

# T Level Technical Qualification in Science

Employer set project (ESP)

## Laboratory Sciences

Project brief

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## Project brief

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# Guidance for students

## Student instructions

- read the project brief and the task guidance carefully before starting your work
- you **must** work independently and make your own decisions on how to approach the tasks within the employer set project – your work should:
  - be in an Arial font 12pt, within standard border sizes, however you may choose to handwrite your work – if you choose to handwrite your work, you should ensure it is clear and legible
  - clearly show where sources have been used to support your own ideas and opinions
  - clearly reference all sources used to support your own ideas and opinions
  - reference any quotations from websites
- you **must** clearly name and date all of the work that you produce during each supervised session

At the end of each supervised session, your tutor will collect all assessment materials before you leave the room. You **must not** take any assessment material outside of the room (such as via a physical memory device). You **must not** upload any work produced to any platform that will allow you to access materials outside of the supervised sessions (including email).

## Student information

This employer set project will assess your knowledge, understanding and skills from across the core content of the qualification.

In order to achieve a grade for the core component, you **must** attempt both of the external examinations and the employer set project. The combined marks from these assessments will be aggregated to form the overall core component grade (A\* to E and U). If you do not attempt one of the assessments or fail to reach the minimum standard across all assessments, you will receive a U grade.

Your tutor will explain how the assessment time is broken down per task and will confirm with you if individual tasks need to be completed across multiple sessions.

You can fail to achieve marks if you do not fully meet the requirements of the task, or equally if you are not able to efficiently meet the requirements of the task.

## Plagiarism

Plagiarism may result in the external assessment task being awarded a U grade. For further guidance, refer to your student handbook.

## Presentation of work

- any work not produced electronically must be agreed with your tutor, and the evidence you produce should be scanned and submitted as an electronic piece of evidence, for example a digital photograph; your tutor will arrange for any digital photographs to be taken
- all your work should be clearly labelled with the relevant task number and your student details and be legible (for example front page and headers)
- electronic files should be given a clear file name for identification purposes (see tasks for any relevant naming conventions)
- all pages of your work should be numbered in the format page X of Y, where X is the page number and Y is the total number of pages
- you must complete and sign the external assessment cover sheet (EACS) – declaration of authenticity form and include it at the front of your assessment task evidence
- you must submit your evidence to the tutor at the end of each session

# Scenario: Long-term storage of drugs

## Introduction

Before new pharmaceuticals are available for sale, they are analysed to decide on the shelf life of the product. The shelf life is from the date of manufacture to when the product is no longer within its approved product specification; for example, the length of time the drug does not prematurely degrade and keeps its potency. Shelf life is usually expressed as a period of months, for example, 12 months, 24 months, up to a maximum of 60 months.

You work for a drug development company. Your line manager has asked you to choose the most appropriate method of short to medium term storage for a new antibody (biologic) drug that is available for sale. Your job is to investigate possible methods of storage for the drug. The drug should be stored at the optimum temperature for the 24 months it will be in storage.

You will need to consider a variety of different elements, including:

- the effect of temperature on the stability of the product
- the cost and ease of storage at different temperatures
- the effect of temperature when transporting the drug across the country.

## Brief

Your line manager has asked you to use this information to design an experimental plan. This plan will inform decision-making about the long-term storage of the drug. You should decide at which temperature the drug should be stored to maximise both its stability and the ease of storage.

Technicians will use an enzyme-linked immunosorbent assay (ELISA – an assay in which antibodies are used to detect and quantify the amount of an antigen of interest in a sample by measuring the amount of antibody that binds to the antigen) to analyse the stability of the drug at the end of each stage in each condition. Results will be provided as a percentage of the ELISA signal still present at the end of each stage in each temperature. Time 0 will be 100 % potency.

You must complete the following steps:

- research
- produce a plan for investigation
- analyse and evaluate the effectiveness of the investigation
- report on your findings to the wider team
- participate in a group discussion
- reflect on the process

Complete the tasks below to guide you through these steps.

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## Task 1: research a strategy

(22 marks)

### What you have to do

You have been provided with a database containing a range of potentially relevant sources for your research. All the resources are linked to the problem of storage of biopharmaceuticals and their shelf life in different conditions. The sources are shown on the source content page of the database. You will need to:

- carry out a literature review
- justify why you have chosen specific sources and rejected others – your justification should be based on:
  - how reliable you think the source is and why
  - how relevant you think the source is and why
- use an academic referencing technique when citing or referencing literature.

Add any notes about your work in your project diary. These notes will **not** be marked. They are to help you to complete task 6 which is a reflective evaluation. You can use any format you like for your project diary – your tutor will discuss this with you.

### Resources

- employer set project brief and task 1 student guidance
- computer access
- literature database
- project diary

### Assessment objectives

AO2: Apply core knowledge and skills to the development of a scientific project (18 marks)

AO4: Use English, mathematics, and digital skills as appropriate (4 marks)

### Core Skills

CS2: Researching

CS7: Reflective evaluation

### The evidence I have to submit for this task

A literature review.

### How the evidence will be assessed

This will be externally marked by examiners.

## **Time for completion of task 1**

3 hours. Plus 30 minutes for completion of project diary.

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## Task 2: plan a project

(36 marks)

### What you have to do

Use the sources you selected in your literature review to complete a project plan.

The project plan must:

- provide a method to explain how you will investigate the potential storage methods for the new biologic drug
- include all appropriate risk assessments relevant to working with biologic drugs at the range of temperature being considered
- identify the data you need to collect prior to the investigation in order to be able to conduct it
- identify the data you would expect to collect throughout the investigation
- describe how you will collect the required data

Add any notes about your work in your project diary. These notes will **not** be marked. They are to help you to complete task 6 which is a reflective evaluation.

### Resources

- project brief and task 2 student guidance
- literature database
- literature review (from task 1)
- project diary
- risk assessment form template
- risk matrix

### Assessment objectives

AO1: Plan their approach to meeting the project brief (12 marks)

AO2: Apply core knowledge and skills to the development of a scientific project (12 marks)

AO4: Use English, mathematics, and digital skills as appropriate (4 marks)

AO5: Realise a project outcome and review how well the outcome meets the brief (8 marks)

### Core Skills

CS1: Project management

CS2: Researching

CS3: Working with others (risk assessment)

CS4: Creativity and innovation

CS6: Communication (written)

CS7: Reflective evaluation

## **The evidence I have to submit for this task**

Your project plan.

## **How the evidence will be assessed**

This will be externally marked by examiners.

## **Time allowed for completion of task 2**

3 hours. Plus 30 minutes for completion of project diary.

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## Task 3: analyse data

(34 marks)

### What you have to do

Due to the limitations of time and resources, you are not required to carry out the investigation you have planned.

You have been provided with a raw data pack, obtained from an organisation which developed and carried out a similar plan to solve the same problem. The raw data pack is in the form of a laboratory information management system (LIMS) spreadsheet.

You must:

- analyse the data provided to measure the effectiveness of the organisation's plan
- produce a report of your analysis, to include:
  - presentation of data to enable peer review
  - selection of appropriate statistical techniques
  - application of appropriate statistical techniques
  - justification for your conclusions

Add any notes about your work in your project diary. These notes will **not** be marked. They are to help you to complete task 6 which is a reflective evaluation.

### Resources

- project brief and task 3 student guidance
- computer access
- NCFE LIMS spreadsheet
- project diary

### Assessment objectives

AO2: Apply core knowledge and skills to the development of a scientific project (16 marks)

AO3: Select relevant techniques and resources to meet the brief (6 marks)

AO4: Use English, mathematics, and digital skills as appropriate (6 marks)

AO5: Realise a project outcome and review how well the outcome meets the brief (6 marks)

### Core Skills

CS4: Creativity, innovation

CS5: Problem solving

CS6: Communication (written)

CS7: Reflective evaluation

## **The evidence I have to submit for this task**

Your analysis report including any charts and graphs.

## **How the evidence will be assessed**

This will be externally marked by examiners.

## **Time allowed for completion of task 3**

3 hours. Plus 30 minutes for completion of project diary.

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## Task 4: present outcomes and conclusions

(28 marks)

### What you have to do

4(a) Use your report from task 3 to produce an A2 scientific poster. The poster may be produced and displayed electronically rather than printed.

Your poster must show:

- the problem being addressed/investigated
- the results of your analysis, including any graphs and charts
- your conclusion

4(b) Present the main points from your poster to your tutor. Your tutor will make observations on your presentation and ask questions if further detail is needed. The presentation will be recorded by video, and this video submitted for marking. Add any notes about your work in your project diary. These notes will **not** be marked. They are to help you to complete task 6 which is a reflective evaluation.

### Resources

- project brief and task 4 student guidance
- computer and printer access
- access to NCFE provided LIMS spreadsheet
- your analysis report
- A2 paper, various coloured markers, scissors and glue and/or IT software/applications to create poster (or parts of) for printing, and printing facilities
- project diary

### Assessment objectives

AO2: Apply core knowledge and skills to the development of a scientific project (12 marks)

AO3: Select relevant techniques and resources to meet the brief (6 marks)

AO4: Use English, mathematics, and digital skills as appropriate (4 marks)

AO5: Realise a project outcome and review how well the outcome meets the brief (6 marks)

### Core skills

CS4: Creativity, innovation

CS6: Communication (written and verbal)

CS7: Reflective evaluation

## **The evidence I have to submit for this task**

Your A2 scientific poster.

Video recording of presentation.

## **How the evidence will be assessed**

This will be externally marked by examiners using the video recording and tutor commentary.

## **Time allowed for completion of task 4**

4(a) 3 hours.

4(b) 1 hour. Plus 30 minutes for completion of project diary.

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## Task 5: group discussion

(9 marks)

### What you have to do

You have been provided with an email from your customer, querying the method you used to store the biologic drug. In your allocated group, discuss the concerns the customer has raised and how it would be best to respond to these concerns. You will need to refer to your research notes to contribute effectively to the discussion. It is suggested 10 minutes are given over to this at the start of the discussion.

Each group member will then take it in turns to make suggestions and to agree an approach. It is suggested that groups consist of 5 or 6 individuals to allow sufficient time for discussion in 40 minutes; this will allow ample time for individuals to give their opinion and respond to others. Your group discussion will be recorded as a video.

Take notes during the team discussion of the points and suggestions made.

Following the discussion, you will need to (individually) draft an email response to the customer to respond to the concerns raised. This response can be handwritten or produced in suitable word processing software – it does not need to be written in an email client. Usual exam conditions apply during this part of the task (max 10 minutes).

There is an overall time limit of 1 hour for this task. In this time, you will:

- be asked to read the email from the customer in your groups
- be given 10 minutes to familiarise yourself with your literature review, your plan, your data analysis and scientific poster
- discuss your suggestions for responding to the customer
- draft an email to the customer to respond to the concerns raised

### Student resources required

- project brief and task 5 student guidance
- your literature review (task 1)
- your project plan (task 2)
- your data analysis and report (task 3)
- your A2 scientific poster and its presentation (task 4)
- email from customer (appendix 1)

### Tutor resources required

- assessment sheet for tutor commentary

- audio visual recording equipment

## **Assessment objectives**

AO2: Apply core knowledge and skills to the development of a scientific project (4 marks)

AO3: Select relevant techniques and resources to meet the brief (2 marks)

AO5: Realise a project outcome and review how well the outcome meets the brief (3 marks)

## **Core skills**

CS3: Working with others

CS4: Creativity, innovation

CS5: Problem solving

CS6: Communication (verbal)

CS7: Reflective evaluation

## **The evidence I have to submit for this task**

Your recorded discussion.

Your email reply to the customer

## **How the evidence will be assessed**

This will be externally marked by examiners.

## **Time allowed for completion of task 5**

1 hour.



## Task 6: reflective evaluation

(18 marks)

### What you have to do

Write a reflective evaluation of your work. This should be based on:

- your literature review (task 1)
- the experience of developing your project plan (task 2)
- your data analysis and report (task 3)
- your A2 scientific poster (task 4)

Your reflections should include:

- an evaluation of your approach to each task, including your chosen tool for analysis
- any changes you would make to your approach to each task, using each of the above bullet points as a section heading.

### Resources

- project brief and task 6 student guidance
- your literature review
- your project plan
- your analysis report
- your A2 scientific poster
- your project diary
- access to the NCFE provided LIMS spreadsheet and literature database
- reflective evaluation template

### Assessment objectives

AO2: Apply core knowledge and skills to the development of a scientific project (7 marks)

AO3: Select relevant techniques and resources to meet the brief (2 marks)

AO4: Use English, mathematics, and digital skills as appropriate (4 marks)

AO5: Realise a project outcome and review how well the outcome meets the brief (5 marks)

### Core skills

CS6: Communication (written)

CS7: Reflective evaluation

## **The evidence I have to submit for this task**

Your written reflective evaluation.

## **How the evidence will be assessed**

This will be externally marked by examiners.

## **Time allowed for completion of task 6**

2 hours.

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## Appendix 1: customer email

Dear Sir/Madam

I am writing to you about a particular biologic drug that you provide and the recommended storage conditions that are associated with it. We have received an enquiry for a batch of this drug from a developing country with poor cold chain supply infrastructure, as such we would ideally need to be able to transport and supply the drug at room temperature.

Please advise whether there is data available on stability of the drug at room temperature and whether the drug is a viable product for use in their country.

Best Wishes

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## Appendix 2: literature database

<https://www.crspharmasolutions.ie/news/pharmaceutical-temperature.html>

<https://www.npr.org/sections/health-shots/2020/11/17/935563377/why-does-pfizers-covid-19-vaccine-need-to-be-kept-colder-than-antarctica?t=1617795750516>

<http://blog.arthritis.org/living-with-arthritis/five-biologics-facts/>

<https://rheumnow.com/content/problems-biologic-drug-storage>

<https://www.gov.mb.ca/health/publichealth/cdc/protocol/ccp.pdf>

<https://www.careinspectorate.com/images/documents/1915/The%20temperature%20requirements%20for%20medicines%20storage.pdf>

<https://www.england.nhs.uk/mids-east/wp-content/uploads/sites/7/2015/07/cold-chain.pdf>

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