would be a market package contains two different products, a market package contains two different strengths of the same product, a blister is overfilled, or the drug or strength on the label does not agree with the contents of the market pack.</p> <p>Other types of emergencies are empty or under filled capsules and extraneous material in a parenteral. Since parenterals are injected into the body, it is critical that our parenterals do not contain extraneous material.</p> <p>Possible microbial contamination in a parenteral, alleged tampering, child-resistant closures have a defect that might cause it not to work, and inhaler mouthpiece is inhaled are other manufacturing/packaging emergencies.</p>	Collage of images describing the types of emergencies.	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: Content Screen		Event #	01-050
Text	Audio	Graphic/Video	
[Page Title]: Reporting Emergencies			
Procedure for Reporting Emergencies:		Image of a checklist or procedural form.	
<ol style="list-style-type: none"> 1. Quickly assemble all available information (lot numbers, dates, names, addresses, telephone numbers, reports of injuries or deaths, if any, etc.) 2. Contact the Information Center at Company A immediately by calling (XXX) XXX-XXXX. Do not delay calling based on a lack of complete information. 3. Call your designated supervisor immediately, providing him or her with the full details of your action. 	<p>[Narrator]:</p> <p>If, in any way, you become aware of a manufacturing emergency or packaging emergency, you should take the following actions, <i>in the order listed</i>:</p> <ol style="list-style-type: none"> 1. Quickly assemble all available information (lot numbers, dates, names, addresses, telephone numbers, reports of injuries or deaths, if any, etc.) 2. Contact the Information Center at Company A immediately by calling (XXX) XXX-XXXX. Do not delay calling based on a lack of complete information. 3. Call your designated supervisor immediately, providing him or her with the full details of your action. 		
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: Content Screen		Event #	01-060
Text	Audio	Graphic/Video	
[Page Title]: Non-Emergency Complaints			
Non-Emergency Complaints: <ul style="list-style-type: none"> Defective packaging, such as short fills, burnt induction seals (except if a child-resistant closure problem is involved) Broken tablets or capsules, extraneous material in non parenterals, changes in color. 	<p>[Narrator]: A non-emergency Product Quality Complaint involves:</p> <p>Defective packaging, such as short fills, burnt induction seals (except if a child-resistant closure problem is involved).</p> <p>Or broken tablets or capsules, extraneous material in non parenterals, changes in color.</p>	Image or Images of the different types of non-emergency complaints. I.e. Defective packages and or a broken label.	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: Content Screen		Event #	01-070
Text	Audio	Graphic/Video	
[Page Title]: Reporting Non-Emergencies			
Procedure for Reporting Non-Emergencies: <ul style="list-style-type: none"> Contact the Information Center at Company A at (XXX) XXX-XXXX Provide all available details. 	[Narrator]: If you become aware of a non-emergency complaint, contact the Information Center at Company A at (XXX) XXX-XXXX to provide all of the available details.	None	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: Content Screen		Event #	01-080
Text	Audio	Graphic/Video	
[Page Title]: Confidentiality			
Confidentiality <ul style="list-style-type: none"> Do not discuss a complaint with anyone except: <ul style="list-style-type: none"> the complainant, your designated supervisor the Information Center at Company A, Quality Assurance Legal Department. Questions directed to you by anyone else can be handled diplomatically by simply stating that, once you get the facts, you will refer the entire matter to: <ul style="list-style-type: none"> The Information Center at Company A (XXX) XXX-XXXX * (8:00 AM - 7:00 PM ET) Monday through Friday, excluding holidays Obtain the information necessary to report the complaint. Do not have further discussions with the complainant, unless the Information Center at Company A directs you to do so. 	<p>[Narrator]:</p> <p>Do not discuss a complaint with anyone except the complainant, your designated supervisor, the Information Center at Company A, Quality Assurance or the Legal Department. Questions directed to you by anyone else can be handled diplomatically by simply stating that, once you get the facts, you will refer the entire matter to:</p> <p>The Information Center at Company A (XXX) XXX-XXXX * (8:00 AM - 7:00 PM ET) Monday through Friday, excluding holidays</p> <p>After you obtain the information necessary to report the complaint, you should have no further discussions with the complainant, unless the Information Center at Company A directs you to do so.</p>	Collage of REP speaking with complainant and taking notes, the REP discussing the issue via phone and filling out a form.	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

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Type: Content Screen		Event #	01-090
Text	Audio	Graphic/Video	
[Page Title]: Response Letters			
Response Letters: A follow-up letter is sent to the customer regarding the complaint.	[Narrator]: A follow-up letter is sent to the customer regarding the complaint.	Image of complainant opening up letter and/or reading a letter. Envelope could be held underneath with Company A logo on it.	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: Content Screen		Event #	01-100
Text	Audio	Graphic/Video	
[Page Title]: Section 1 Summary			
<p>You should now be able to: In this lesson we learned that Company A has a policy that covers two types of packaging complaints, emergencies. When a manufacturing/packaging emergency occurs it is imperative that no matter how much information has been assembled contact the Information Center at Company A.</p> <p>Also be sure to call your designated supervisor upon contacting Company A.</p> <p>Finally remember complaints are confidential and should not be discussed further with the complainant unless the Information Center at Company A directs you to do so.</p>	<p>[Narrator]: In this lesson we learned that Company A has a policy that covers two types of packaging complaints, emergencies. When a manufacturing/packaging emergency occurs it is imperative that no matter how much information has been assembled contact the Information Center at Company A.</p> <p>Also be sure to call your designated supervisor upon contacting Company A.</p> <p>Finally remember complaints are confidential and should not be discussed further with the complainant unless the Information Center at Company A directs you to do so.</p>	Collage of images used from previous screens.	
Buttons		Screen Prompt	
[None]		Click Next to continue.	
Notes			

Type: Multiple Choice Self Check		Event #	01-110
Text	Audio	Graphic/Video	
[Page Title]: Confidentiality			
[Question]: You can discuss a complaint with any of the following: [Options]: a. Quality Assurance b. Legal Department c. Research Department d. The Complainant	You can discuss a complaint with any of the following: Click the best answer, and then click the Submit button.	None	
Buttons		Screen Prompt	
Submit		Click the best answer, and then click the Submit button.	
Navigation			
Main Navigation panel			
Notes			

Type: Submit Button Click		Event #	01-110A
Status		Feedback/Update	
[Incorrect = A, B, D]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Incorrect. Do not discuss a complaint with anyone except the complainant, your designated supervisor, the Information Center at Company A, Quality Assurance or the Legal Department.	
	Screen Prompt		
[Correct= C]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Correct! Do not discuss a complaint with anyone except the complainant, your designated supervisor, the Information Center at Company A, Quality Assurance or the Legal Department.	
	Screen Prompt	Click the Next to continue.	

Button

Type: Popup		Event #	01-110B
Buttons		Screen Prompt	

Type: Multiple Choice Self Check		Event #	01-120
Text	Audio	Graphic/Video	
[Page Title]: Manufacturing/Packaging Emergency			
<p>[Question]: Which of the following is not considered a manufacturing/packaging emergency?</p> <p>[Options]:</p> <ul style="list-style-type: none"> a. Child-resistant closure has a defect that might cause it not to work b. Extraneous material in non parenterals c. Inhaler mouthpiece is inhaled d. Empty or under filled capsules e. Extraneous material in a parenteral 	<p>Which of the following is not considered a manufacturing/packaging emergency?</p> <p>Click the best answer, and then click the Submit button.</p>	None	
Buttons		Screen Prompt	
Submit		Click the best answer, and then click the Submit button.	
Navigation			
Main Navigation panel			
Notes			

Type: Submit Button Click		Event #	01-120A
Status		Feedback/Update	
[Incorrect = A, C, D]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	<p>Incorrect. Mislabeling or product mix-up occurs. Examples of this would be a market package contains two different products, a market package contains two different strengths of the same product, a blister is overfilled, or the drug or strength on the label does not agree with the contents of the market pack.</p> <p>Other types of emergencies are empty or under filled capsules and extraneous material in a parenteral. Since parenterals are injected into the body, it is critical that our parenterals do not contain extraneous material.</p> <p>Possible microbial contamination in a parenteral, alleged tampering, child-resistant closures have a defect that might cause it not to work, and inhaler mouthpiece is inhaled are other manufacturing/packaging emergencies.</p>	
	Screen Prompt		
[Correct= B]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Correct! Extraneous materials in non parenterals are considered non-emergency complaints.	
	Screen Prompt	Click the Next to continue.	

Button

Type: Popup		Event #	01-120B
Buttons	Screen Prompt		

Type: Multiple Choice Self Check	Event #	01-130
Text	Audio	Graphic/Animation/Video
[Page Title]: Non-Emergency Complaints		
The following are non-emergency examples except: <ul style="list-style-type: none"> a. Short fills b. Alleged tampering c. Burnt induction seals d. Changes in color 	The following are non-emergency examples except: Click the best answer, and then click the Submit button.	None
Buttons		Screen Prompt
Submit		Click the best answer, and then click the Submit button.
Navigation		
Main navigation panel		
Notes		

Type: Submit Button Click		Event #	01-130A
Status		Feedback/Update	
[Incorrect = A, C, D]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Incorrect. Alleged tampering is considered a Manufacturing/Packaging Emergency that needs to be reported immediately even if all information has not been gathered completely about the situation.	
	Screen Prompt		
[Correct= B]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Correct. Alleged tampering is considered a Manufacturing/Packaging Emergency that needs to be reported immediately even if all information has not been gathered completely about the situation.	
	Screen Prompt		

Button

Type: Popup		Event #	01-130B
Buttons		Screen Prompt	

Type: Multiple Choice Self Check	Event #	01-140
Text	Audio	Graphic/Animation/Video
[Page Title]: Policy		
Product and packaging complaints are classified as: <ul style="list-style-type: none"> a. Emergencies and non-emergencies b. Solicited and unsolicited c. High risk and low risk d. Severed and non-severe 	Product and packaging complaints are classified as: Click the best answer, and then click the Submit button.	None
Buttons		Screen Prompt
Submit		Click the best answer, and then click the Submit button.
Navigation		
Main navigation panel		
Notes		

Type: Submit Button Click		Event #	01-140A
Status		Feedback/Update	
[Incorrect = B, C, D]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Incorrect.	
	Screen Prompt		
[Correct= A]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Correct. .	
	Screen Prompt		

Button

Type: Popup		Event #	01-140B
Buttons		Screen Prompt	

Type: Multiple Choice Self Check		Event #	01-150
Text	Audio	Graphic/Animation/Video	
[Page Title]: Reporting Emergencies			
<p>The order in which you should take action after a manufacturing emergency is as follows:</p> <ul style="list-style-type: none"> a. Call your supervisor, quickly assemble all available information, and contact the information center at COMPANY A immediately b. Quickly assemble all available information, contact the information center at COMPANY A immediately, and call your supervisor c. Contact the information center at COMPANY A immediately, quickly assemble all available information, call your supervisor d. Quickly assemble all available information, call your supervisor, contact the information center at COMPANY A 	<p>The order in which you should take action after a manufacturing emergency is as follows:</p> <p>Click the best answer, and then click the Submit button.</p>	None	
Buttons		Screen Prompt	
Submit		Click the best answer, and then click the Submit button.	
Navigation			
Main navigation panel			
Notes			

Type: Submit Button Click		Event #	01-150A
Status		Feedback/Update	
[Incorrect = A C, D]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Incorrect.	
	Screen Prompt		
[Correct= B]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Correct. .	
	Screen Prompt		

Button

Type: Popup		Event #	01-150B
Buttons		Screen Prompt	

Type: Multiple Choice Self Check	Event #	01-160
Text	Audio	Graphic/Animation/Video
[Page Title]: Reporting Non-Emergency Complaints		
When reporting non-emergencies you should: <ul style="list-style-type: none"> a. Provide all available details b. Contact your supervisor c. Contact the information center at COMPANY A d. Both A and C 	When reporting non-emergencies you should: Click the best answer, and then click the Submit button.	None
Buttons		Screen Prompt
Submit		Click the best answer, and then click the Submit button.
Navigation		
Main navigation panel		
Notes		

Type: Submit Button Click		Event #	01-160A
Status		Feedback/Update	
[Incorrect = A, B, C]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Incorrect.	
	Screen Prompt		
[Correct= D]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Correct. .	
	Screen Prompt		

Button

Type: Popup		Event #	01-160B
Buttons		Screen Prompt	

Type: Multiple Choice Self Check	Event #	01-170
Text	Audio	Graphic/Animation/Video
[Page Title]: Response Letters		
A follow-up response letter is sent to: <ul style="list-style-type: none"> a. REP b. FDA c. The Customer d. DDMAC 	A follow-up response letter is sent to: Click the best answer, and then click the Submit button.	None
Buttons		Screen Prompt
Submit		Click the best answer, and then click the Submit button.
Navigation		
Main navigation panel		
Notes		

Type: Submit Button Click		Event #	01-170A
Status		Feedback/Update	
[Incorrect = A, B, D]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Incorrect.	
	Screen Prompt		
[Correct= C]	Graphic	Retain learner's answer. Indicate the correct answer.	
	Text	Correct. .	
	Screen Prompt		

Button

Type: Popup		Event #	01-170B
Buttons		Screen Prompt	

Type: Content Screen		Event #	01-999
Text	Audio	Graphic	
Lesson Completion			
<p>Congratulations, you have finished the lesson entitled XXX.</p> <p>Click the Exit button to close this window and then select the next lesson in this training program.</p>	<p>[Narrator]: Congratulations, you have finished the lesson entitled XXX.</p> <p>Click the Exit button to close this window and then select the next lesson in this training program.</p>		
Buttons		Screen Prompt	
[None]		Click the Exit button to continue.	
Navigation			
Main navigation panel			
Notes			