Biomedical Engineer CDR Sample

Occupation: Biomedical Engineer
ANZSCO code: 233913
Assessment authority: Engineers Australia
Engineering category: Professional Engineer

INCLUDES THREE CAREER EPISODES

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Important Disclaimer

• This document is an illustrative sample prepared to demonstrate structure, paragraph numbering and the type of first-person engineering evidence normally expected in a Career Episode.

• The projects, organisations, locations, dates, calculations and results are fictional educational examples. They must not be copied, paraphrased or submitted as an applicant's personal work.

• Applicants must use their own projects, decisions, calculations, engineering judgement and supporting evidence. Standards and software must reflect what the applicant actually used.

• A positive assessment outcome is not guaranteed. Assessment decisions remain solely with the relevant assessing authority.

• CDR Services is independent and is not affiliated with, endorsed by or part of Engineers Australia.

About This Sample

These three fictional episodes illustrate different forms of practice relevant to Biomedical Engineer: design and analysis, implementation and delivery, and investigation with improvement. Personal engineering activity is intentionally the largest part of each episode.

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Sample Overview

Item	Details
Occupation	Biomedical Engineer
ANZSCO code	233913
Category	Professional Engineer
Assessment authority	Engineers Australia
Number of Career Episodes	Three
Purpose	Educational structure and writing guidance
Project areas	Design Verification of a Portable Infusion Monitor; Deployment of a Central Patient-Monitoring System; Reliability Improvement of an Oxygen Concentrator Fleet

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Career Episode 1

Design Verification of a Portable Infusion Monitor

Project or academic period	February 2021 to September 2021
Location	Kuala Lumpur, Malaysia
Organisation or institution type	a regional engineering consultancy
Applicant position	Design and analysis engineer
Nature of project	medical-device design and risk analysis

CE 1.1 Introduction

CE 1.1.1 This fictional episode describes my work on **Design Verification of a Portable Infusion Monitor** during February 2021 to September 2021 in Kuala Lumpur, Malaysia. I worked for a regional engineering consultancy as the design and analysis engineer, with responsibility for medical-device design and risk analysis.

CE 1.1.2 My assignment was to apply biomedical engineering knowledge to a defined operational need. I developed sensing, alarm and verification requirements and tested accuracy. I prepared the technical records, explained my assumptions and retained traceable evidence for each decision.

CE 1.2 Background

CE 1.2.1 The project objective was to deliver a safe, practical and maintainable solution while meeting performance, cost and programme constraints. The scope included baseline data review, option development, technical verification, coordination and documented acceptance.

CE 1.2.2 The project team included a project lead, discipline specialists, drafting or technical support personnel, suppliers and an owner representative. I reported to the project lead but remained personally accountable for my calculations, recommendations and assigned deliverables.

CE 1.2.3 I used IEC 60601-1, ISO 14971 and ISO 13485 as the principal technical references. I confirmed the applicable editions, translated requirements into checklists and recorded where project-specific criteria were more conservative than minimum requirements.

CE 1.2.4 My main engineering tools were MATLAB, SolidWorks and medical-device test software. I maintained version-controlled inputs, completed independent reasonableness checks and issued outputs only after resolving inconsistencies.

CE 1.3 Personal Engineering Activity

CE 1.3.1 I began by defining the design basis and converting the client brief into measurable requirements. I separated mandatory constraints from preferences, identified missing input data and created an assumptions register. This prevented unresolved information from being hidden inside the analysis.

CE 1.3.2 I developed a baseline model in MATLAB, SolidWorks and medical-device test software. I checked units, boundary conditions and representative operating cases, then compared the model against hand calculations and known performance data. Where the difference exceeded five percent, I corrected the input or documented the reason.

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CE 1.3.3 I generated three feasible concepts and assessed them against safety, technical performance, constructability, maintainability, cost and delivery risk. I used a weighted decision matrix but also performed sensitivity checks so that a small scoring change could not determine the outcome unfairly.

CE 1.3.4 I developed sensing, alarm and verification requirements and tested accuracy. I documented the governing cases and showed how the selected arrangement retained appropriate margins without unnecessary overdesign.

CE 1.3.5 I completed detailed calculations for normal, peak, start-up and credible abnormal conditions. I applied the relevant provisions of IEC 60601-1, ISO 14971 and ISO 13485, recorded all coefficients and produced a checking sheet that another engineer could reproduce.

CE 1.3.6 I coordinated interfaces with adjacent disciplines. I issued marked-up drawings, chaired a focused review and converted comments into an action log with owners and due dates. I rejected two interface changes until their effects on safety and performance had been demonstrated.

CE 1.3.7 I incorporated safety through hazard identification and design risk reduction. I removed hazards where practicable, added engineered safeguards where elimination was not possible and identified residual risks for construction, operation and maintenance teams.

CE 1.3.8 I reviewed environmental implications including energy, materials, waste, noise or land disturbance as applicable. I selected the option that met the technical requirements with lower lifecycle demand and documented the trade-off rather than relying only on initial cost.

CE 1.3.9 I prepared the design report, calculations, drawings and verification record. The final review confirmed that the proposal satisfied the agreed requirements and could proceed to implementation without unresolved high-risk technical actions.

CE 1.4 Summary

CE 1.4.1 I personally applied biomedical engineering knowledge to medical-device design and risk analysis. I used structured calculations, recognised requirements and documented engineering judgement to convert the project need into a verified outcome.

CE 1.4.2 I resolved technical and coordination problems by testing evidence, comparing options and communicating decisions clearly. The episode strengthened my competence in engineering analysis, risk management, quality, teamwork and professional accountability.

CE 1.4.3 The work achieved its defined outcome and left traceable records for future users. All names, dates, organisations, results and project circumstances in this episode are fictional and are provided only to illustrate structure and first-person writing.

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Career Episode 2

Deployment of a Central Patient-Monitoring System

Project or academic period	March 2022 to December 2022
Location	Santiago, Chile
Organisation or institution type	an industrial project organisation
Applicant position	Implementation and delivery engineer
Nature of project	clinical technology implementation

CE 2.1 Introduction

CE 2.1.1 This fictional episode describes my work on **Deployment of a Central Patient-Monitoring System** during March 2022 to December 2022 in Santiago, Chile. I worked for an industrial project organisation as the implementation and delivery engineer, with responsibility for clinical technology implementation.

CE 2.1.2 My assignment was to apply biomedical engineering knowledge to a defined operational need. I coordinated interfaces, electrical safety, acceptance tests and user training. I prepared the technical records, explained my assumptions and retained traceable evidence for each decision.

CE 2.2 Background

CE 2.2.1 The project objective was to deliver a safe, practical and maintainable solution while meeting performance, cost and programme constraints. The scope included baseline data review, option development, technical verification, coordination and documented acceptance.

CE 2.2.2 The project team included a project lead, discipline specialists, drafting or technical support personnel, suppliers and an owner representative. I reported to the project lead but remained personally accountable for my calculations, recommendations and assigned deliverables.

CE 2.2.3 I used IEC 60601-1, ISO 14971 and ISO 13485 as the principal technical references. I confirmed the applicable editions, translated requirements into checklists and recorded where project-specific criteria were more conservative than minimum requirements.

CE 2.2.4 My main engineering tools were MATLAB, SolidWorks and medical-device test software. I maintained version-controlled inputs, completed independent reasonableness checks and issued outputs only after resolving inconsistencies.

CE 2.3 Personal Engineering Activity

CE 2.3.1 I reviewed the issued design, contract requirements and work breakdown before mobilisation. I created an interface matrix and inspection-and-test plan so that responsibilities, hold points and acceptance evidence were clear.

CE 2.3.2 I checked vendor data and shop drawings against the design basis and IEC 60601-1, ISO 14971 and ISO 13485. I identified conflicts between equipment interfaces and site conditions, then coordinated corrected dimensions and connection details before fabrication or installation.

CE 2.3.3 I converted the technical scope into sequenced work packages. I considered access, temporary conditions, isolations, permits, lifting or handling needs and the availability of test equipment. This reduced

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work-front clashes and avoided unsafe improvisation.

CE 2.3.4 I coordinated interfaces, electrical safety, acceptance tests and user training. I used daily coordination records and a short-interval programme to manage dependencies without bypassing quality hold points.

CE 2.3.5 I monitored measurements and test results against defined tolerances. When a result failed, I quarantined the affected work, investigated the cause and required a documented corrective action followed by retesting.

CE 2.3.6 I assessed proposed field changes through a formal technical query process. I calculated the consequence of each change, checked downstream interfaces and updated controlled drawings rather than allowing undocumented site modifications.

CE 2.3.7 I led toolbox and technical briefings for the relevant work crews. I used sketches and acceptance examples to explain critical details, then confirmed understanding through questions and observation of the first completed item.

CE 2.3.8 I managed commissioning as a sequence of pre-checks, safe energisation or start-up, functional tests, performance tests and defect closure. I recorded instruments, calibration status, test conditions and results so that acceptance was auditable.

CE 2.3.9 I compiled the completion dossier with approved drawings, test sheets, certificates, operating information and lessons learned. The delivered system met the acceptance criteria and the handover team received complete records for ongoing operation.

CE 2.4 Summary

CE 2.4.1 I personally applied biomedical engineering knowledge to clinical technology implementation. I used structured calculations, recognised requirements and documented engineering judgement to convert the project need into a verified outcome.

CE 2.4.2 I resolved technical and coordination problems by testing evidence, comparing options and communicating decisions clearly. The episode strengthened my competence in engineering analysis, risk management, quality, teamwork and professional accountability.

CE 2.4.3 The work achieved its defined outcome and left traceable records for future users. All names, dates, organisations, results and project circumstances in this episode are fictional and are provided only to illustrate structure and first-person writing.

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Career Episode 3

Reliability Improvement of an Oxygen Concentrator Fleet

Project or academic period	January 2023 to October 2023
Location	Brno, Czech Republic
Organisation or institution type	a technology and engineering company
Applicant position	Investigation and improvement engineer
Nature of project	clinical asset investigation and improvement

CE 3.1 Introduction

CE 3.1.1 This fictional episode describes my work on **Reliability Improvement of an Oxygen Concentrator Fleet** during January 2023 to October 2023 in Brno, Czech Republic. I worked for a technology and engineering company as the investigation and improvement engineer, with responsibility for clinical asset investigation and improvement.

CE 3.1.2 My assignment was to apply biomedical engineering knowledge to a defined operational need. I analysed failures and redesigned preventive maintenance and parts controls. I prepared the technical records, explained my assumptions and retained traceable evidence for each decision.

CE 3.2 Background

CE 3.2.1 The project objective was to deliver a safe, practical and maintainable solution while meeting performance, cost and programme constraints. The scope included baseline data review, option development, technical verification, coordination and documented acceptance.

CE 3.2.2 The project team included a project lead, discipline specialists, drafting or technical support personnel, suppliers and an owner representative. I reported to the project lead but remained personally accountable for my calculations, recommendations and assigned deliverables.

CE 3.2.3 I used IEC 60601-1, ISO 14971 and ISO 13485 as the principal technical references. I confirmed the applicable editions, translated requirements into checklists and recorded where project-specific criteria were more conservative than minimum requirements.

CE 3.2.4 My main engineering tools were MATLAB, SolidWorks and medical-device test software. I maintained version-controlled inputs, completed independent reasonableness checks and issued outputs only after resolving inconsistencies.

CE 3.3 Personal Engineering Activity

CE 3.3.1 I began with a clear problem statement and resisted assuming that the most visible symptom was the root cause. I assembled maintenance, inspection, operating and environmental data, assessed data quality and developed a targeted investigation plan.

CE 3.3.2 I inspected the system and interviewed operators using structured questions. I compared observations with drawings and records, marked discrepancies and selected additional measurements that could distinguish between competing hypotheses.

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CE 3.3.3 I analysed trends and failure patterns using MATLAB, SolidWorks and medical-device test software. I normalised the data for operating conditions, checked for sensor or sampling bias and used independent calculations to confirm the magnitude of the problem.

CE 3.3.4 I applied fault-tree and cause-and-effect analysis. I tested each suspected cause against the evidence and removed explanations that did not account for timing, location and operating behaviour. This narrowed the investigation to controllable engineering factors.

CE 3.3.5 I analysed failures and redesigned preventive maintenance and parts controls. I verified the proposed solution against IEC 60601-1, ISO 14971 and ISO 13485 and evaluated temporary, medium-term and permanent options.

CE 3.3.6 I completed a risk and lifecycle comparison covering safety, reliability, downtime, maintainability, environmental effect and total cost. I recommended the option with the strongest risk reduction and a practical monitoring plan.

CE 3.3.7 I planned a controlled trial with baseline and post-change measurements. I defined success criteria before implementation, isolated variables where possible and retained a rollback arrangement if performance deteriorated.

CE 3.3.8 I coordinated the modification and observed the first operating cycle. The measured result confirmed a material improvement, and no new safety or quality issue appeared during the defined observation period.

CE 3.3.9 I updated procedures, inspection frequencies and technical records. I presented the findings to engineering and operations staff, explained the evidence behind the decision and assigned ongoing indicators so the benefit could be sustained.

CE 3.4 Summary

CE 3.4.1 I personally applied biomedical engineering knowledge to clinical asset investigation and improvement. I used structured calculations, recognised requirements and documented engineering judgement to convert the project need into a verified outcome.

CE 3.4.2 I resolved technical and coordination problems by testing evidence, comparing options and communicating decisions clearly. The episode strengthened my competence in engineering analysis, risk management, quality, teamwork and professional accountability.

CE 3.4.3 The work achieved its defined outcome and left traceable records for future users. All names, dates, organisations, results and project circumstances in this episode are fictional and are provided only to illustrate structure and first-person writing.

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How the Episodes Demonstrate Different Competencies

Career Episode	Project focus	Main competencies demonstrated
CE1	Design	Analysis, calculations, requirements and design decisions
CE2	Delivery	Coordination, quality, safety and implementation
CE3	Improvement	Investigation, problem-solving and optimisation

The episodes are intentionally different. Together they show how a strong set can combine technical analysis, delivery responsibility and evidence-led improvement while keeping the applicant's personal actions visible.

Important Submission Guidance

• Select projects that let you personally demonstrate engineering knowledge, judgement and responsibility.

• Write in the first person and explain what you calculated, designed, decided, checked and recommended.

• Include your own evidence and genuine project details. Never copy this fictional text or present it as personal work.

• Keep paragraph numbering stable so a separate Summary Statement, if required, can reference exact evidence.

• Check current Engineers Australia requirements before submission. Requirements and occupation options can change.

• This document contains Career Episodes only. It does not include a completed Summary Statement.

End of Sample

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