REGULATORY IMPACT ASSESSMENT ASSISTANT (FOR GOVERNANCE & REGULATORY AFFAIRS

Australian Red Cross Lifeblood

Contents

REGULATORY IMPACT ASSESSMENT ASSISTANT

Project Proposal Report

Project Title: Regulatory Impact Assessment Assistant for Governance & Regulatory Affairs
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Executive Summary

Australian Red Cross Lifeblood operates within one of Australia's most heavily regulated healthcare environments, where regulatory compliance directly impacts patient safety and organisational viability. The Governance & Regulatory Affairs team currently faces an unprecedented operational challenge, manually reviewing more than 50 documents for every Regulatory Impact Assessment (RIA) across over 2,600 assessments annually. Each assessment requires up to eight days to complete, creating significant bottlenecks and resulting in an estimated $8 million in annual productivity losses.

This project proposes developing an AI-powered Regulatory Impact Assessment Assistant, designed as a secure chatbot embedded within Lifeblood's internal website. The system will enable employees to input change-related queries and receive rapid, AI-generated regulatory interpretations grounded in current Therapeutic Goods Administration (TGA) requirements. Initially operating under supervised conditions with human expert oversight, the system will progressively transition toward greater automation for routine assessments while maintaining human authority for complex regulatory decisions.

The anticipated transformation includes reducing assessment turnaround times from eight days to less than one day, achieving cost savings of approximately $8 million annually, significantly reducing workload pressure on regulatory staff, and enhancing organisational agility in responding to regulatory changes. This represents a strategic investment positioning Lifeblood as a leader in regulatory technology adoption within the Australian healthcare sector.

Client and Background

Australian Red Cross Lifeblood serves as Australia's national blood service, operating as a critical component of the country's healthcare infrastructure. The organisation collects, processes, and supplies blood and biological products to hospitals nationwide while contributing to biomedical research and diagnostic services. Given the life-critical nature of these operations, Lifeblood operates under stringent Therapeutic Goods Administration (TGA)

requirements, where regulatory compliance is essential to patient safety and operational continuity.

Lifeblood has established a sophisticated technology environment providing a strong foundation for AI integration. Their Microsoft-centric infrastructure includes the Power Platform ecosystem (PowerBI, Power Automate, PowerApps), Microsoft AI Services (Azure GPT, Copilot Studio, AI Studio), and AWS Bedrock for scalable AI experimentation. This technological sophistication indicates organisational readiness for advanced AI implementation.

From a management perspective, Lifeblood applies design thinking principles and the Double Diamond framework, ensuring problem exploration precedes solution development. The organisation operates under Agile project management principles, enabling rapid feedback cycles and iterative development. This methodological alignment creates favourable conditions for AI assistant development.

The regulatory challenge emerges from the intersection of increasing regulatory complexity and organisational growth. The Governance & Regulatory Affairs team, led by Andrew [Last Name], comprises eight highly experienced professionals with 184 years of combined regulatory expertise. However, this concentrated expertise creates both a strategic asset and potential vulnerability, as capacity constraints limit organisational responsiveness to regulatory changes and business improvement initiatives.

Problem Statement

The current Regulatory Impact Assessment process represents a critical organisational bottleneck extending far beyond the Governance & Regulatory Affairs team, creating systemic inefficiencies that impact strategic decision-making, operational improvements, and organisational competitiveness. The manual review approach, while historically effective, has become fundamentally unsustainable given increasing regulatory complexity and frequency of updates.

The primary inefficiency manifests in requiring manual review of more than 50 documents per assessment, with each evaluation cycle consuming approximately eight days of professional time. This translates to over 20,800 annual workdays devoted to regulatory assessment activities, representing substantial allocation of scarce professional expertise to routine analytical tasks. The eight-member team faces an average workload exceeding 325 assessments per professional annually, creating unsustainable pressure risking quality degradation and staff burnout.

Resource strain encompasses both quantitative workload measures and qualitative challenges in maintaining consistency across assessments. Manual approaches inherently introduce variation in analytical focus, depth, and interpretation, potentially creating compliance risks and reducing predictability of assessment outcomes. Knowledge vulnerability represents strategic risk, as regulatory expertise remains concentrated within a small professional team, creating dependencies that could become critical during staff unavailability or organisational growth.

The quantified impact includes direct productivity losses estimated between $3 and $8 million annually, calculated based on professional time allocation, delayed business improvements, and opportunity costs associated with reduced organisational agility. Beyond financial measures, the current process delays innovation initiatives, slows strategic decision implementation, and reduces Lifeblood's capacity to respond rapidly to regulatory changes or market opportunities.

Project Aims

Primary Aim

The fundamental objective is to design, develop, and implement a sophisticated Regulatory Impact Assessment Assistant that transforms compliance evaluation from an eight-day manual review cycle to rapid, AI-powered analysis completed in less than one day, while maintaining or enhancing regulatory accuracy, thoroughness, and compliance assurance.

The system will be architected as a secure, conversational chatbot integrated within Lifeblood's internal website infrastructure, ensuring exclusive access to authorised employees while maintaining data security and regulatory compliance. The assistant will provide rapid, AI-powered responses to regulatory queries, supported by comprehensive human oversight mechanisms during initial implementation phases.

Secondary Aims

Employee Access and Usability Enhancement: Prioritise intuitive user experience through seamless chatbot integration within existing website infrastructure, ensuring employees across various technical proficiency levels can efficiently access regulatory guidance without extensive training.

Advanced Document Analysis Capabilities: Incorporate state-of-the-art generative AI capabilities specifically optimised for interpreting complex TGA regulatory texts, internal compliance protocols, and cross-referenced regulatory frameworks.

Flexible Integration Architecture: Design for seamless integration with Microsoft Power Platform components while maintaining architectural flexibility for future adaptations and potential integration with other organisational systems.

Expert-Assisted AI Implementation: Preserve human professional judgement at the centre of compliance decision-making, positioning AI as a powerful analytical tool that enhances rather than replaces human expertise.

Methodology and Data Strategy

Approaches Under Consideration

The project team is engaging stakeholders through comprehensive discovery workshops and feasibility analysis to evaluate three distinct solution pathways. The final implementation may adopt a single approach or incorporate hybrid elements based on stakeholder requirements, technical feasibility, and performance optimization outcomes.

Solution 1: Retrieval Augmented Generation (RAG) with Vector Database

This approach combines semantic retrieval capabilities with advanced generative AI to provide accurate, contextually grounded responses to regulatory queries. The system stores regulatory documents as high-dimensional vector embeddings within a specialised semantic database, enabling meaning-based rather than keyword-based document retrieval.

The RAG pipeline operates through semantic query analysis, where user queries are converted into vector embeddings and compared against comprehensive document embeddings through cosine similarity calculations. The augmentation phase dynamically injects relevant retrieved document chunks into AI prompt context, ensuring responses remain grounded in actual regulatory content. The generation phase synthesises comprehensive responses integrating retrieved content with contextual interpretation while maintaining complete traceability through automatic source citations.

Benefits: Ensures consistently up-to-date responses by accessing current regulatory documents at query time, demonstrates excellent scalability for large document collections exceeding 20GB, and provides crucial explainability through automatic citation generation supporting compliance accountability.

Challenges: Requires sophisticated document chunking strategies balancing contextual coherence with retrieval precision, careful embedding model selection impacting both accuracy and computational requirements, and extensive testing to optimise retrieval thresholds.

Solution 2: Semantic Knowledge Assistant (Information-Focused)

This solution combines semantic retrieval and structured generation to give staff quick, accurate answers to operational or regulatory questions. Instead of relying on keyword matching, the system understands the meaning of user queries and connects them to the most relevant information stored in a clause-level knowledge base.

All documents are broken down into smaller, searchable sections and stored in a semantic index. Each section is converted into a vector embedding (a numerical representation of meaning), which allows the system to perform similarity searches when a user asks a question. Queries are also converted into embeddings, and the system retrieves the closest-matching document sections using cosine similarity or other ranking methods.

In the augmentation stage, the retrieved sections are injected into the context of the chatbot's response. The chatbot then generates a short information card 3 to 5 clear bullet points summarising the key points directly from the retrieved text. To ensure traceability and trust, each answer automatically includes citations showing which document sections the information came from, along with version and source references.

The pipeline also includes confidence thresholds and safety rules. If the system is not confident, or if the query is ambiguous, it will ask a clarifying follow up question or escalate to a human team member instead of guessing. All interactions are stored with audit logs for accountability, and the document library is version-controlled so that older answers remain reproducible even after documents are updated.

Solution 3: Rule-Based + GenAI/NLP System

The Hybrid Rule-Based + GenAI/NLP approach combines the deterministic reliability of rule-based compliance checks with the flexibility and summarisation power of generative AI. In this system, regulations are first codified into structured rules by subject matter experts (SMEs), which form the foundation for hard compliance checks. At the same time, regulatory documents are ingested, chunked, and indexed for semantic retrieval, allowing a generative AI model to provide natural language answers, summaries, and contextual insights.

The chatbot thus delivers both:

A structured compliance checklist (Pass/Fail/Flag, with explicit rules and citations).

A narrative summary generated by AI, highlighting key obligations, risks, and gaps.

This hybrid design ensures that outputs are both auditable and user-friendly, addressing the need for regulatory accuracy while also improving efficiency.

Benefits

Auditability and Trust: Every compliance decision is traceable to a specific rule and regulation section.

Flexibility: GenAI can handle ambiguous queries, varied phrasing, and large unstructured documents.

Efficiency: Rules automate repetitive checks, while AI provides summaries and explanations for faster decision-making.

SME Alignment: Rules can be refined with SME input, while GenAI makes outputs more accessible for everyday staff.

Balanced Risk: Provides predictable outputs where it matters (rules) while allowing AI assistance in grey areas.

Drawbacks

Setup Overhead: Requires SMEs to codify rules initially, which can be labour-intensive.

Maintenance Burden: Rules must be regularly updated as regulations change.

System Complexity: Running and maintaining two components (rules + GenAI) requires careful orchestration.

AI Reliability: GenAI outputs must be carefully constrained with guardrails to avoid hallucinations or misinterpretations.

Expected Deliverables

The project will deliver a comprehensive solution encompassing technological components and supporting materials necessary for successful implementation and ongoing operation.

Primary Technical Deliverables:

- Fully functional conversational chatbot interface embedded within Lifeblood's internal website
- Intelligent document repository system with automated version tracking and comprehensive search capabilities
- Automated compliance report generation system producing structured analyses with comprehensive source citations
- Seamless Microsoft Power Platform integration enabling data sharing and workflow automation

Supporting Documentation:

- Comprehensive technical documentation covering system architecture, integration procedures, and maintenance requirements
- User training materials including interactive tutorials, reference guides, and best practice recommendations
- Administrative dashboards and analytics tools providing insights into system usage patterns and performance metrics

Project Plan

The project implementation follows Agile methodology principles, ensuring iterative progress and continuous stakeholder validation across four distinct phases.

Phase 1: Discovery and Solution Prototyping (Weeks 1-4)

Conduct comprehensive stakeholder interviews with Regulatory Affairs team members, document analysis examining representative assessment examples, and rapid prototyping of three proposed solution approaches. Stakeholder workshops will validate project objectives and inform final solution selection through comparative evaluation based on accuracy, performance, and usability criteria.

Phase 2: Core Development (Weeks 5-8)

Develop document ingestion pipelines, implement AI analysis engines, and create chatbot interfaces with comprehensive usability testing. Establish Microsoft Power Platform integration and implement security measures ensuring compliance with organisational policies and healthcare data protection requirements.

Phase 3: Testing and Refinement (Weeks 9-11)

Systematically evaluate AI-generated analyses against historical assessment data and expert professional judgement, conduct comprehensive performance testing assessing system responsiveness and scalability, and engage Regulatory Affairs team members in user acceptance testing. Implement system refinements addressing identified issues and optimising performance characteristics.

Phase 4: Finalisation and Handover (Week 12)

Complete final system evaluation validating all functionality against established requirements, conduct comprehensive training sessions ensuring effective system utilisation, and establish procedures for ongoing system maintenance and continuous improvement processes ensuring long-term effectiveness.

Risk Analysis and Ethical Considerations

Technical Risk Management

AI Accuracy Risks: Primary concerns involve potential AI hallucination or misinterpretation leading to incorrect compliance advice. Mitigation strategies include comprehensive RAG architectures grounding responses in verified sources, extensive citation systems enabling response verification, and mandatory human-in-the-loop review processes with confidence scoring mechanisms flagging uncertain responses.

Data Security Risks: Given sensitive regulatory information, comprehensive mitigation includes utilising only non-confidential regulatory information, implementing robust encryption for transmission and storage, and ensuring secure integration with existing systems through regular security audits and penetration testing.

Organisational and Ethical Considerations

Change Management: Address potential staff resistance by positioning AI as analytical assistant enhancing rather than replacing human expertise, providing comprehensive training and support, and implementing gradual rollout approaches demonstrating value while maintaining human authority over final decisions.

Transparency and Accountability: Ensure ethical AI implementation through comprehensive citation systems, clear explanations of analysis methodologies, and

transparency about system limitations while preserving human authority over all compliance decisions and implementing bias detection and correction mechanisms.

Expected Business Impact

The implementation will deliver substantial improvements across financial, operational, and strategic dimensions. Financial impact includes productivity savings worth up to $8 million annually and capacity expansion capabilities without proportional staff increases. Operational excellence improvements encompass transformed assessment turnaround times, enhanced consistency and quality through systematic analytical approaches, and improved staff experience enabling focus on higher-value work.

Strategic competitive advantages include enhanced regulatory agility enabling faster response to market opportunities, innovation enablement through accelerated regulatory assessment of new initiatives, and industry leadership positioning in regulatory technology adoption. Enhanced risk management capabilities will improve compliance documentation quality and reduce likelihood of regulatory non-compliance.

Conclusion

The proposed Regulatory Impact Assessment Assistant represents a transformative opportunity for Australian Red Cross Lifeblood to address critical operational challenges while establishing industry leadership in AI-driven regulatory compliance. The comprehensive analysis of three potential solution approaches demonstrates commitment to evidence-based decision-making and stakeholder-driven development.

The project's emphasis on human-in-the-loop approaches ensures AI enhancement preserves professional accountability while delivering substantial efficiency improvements. The phased implementation strategy featuring comprehensive testing and stakeholder validation provides a robust framework for successful deployment and ongoing operation.

The anticipated benefits extend beyond immediate productivity improvements to encompass strategic advantages including enhanced organisational agility, improved risk management, and industry leadership positioning. The estimated $8 million annual savings represent substantial return on investment while operational improvements enhance staff satisfaction and organisational capability.

This project provides exceptional opportunity for academic learning, enabling the student team to apply advanced AI and data science techniques in high-impact healthcare settings while contributing to organisational transformation and industry advancement. The combination of technical challenge, business impact, and ethical responsibility creates an ideal environment for advanced academic work generating both immediate practical value and broader knowledge contribution to AI-driven regulatory compliance.

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