



Pacific Edge Cancer Diagnostics digitises its Quality Management System with iPassport from Genial



- **Pacific Edge** is a global cancer diagnostics company leading the way in the development and commercialization of bladder cancer diagnostic tests for patients presenting with hematuria or surveillance of recurrent disease. Headquartered in New Zealand, the company provides its suite of Cxbladder non-invasive genomic urine tests globally through its wholly owned and certified laboratories in New Zealand and the USA.

Cxbladder tests help to reduce the need for invasive procedures so improve the overall patient experience, while prioritizing time and clinical resources to optimize practice workflow and improve efficiency. Each year Pacific Edge labs process thousands of samples for clinical evaluation.

Operating in a highly-regulated sector means Pacific Edge places significant emphasis on compliance and quality management. The systems that underpin these areas are vital to the company's business processes and are used by every member of the 100+ strong global team.

The Global Business Challenge

Pacific Edge was relying heavily on a combination of paper-based processes and shared network drives to manage their documentation. This approach, whilst once sufficient, was fast becoming inefficient, difficult to manage, and unsustainable.

Operating across different continents also adds complexity for the highly-regulated operations of the company. Numerous stringent regulatory requirements must be met. These include Clinical Laboratory Improvement Amendments (CLIA) and International Standards Organisation for clinical diagnostics laboratories (ISO15189) standards; International Accreditation New Zealand (IANZ); College of American Pathologists (CAP) and New York State (NYS) accreditations.

Recognising the limitations of their existing system and the need for a more integrated approach, Pacific Edge set out to modernise its QMS in preparation for ISO 13485 (medical device) certification. This goal highlighted the necessity for a robust, flexible digital solution that would support improved, more streamlined processes, better traceability, usability, collaboration and more granular role-based access controls.



The Solution: iPassport QMS from Genial

Pacific Edge selected **iPassport** from **Genial** to replace its fragmented and manual systems with a comprehensive, cloud-based QMS. Specifically designed to meet the needs of regulated laboratories, the system digitises and streamlines quality and supports complex compliance and accreditation processes.

Initially adopted as a document management system, iPassport's end-to-end capabilities soon became evident. Use of the system was expanded to encompass full quality management, including non-conformance reporting, monitoring and management, competence tracking, change control, and audit readiness.

The implementation of iPassport provided an opportunity to not just digitise existing processes but to improve them. Pacific Edge worked collaboratively with Genial to review their current procedures, redesign workflows, and align system configuration to their own requirements.

The result was a single, streamlined solution that supports both New Zealand and U.S. operations, with the inclusion of granular access and visibility controls for every business unit, department, and user role.

For Shahil Singh, Quality Systems Manager at Pacific Edge, this was an important feature enabling secure and efficient access for both internal users and external auditors.

He commented:

“iPassport’s granular role-based access controls allow us to limit views and permissions based on different needs across our various sites, business units and teams. It also caters for multiple roles with different permissions for a single user. This has been a significant benefit for us and provides a useful Responsible, Accountable, Consulted, and Informed (RACI) matrix for the organisation. It also means we can reliably and securely enable access for external auditors which is a quite unique capability. It streamlines the process for everyone involved.”



Challenges and How They Were Overcome

Any new system implementation presents challenges and moving from paper-based processes to a digitised, end-to-end QMS is no exception. Change management, staff training, and process adaptation are all typically required. However, unlike many other off-the-shelf products, iPassport is customisable. This allowed Pacific Edge to tailor the system to meet their needs.

With a global workforce of 175, staff training felt like a daunting and potentially time-consuming undertaking. Here, the platform's embedded help guides, contextual prompts, and integrated e-learning module made onboarding significantly easier. These features not only helped users complete tasks, but also explained the purpose and importance of each process, promoting a deeper understanding of quality management principles across the workforce.

A user commented during training:

“If you don't understand why you need to do something, iPassport clarifies it really simply. That context helps us, as users, understand the value behind each step.”

Working with Genial

Genial's approach, both during the implementation phase and as part of on-going support services, has focused on collaboration and knowledge sharing.

Genial shared a comprehensive validation package, for example, allowing Pacific Edge to tailor their own validation protocols more efficiently, blending off-the-shelf components with customised elements.

Shahil commented on the working relationship:

“Their team was consistently available, responsive, transparent and incredibly supportive. We are also kept informed about new features in the product and are able to feed into the future roadmap.

Genial develop innovative ideologies and are dedicated to solving specific industry challenges. This, for me, has made them a standout vendor in the QMS space.”

 Genial

Operational Efficiency & Compliance

The platform supports full document control aligned to the newly redesigned Pacific Edge processes. Automated streamlined workflows, with timely and targeted task notifications built-in, ensure accuracy and consistency. A clear audit trail is maintained throughout.

Non-conformance reporting is now entirely digital, with findings easy to export in standard formats and integrate with third-party tools.

The system's checklist functionality has transformed internal auditing making the process much faster and more efficient. Checklists are reusable, so they can quickly be applied for use across multiple different types of audit.

A particularly well-received feature among external auditors is the ability to embed regulatory standards directly into audits. This allows them to evaluate performance directly against the multiple standards and accreditations applicable to Pacific Edge, such as ISO and CLIA requirements. This visibility provides confidence and clarity during external inspections.

Shahil explained:

“It’s great that you can add in multiple standards, outline the specific regulation and course of action and then, simultaneously and easily, audit against each one. Our external auditors love this capability and I think it is quite unique to iPassport.”

Impacts and benefits

Since implementing iPassport, Pacific Edge has experienced a wide range of tangible benefits.

In summary, the system has:



Improved internal audits with reusable checklists and integrated standards.



Enabled more transparent, efficient collaboration with external auditors and stakeholders.



Better management insights through reporting on CAPA, change control, and training compliance.



Consistently successful regulatory inspections since implementation.

Training & Competence

The Competence module in iPassport has also proven to be a game-changer. It tracks staff training against Standard Operating Procedures (SOP), including when changes are made. An audit trail is available to demonstrate employee understanding and readiness. This capability aligns with regulatory requirements that place great emphasis on competence, training, and role-base accountability.

Shahil continued:

“The competence module in iPassport is extremely good. It gives us confidence that our training is equipping staff with the knowledge and expertise they need to perform the required tasks and activities. The system also provides evidence for auditors of the training provided, which makes the whole process much more efficient for everyone involved.”

Reporting

From a managerial perspective, iPassport supports robust reporting, providing insights into compliance trends, conformance, Corrective and Preventative Action (CAPA) status, as well as staff training and competence.

Shahil continued:

“The reporting and analytics capabilities provide comprehensive insights and are essential in helping us track progress, and for risk mitigation, development and continued improvement.”

Security & Access Control

Single Sign-On (SSO) and Multi-Factor Authentication (MFA) were deployed to support secure, streamlined access for users.

The system’s very granular Role-Based Access Controls (RBAC) have also proved vital for the business. Staff see only the SOPs, tasks, and documents and have the appropriate permissions assigned according to their role(s) across the various global business units.

Unique to iPassport, controlled external access for auditors has proved to be particularly beneficial, supporting much quicker and streamlined collaboration. There is no longer any need to scan and share hundreds of documents manually.

Results

Just some of the key improvements noted against Pacific Edge Key Performance Indicators (KPIs). The baseline was set in November 2022. Latest figures are provided from June 2025.

100%

of Non-Conformance Reports logged properly and promptly.

91%

of CAPAs closed to KPI targets, an increase of 23%

93%

of documents are being reviewed within KPI targets, up 36%

Zero

critical observations from external audits, with responses filed, as required, within 30 days.



What's next

With a solid QMS foundation now in place, Pacific Edge is preparing to expand the platform's use even further. Upcoming priorities include embedding custom training videos, fully integrating the risk management module, and expanding granular access across more teams.

This continuous improvement approach reflects the commitment to maintaining the highest standards of quality, compliance, and operational efficiency.

Conclusion

Through its partnership with Genial, Pacific Edge has transformed its approach to quality management. The implementation of iPassport has not only streamlined compliance and audit readiness but also helped embed a culture of quality throughout the organisation.

With stringent regulations and compliance consistently met and staff more engaged, the system has become an essential foundation to the company's success.

“We work in the highly-regulated medical diagnostics industry, so we take quality management and compliance very seriously. iPassport is one of our key software solutions and it's more than a QMS. It's a learning tool, a communication platform, and an essential foundation for compliance across our organisation.”

Shahil Singh, Pacific Edge Quality Systems Manager.