

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

**Production Script**

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**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

<b>Type:</b> Content Screen		<b>Event #</b>	00-000
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Lesson Title]: Product Quality Complaints policy</b>			
<b>Introduction</b>			
<ul style="list-style-type: none"> <li>Welcome to the training for Product Quality Complaints.</li> </ul> <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>		
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

<b>Type:</b> LO Screen		<b>Event #</b>	01-020
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Lesson Title]: Product and Packaging Complaints: Section 3</b>			
<b>Learning Objectives</b>			
<p><b>At the end of this section, you will be able to:</b></p> <ul style="list-style-type: none"> <li>• Describe the Product and Packaging Complaint policy.</li> <li>• Identify a manufacturing/packaging emergency.</li> <li>• Identify a non-emergency complaint.</li> <li>• Describe the confidentiality policy on handling complaints.</li> <li>• Describe the follow-up process to the complainant.</li> </ul>	<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>	
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

<b>Type:</b> Content Screen		<b>Event #</b>	01-030
<b>Text</b>	<b>Audio</b>	<b>Graphic/Animation/Video</b>	
<b>[Page Title]: Policy</b>			
<p><b>Policy</b></p> <p>Product and packaging complaints are classified as:</p> <ul style="list-style-type: none"> <li>• Emergencies</li> <li>• Non-emergencies.</li> </ul> <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>	
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Navigation</b>			
Main navigation panel			
<b>Notes</b>			

<b>Type:</b> Content Screen		<b>Event #</b>	01-040
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Page Title]: Manufacturing/Packaging Emergencies</b>			
<b>Manufacturing/Packaging Emergencies:</b> <ul style="list-style-type: none"> <li>• Mislabeling or product mix-up</li> <li>• Empty or under filled capsules</li> <li>• Extraneous material in a parenteral</li> <li>• Possible microbial contamination in a parenteral</li> <li>• Alleged tampering</li> <li>• Child-resistant closure has a defect that might cause it not to work</li> <li>• Inhaler mouthpiece is inhaled</li> </ul>	<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.	
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

<b>Type:</b> Content Screen		<b>Event #</b>	01-050
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Page Title]: Reporting Emergencies</b>			
<b>Procedure for Reporting Emergencies:</b>		Image of a checklist or procedural form.	
<ol style="list-style-type: none"> <li>1. Quickly assemble all available information (lot numbers, dates, names, addresses, telephone numbers, reports of injuries or deaths, if any, etc.)</li> <li>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.</li> <li>3. Call your designated supervisor immediately, providing him or her with the full details of your action.</li> </ol>	<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"> <li>1. Quickly assemble all available information (lot numbers, dates, names, addresses, telephone numbers, reports of injuries or deaths, if any, etc.)</li> <li>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.</li> <li>3. Call your designated supervisor immediately, providing him or her with the full details of your action.</li> </ol>		
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

<b>Type:</b> Content Screen		<b>Event #</b>	01-060
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Page Title]: Non-Emergency Complaints</b>			
<b>Non-Emergency Complaints:</b> <ul style="list-style-type: none"> <li>Defective packaging, such as short fills, burnt induction seals (except if a child-resistant closure problem is involved)</li> <li>Broken tablets or capsules, extraneous material in non parenterals, changes in color.</li> </ul>	<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.	
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

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

<b>Type:</b> Content Screen		<b>Event #</b>	01-080
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Page Title]: Confidentiality</b>			
<p><b>Confidentiality</b></p> <ul style="list-style-type: none"> <li>Do not discuss a complaint with anyone except: <ul style="list-style-type: none"> <li>the complainant,</li> <li>your designated supervisor</li> <li>the Information Center at Company A,</li> <li>Quality Assurance</li> <li>Legal Department.</li> </ul> </li> <li>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"> <li>The Information Center at Company A (XXX) XXX-XXXX * (8:00 AM - 7:00 PM ET) Monday through Friday, excluding holidays</li> </ul> </li> <li>Obtain the information necessary to report the complaint.</li> <li>Do not have further discussions with the complainant, unless the Information Center at Company A directs you to do so.</li> </ul>	<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>	<p>Collage of REP speaking with complainant and taking notes, the REP discussing the issue via phone and filling out a form.</p>	
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

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<b>Type:</b> Content Screen		<b>Event #</b>	01-090
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Page Title]: Response Letters</b>			
<b>Response Letters:</b> 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.	
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

<b>Type:</b> Content Screen		<b>Event #</b>	01-100
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Page Title]: Section 1 Summary</b>			
<p><b>You should now be able to:</b>  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.	
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click Next to continue.	
<b>Notes</b>			

<b>Type:</b> Multiple Choice Self Check		<b>Event #</b>	01-110
<b>Text</b>	<b>Audio</b>	<b>Graphic/Video</b>	
<b>[Page Title]: Confidentiality</b>			
[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	
<b>Buttons</b>		<b>Screen Prompt</b>	
Submit		Click the best answer, and then click the Submit button.	
<b>Navigation</b>			
<b>Main Navigation panel</b>			
<b>Notes</b>			

<b>Type:</b> Submit Button Click		<b>Event #</b>	<b>01-110A</b>
<b>Status</b>		<b>Feedback/Update</b>	
[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.	

<b>Button</b>

<b>Type:</b> Popup		<b>Event #</b>	<b>01-110B</b>
<b>Buttons</b>		<b>Screen Prompt</b>	

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

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		

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

<b>Type:</b> Submit Button Click		<b>Event #</b>	<b>01-130A</b>
<b>Status</b>		<b>Feedback/Update</b>	
[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		

<b>Button</b>

<b>Type:</b> Popup		<b>Event #</b>	<b>01-130B</b>
<b>Buttons</b>		<b>Screen Prompt</b>	

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

<b>Type:</b> Submit Button Click		<b>Event #</b>	<b>01-140A</b>
<b>Status</b>		<b>Feedback/Update</b>	
[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		

<b>Button</b>

<b>Type:</b> Popup		<b>Event #</b>	<b>01-140B</b>
<b>Buttons</b>		<b>Screen Prompt</b>	

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

<b>Type:</b> Submit Button Click		<b>Event #</b>	<b>01-150A</b>
<b>Status</b>		<b>Feedback/Update</b>	
[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		

<b>Button</b>

<b>Type:</b> Popup		<b>Event #</b>	<b>01-150B</b>
<b>Buttons</b>		<b>Screen Prompt</b>	

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

<b>Type:</b> Submit Button Click		<b>Event #</b>	<b>01-160A</b>
<b>Status</b>		<b>Feedback/Update</b>	
[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		

<b>Button</b>

<b>Type:</b> Popup		<b>Event #</b>	<b>01-160B</b>
<b>Buttons</b>		<b>Screen Prompt</b>	

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

<b>Type:</b> Submit Button Click		<b>Event #</b>	<b>01-170A</b>
<b>Status</b>		<b>Feedback/Update</b>	
[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		

<b>Button</b>

<b>Type:</b> Popup		<b>Event #</b>	<b>01-170B</b>
<b>Buttons</b>		<b>Screen Prompt</b>	

<b>Type:</b> Content Screen		<b>Event #</b>	01-999
<b>Text</b>	<b>Audio</b>	<b>Graphic</b>	
<b>Lesson Completion</b>			
<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>		
<b>Buttons</b>		<b>Screen Prompt</b>	
[None]		Click the Exit button to continue.	
<b>Navigation</b>			
Main navigation panel			
<b>Notes</b>			