| 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**<br><br>Apply compliance requirements to ingredient selection |
|---|---|---|
| | | Read 5th 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 |
| ***Only continue to the next unit once you have completed all items in order*** | | |

**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<br>% 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. | **Item/Unit**<br><br>**Do not proceed to the next item until previous item is ticked off/completed** |
|---|---|---|
| [insert your planned due dates to self-pace your study in this column for each activity] | | Read 1st 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. |
| ***Only continue to the next unit once you have completed all items in order*** | | |

## 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)** |
|---|---|---|---|---|
| **CofA** | *Parameters with which product must comply* | *Identification, components, test method, limits* | *Cosmetic: refer to local country* | *Manufacturer; R&D* |
| **SDS** | | | | |
| **Product Specification** | | | | |

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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**<br><br>Apply microbiology techniques for product safety |
|---|---|---|
| | | Read 2nd 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 |
| ***Only continue to the next unit once you have completed all items in order*** | | |

**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.

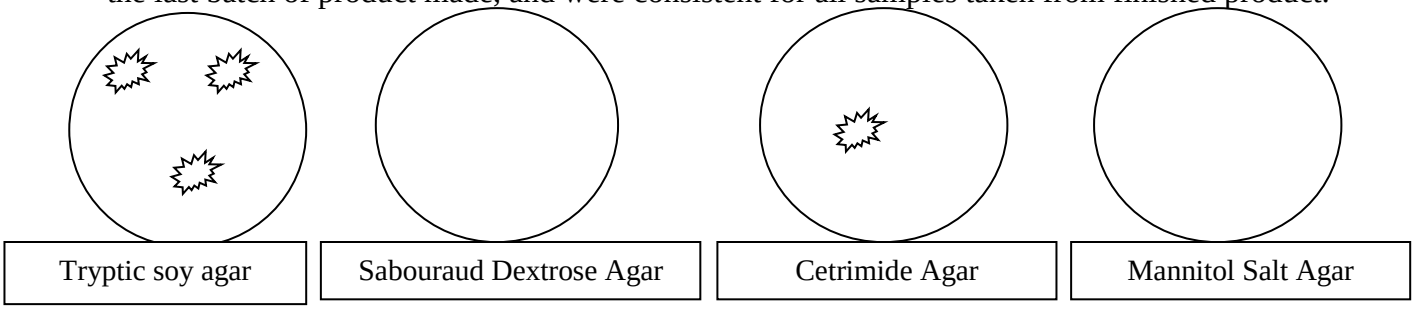
2.9 Provide 'ideal' systems to reduce microbial introduction in respect of:

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.




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 | **Item/Unit**<br><br>Develop stable product formulations |
|---|---|---|
| | | Read 3rd 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 |
| ***Only continue to the next unit once you have completed all items in order*** | | |

**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 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, ceteareth-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.

| 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. | **Item/Unit**<br><br>**Do not proceed to the next item until previous item is ticked off/completed** |
|---|---|---|
| [insert your planned due dates to self-pace your study in this column for each activity] | | Read 4th 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. |
| **Only submit your Assessment when ALL sections of ALL questions have been completed.<br>Revisit the text, lectures, videos and especially the TUTORIALS to ensure you have answered all questions to the best of your ability.<br>This also helps ensure the best quality of learning! Happy studying ☺** | | |

## 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*