

# Regulatory Medical Writer - Writing Task

**Device: MantraHeal**

**Company: Mantra Systems Ltd**

## Background:

MantraHeal is a silver wound dressing medical device manufactured by Mantra Systems Ltd. The company is seeking CE marking for MantraHeal and has engaged you to support the certification.

Intended Purpose	MantraHeal is intended for use in the management of surgical wounds and to provide a physical, bacterial barrier.
Similar Device	AquacelAg

You are asked to complete the following tasks to demonstrate your approach to literature evaluation, clinical writing, and client communication.

## Task 1: Literature Search and State of the Art Summary

### Literature Search

1. Create a PICO table relevant to MantraHeal's intended purpose
2. Based on your PICO, develop appropriate search terms and conduct a literature search in PubMed
3. Limit your search to publications from 2023–2026
4. From the results, select the three most relevant papers

In your submission, please include:

- The completed PICO table
- The search terms used and results produced
- A brief justification for inclusion of each of the three selected papers
- A brief justification for exclusion of papers that were screened but not taken forward

### State of the Art Summary

Using the 3 selected papers from Task 1, write a State-of-the-Art summary (maximum 2 A4 pages).

Your summary should address:

- The current understanding of the clinical field in which MantraHeal operates
- Existing technologies or medical devices with a similar intended purpose

- Relevant regulatory standards or clinical guidelines (e.g. NICE), including recommended best practices
- Known clinical outcomes, benefits, and risks associated with existing technologies

Please reference the 3 selected papers and any additional guidelines or standards used. All references should be cited in AMA style, provided as footnotes within the text.

## Task 2: Client Communication

Using the evidence identified and appraised in Task 1, draft a professional email to the manufacturer of MantraHeal.

The email should:

- Summarise the key clinical evidence
- Propose potential clinical benefits that could be claimed for MantraHeal
- Be written in a clear, client-appropriate tone

***PS: Please submit your exercise document as a single Word file or PDF.***