



**Example study checklist and assessment questions:**  
**Certificate of Regulatory Compliance**

Pace yourself! Set a due date of 2 weeks on each unit if studying 10-15hrs/wk or adjust accordingly	Tick when each time completed	Item/Unit
		Evaluate the functions of ingredients in personal care products
		Read 1 <sup>st</sup> Chapter – Evaluate the functions of ingredients in personal care products – <i>access dropbox Evaluate functions folder to find the text so you can start studying straight away while you wait for your study materials to arrive!</i>
		Watch Evaluate Functions Lecture and complete all lecture activities – <i>refer to dropbox for required lecture activity information sheets in the Evaluate functions folder.</i>
		Watch Evaluate Functions lecture video ( <i>in your on-line lecture system</i> ).
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lecture/video at this point (optional)
		Watch on-line Tutorial
		Complete all Section 1 questions of the Assessment
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

**Some Example Assessment Questions:**

1.4 Complete the tables for each product – use information provided in dropbox and processing information provided in the text to answer this question.

<b>Lamesoft PO65</b>		
<b>Starting Material/s</b>	<b>Processing involved</b>	<b>Natural or synthetic status</b>
<b>Incroquat Behenyl</b>		
<b>Starting Material/s</b>	<b>Processing involved</b>	<b>Natural or synthetic status</b>




1.5 How much of each component of each material would be present if it were used at 5% in a finished product?

<b>Lamesoft PO65</b>		
Component	% present in material	% present when used at 5% in a finished product

<b>Incroquat Behenyl</b>		
Component	% present in material	% present when used at 5% in a finished product



<b>Pace yourself! Set a due date of 2 weeks on each unit if studying 10-15hrs/wk or adjust accordingly</b>	<b>Tick when each time completed</b>	<b>Item/Unit</b>
		Evaluate the safety of a product formulation
		Read 2 <sup>nd</sup> Chapter – Evaluate the safety of a product formulation
		Watch Evaluate Safety Lectures 1 & 2 and complete all lecture activities - refer to dropbox for required lecture activity information sheets in the Evaluate safety folder.
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lectures at this point (optional)
		Watch on-line Tutorial
		Complete all Section 2 questions of the Assessment
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

**Some Example Assessment Questions:**

2.2 Identify comedogenic ingredients in personal care products.

2.6 Identify 2 common allergenic ingredients in personal care products, and their usual role in a product formulation.

2.8 Describe the principles of hypoallergenic products.

2.12 Interpret the results of product and raw material testing as described below:

2.12.1 a score of 4 in a draize rabbit model for a wash off ingredient.

2.12.2 a strong irritation using the immersion assay for a wash off ingredient in guinea pigs.

2.12.3 a mild reaction using cumulative irritation testing in humans for a leave on product.

2.12.4 a strong irritation using an epiderm in vitro test for a leave on product.

2.12.5 a mild reaction in 1 subject out of 18 in real-life safety evaluation of a wash off product.



<b>Pace yourself! Set a due date of 2 weeks on each unit if studying 10-15hrs/wk or adjust accordingly</b>	<b>Tick when each time completed</b>	<b>Item/Unit</b>
		Design evaluations of personal care product performance
		Read 3 <sup>rd</sup> Chapter – Design evaluations of personal care product performance
		Watch Design Evaluations lecture 1 and complete all lecture activities, including watching the On-Line video showing various product evaluation techniques
		Watch Design Evaluations lecture 2 and complete all lecture activities
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lectures and video at this point (optional)
		Watch on-line Tutorial
		Complete all Section 3 questions of the Assessment
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

### **Some Example Assessment Questions**

3.1 Identify and briefly discuss the two main branches of product evaluation used for personal care products.

3.2 Consider the following two products and performance aspects to be evaluated:

- 3.2.1 conditioning performance of a conditioner
- 3.2.2 anti-wrinkle performance of a moisturiser

Write a product evaluation protocol to evaluate the performance of **each product**. Assume the following:

- you are in a small company of 15 employees
- your results are statistically significant

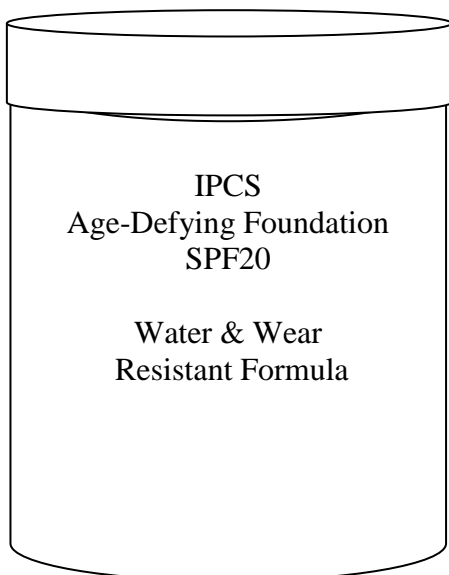


Pace yourself! Set a due date of 2 weeks on each unit if studying 10-15hrs/wk or adjust accordingly	Tick when each time completed	Item/Unit  Apply compliance requirements to promotions
		Read 4 <sup>th</sup> Chapter – Apply compliance requirements to promotions. <i>Note: ingredient list overview and label checklist has been provided in Dropbox for you to practice with and use in the workplace.</i>
		Watch Apply compliance requirements to promotions lecture 1 and complete all lecture activities
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lecture at this point (optional)
		Watch on-line Tutorial
		Complete all Section 4 questions of the Assessment
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

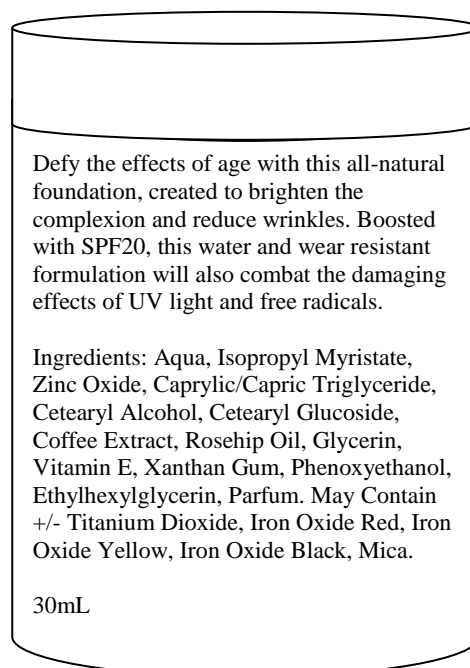
### Some Example Assessment Questions

4.4 Review the following label and provide required updates to make it fully compliant. (Note: use correct INCI names). Provide the changes required as if reporting to internal personnel for approval.

Front:



Back:





<b>Pace yourself! Set a due date of 2 weeks on each unit if studying 10-15hrs/wk or adjust accordingly</b>	<b>Tick when each time completed</b>	<b>Item/Unit</b>
		Apply compliance requirements to ingredient selection
		Read 5 <sup>th</sup> Chapter – Apply compliance requirements to ingredient selection
		Watch Apply compliance lectures 1, 2 & 3 and complete all lecture activities
		Watch Global Compliance lectures 1, 2 & 3 and complete all lecture activities
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lectures at this point (optional)
		Watch on-line Tutorial for the Assessment
		Watch on-line Tutorial SPECIFICALLY for Question 5.6
		Complete all Section 5 questions of the Assessment
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

### **Some Example Assessment Questions**

5.5 For the following product formulation (refer to dropbox for all required ingredient information):

5.5.1 Conduct searches and complete the table for all ingredients listed.

5.5.2 Provide a fully compliant ingredient list ready for a label using INCIs and % listing rules.

5.5.3 What marketing claims could be made on the label?



Brightening Serum % w/w Material		INCI Name/s	CAS Number/s	On AICS? Y/N	EU Limit %
To 100	Purified water				N/a
4.0	Glycerin				
5.0	Myritol 318®				
1.0	Apricot kernel oil				
5.0	Versaflex V-175®				
5.0	Belides®				
0.2	Tocopherol				
1.0	Geogard ECT				

5.6 Complete the following table:

Material	CAS	SUSMP limit (cosmetic, not S5 or S6)	EU limit
Lime essential oil (expressed) in a lotion			
Thioglycolic acid (in depilatory cream)			



MODULE 2

Pace yourself! Set a due date of 2-3 weeks on each unit if studying 10-15hrs/wk or adjust accordingly	Tick when each time completed; make sure to complete in order.	<b>Item/Unit</b>  <b>Do not proceed to the next item until previous item is ticked off/completed</b>
[insert your planned due dates to self-pace your study in this column for each activity]		Read 1 <sup>st</sup> Chapter – Design and evaluate regulatory documentation
		Watch Design and evaluate regulatory documentation lecture 1 and complete all lecture activities
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lecture at this point (optional)
		Watch on-line tutorial
		Complete all Section 1 questions of the Assessment – questions start following this table.
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

**Assessment Questions for Section 1: Design and evaluate regulatory documentation**

1.3 Complete the following table as per our example:

Document	Purpose (reason for the document)	Scope (essential information)	Authority (external)	Personnel involved (ext/int)
<b>CofA</b>	<i>Parameters with which product must comply</i>	<i>Identification, components, test method, limits</i>	<i>Cosmetic: refer to local country</i>	<i>Manufacturer; R&amp;D</i>
<b>SDS</b>				
<b>Product Specification</b>				





1.4 Prepare a CofA for a finished product – it can be from your workplace. With the CofA, make sure to provide:

- reference to the standards you used to determine what should be in the CofA
- the user guide you prepared based on the standards
- a template that could be used for future CofAs
- the final CofA relevant to a finished product

1.5 Imagine you submit the finished product CofA you prepared in question 1.4 to your development team and they came back with the following changes:

- remove reference to batch number
- change/remove physical tests

How would you document these requests and notify personnel which can be adapted and which cannot? What recommendations can you then make to satisfy their requests?



Pace yourself! Set a due date of 2 weeks on each unit if studying 10-15hrs/wk or adjust accordingly	Tick when each time completed	Item/Unit
		Apply microbiology techniques for product safety
		Read 2 <sup>nd</sup> Chapter – Apply microbiology techniques for product safety
		Watch Microbiology lectures 1, 2 and the lecture video (in your on-line lecture system), and complete all lecture activities
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lectures at this point (optional)
		Watch on-line Tutorial for the Assessment
		Complete all Section 2 questions of the Assessment
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

**Some Example Assessment Questions**

2.2 Complete the following table:

Org.	Product Type	Microbial Limits
TGA	Application on skin	
EU	Eye area, mucous membranes & children <3yrs	
EU	Other products	
TGA/EU	Raw materials	

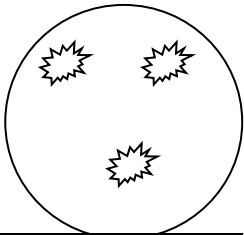
2.3 How would you sample raw materials and finished products? Include details of the equipment, types of agar and methods you would use.



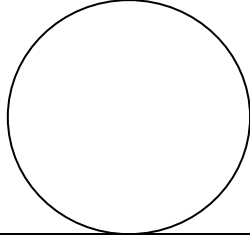
2.9 Provide 'ideal' systems to reduce microbial introduction in respect of:

- 2.9.1 the water system
- 2.9.2 the air system
- 2.9.3 a sanitising system for equipment

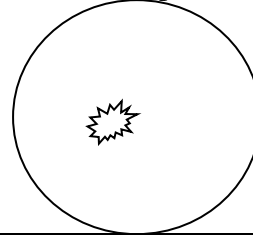
2.10 Imagine you are in charge of testing Quality of finished product. These are the results from the last batch of product made, and were consistent for all samples taken from finished product.



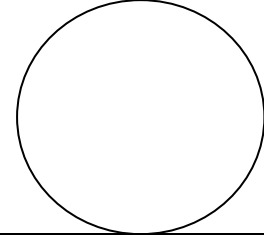
Tryptic soy agar



Sabouraud Dextrose Agar



Cetrimide Agar



Mannitol Salt Agar

- 2.10.1 Interpret the results – what would be the cfu count?
- 2.10.2 Provide steps of the investigation you would conduct to investigate the cause.
- 2.10.3 What should you do with this batch?



Pace yourself! Set a due date of 2-3 weeks on each unit if studying 10-15hrs/wk or adjust accordingly	Tick when each time completed	<b>Item/Unit</b>  Develop stable product formulations
		Read 3 <sup>rd</sup> Chapter – Develop stable product formulations.
		Watch Develop stable product formulations lectures 1 & 2 and complete all lecture activities.
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lectures at this point (optional)
		Watch on-line Tutorial
		Complete all Section 3 questions of the Assessment
<b><i>Only continue to the next unit once you have completed all items in order</i></b>		

### **Some Example Assessment Questions**

3.2 Describe when and why you would perform stability testing throughout the development of a product from concept through to product launch. In your answer, provide examples of the types of stability testing which may be best to perform at each stage.

3.3 Discuss the following considerations and how they may affect product stability:

- 3.3.1 climate in which the product is being sold
- 3.3.2 changing suppliers of raw materials
- 3.3.3 changing manufacturing equipment

3.4 Using the stability templates following this question, prepare real time and accelerated stability testing schedules for EACH of the following products:

3.4.1 a moisturiser to be stored at 30°C with ideal specifications:

- glossy white medium viscosity cream with characteristic coconut aroma
- pH: 5.5
- specific gravity: 0.85
- viscosity: 40,000 cps

In your answer include the types of tests you would perform and why.



3.6 Below is an example body lotion. This lotion has shown signs of separation, changes in fragrance and colouration and viscosity after 6 months. The product is packed in a clear plastic bottle with flip top cap. Suggest ways to improve the stability of this product and provide reasons why you have made those suggestions.

### Example body lotion

PHASE	ADDED %w/w	RAW MATERIALS	FUNCTION
A	To 100	Purified water	Solvent
A	5.0	Glycerin	Humectant/solvent
B	4.0	Cetearyl alcohol, cetareth-20	Emulsifier blend
B	0.5	Stearic acid	Emulsifier
B	9.0	Grapeseed oil	Emollient
B	2.0	Almond oil	Emollient
B	2.0	Shea butter	Emollient
C	0.5	Calendula extract	Skin feel/advertising claims
C	0.5	Chamomile extract	Skin feel/advertising claims
D	0.2	Germall plus	Preservative
D	0.5	Vanilla essential oil	Fragrance
E	q.s	Citric acid	pH adjustment

### METHOD

1. Combine ingredients in phase A and heat to 65 - 70°C.
2. Combine ingredients in phase B and heat to 65°C.
3. Add phase B to phase A and stir. Emulsify and stir while cooling.
4. When cooled below 30°C add ingredients from phase C and D; stir under low shear until mixed thoroughly.

Adjust pH to 5.5 – 5.8.



<b>Pace yourself! Set a due date of 2-3 weeks on each unit if studying 10-15hrs/wk or adjust accordingly</b>	<b>Tick when each time completed; make sure to complete in order.</b>	<b>Item/Unit</b>  <b>Do not proceed to the next item until previous item is ticked off/completed</b>
[insert your planned due dates to self-pace your study in this column for each activity]		Read 4 <sup>th</sup> Chapter – Design & manage a product recall
		Watch Design & manage a product recall lecture 1 and complete all lecture activities
		Re-read text in relevant sections and ensure all text activities are completed; you may also choose to re-watch the lecture at this point (optional)
		Watch on-line tutorial
		Complete all Section 4 questions of the Assessment – questions start below this table.
<b>Only submit your Assessment when ALL sections of ALL questions have been completed. Revisit the text, lectures, videos and especially the TUTORIALS to ensure you have answered all questions to the best of your ability.</b> <b>This also helps ensure the best quality of learning! Happy studying ☺</b>		

### **Assessment Questions for Section 4: Design and manage a product recall**

4.1 Briefly describe how you would determine if a recall was necessary. Include details of:

- who you would consult as part of the process
- what information you would require
- what documentation you would require

4.2 Briefly describe the steps you would take in initiating a product recall.

4.3 List the information required in:

- 4.3.1 an initial notification
- 4.3.2 an interim report
- 4.3.3 a final report

4.4 You have received a complaint from a 45 year old woman using a night cream from your organisation, containing a peptide. She has used it twice and come up with a rash both times. She has now discontinued use. What investigations and actions would you take based on this report?



4.5 Later that same day you received 4 more complaints from women of similar ages using the same product. They have been using it as directed, all have experienced rashes shortly after use. They have all discontinued use after seeing a Doctor, who advised them to contact your company. What investigations and actions would you take based on this report?

*When answering 4.4 and 4.5, please provide details of who you would consult during investigations and in determining your required actions. Please provide the full processes you would take in both cases including how you would implement, conduct and finalise the recall where necessary. Make sure your answer to 4.5 includes examples of:*

- *form/s you would use*
- *the information you would compile in a report at each stage*
- *advertisement that would be run*
- *written and verbal communications to internal and external personnel advising them of the recall*
- *what you will do with returned product*