# HOW IVD MANUFACTURER STREAMLINED PRODUCTION AND IMPROVED QUALITY PROCESSES WITH INDUSTRY-SPECIFIC QMS

The IVD market reaches into all corners of the world, and for many device companies this niche product is often characterized by operating in multiple regulatory jurisdictions. This is the case for Canterbury Scientific, an IVD company with a global client base.

When CEO, Clive Seymour came onboard, he found a QMS that worked but had several challenges and inefficiencies associated with it. With a robust QMS being a necessary foundation of their work, Clive and the team set out to find a streamlined solution.

## CANTERBURY SCIENTIFIC: DEVELOPING INNOVATIVE AND EFFECTIVE IN-VITRO DIAGNOSTIC PRODUCTS

Canterbury Scientific is a leading global OEM supplier of high-quality, stable IVD Controls and Calibrators for diabetes and hemoglobinopathy assays. With a global footprint, this means that they must know and adhere to several different sets of regulations, including FDA, EU MDR and IVDR.

They have obtained and maintained: 510(k) clearances, CE Marks and ISO 13485:2016 certification.

As CEO, Clive Seymour came into the business with a global background in life sciences at VP and EVP level. He has been able to successfully integrate this experience into the business's quality and regulatory system, becoming an advocate for improvements and staying actively engaged in the management of the QMS.

## EXPERIENCING THE LIMITATIONS OF A PAPER-BASED QMS

Looking back, Clive describes the QMS they were using at the time as "a pretty good QMS, but very paper-based." Clive describes the paper-based system as presenting very traditional problems which were very frustrating for him as CEO.

Problems included issues with checking on progression and timeline management for Nonconformances and Change Controls, with often extended cycles of checking the documents and redistributing them if a correction needed to be made.

CANTERBURY scientific

**HQ:** Christchurch, New Zealand

**End Markets:** USA (FDA), EU, China

**Device Classification:** IVD; Class II

**Certifications:** ISO 13485:2016

**Greenlight Guru Champion:** Clive Seymour, CEO of Canterbury Scientific

> ***IF I WERE TO QUANTIFY IT, IT'S DAYS OF TIME SAVED. WHAT USED TO TAKE US SIX WEEKS, NOW TAKES A MUCH SHORTER TIME PERIOD. THE COST OF GREENLIGHT GURU IS REPAID IN EFFICIENCY***

**Clive Seymour,**
CEO of Canterbury Scientific

> **CHALLENGE:** KEEPING TRACK OF ALL DOCUMENTS AS THEY PROGRESSED THROUGH REVIEWS AND UPDATES WAS A CHALLENGE REQUIRING CONSTANT QUALITY TEAM INVOLVEMENT.

Clive recalls "we'd have folders with 40-50 SOPs and other folders with the best part of 250 work instructions. Every time you updated something, you'd have to send the folders around the whole building to get signed."

The most impacted teams included manufacturing, with the majority of SOPs and work instructions being manufacturing-based, and the Science, Design and Development team, with design history files and design manufacturing files needing updating.

> ***"DOCUMENT CONTROL IS CRUCIAL TO THE BUSINESS,"*** *CLIVE SAYS,* ***"CHANGE & VERSION CONTROL WAS A CONSTANT CHALLENGE FOR THE COMPANY."***
>
> *Clive Seymour, CEO of Canterbury Scientific*

## CATALYST FOR QMS CHANGE

"We had a system, the system worked in that we had our ISO 13485 certification, but it wasn't a system that you'd consider in the 21st Century to be appropriate going forward," says Clive. This realization sparked the need for change with their quality solution as they needed a system in place that would scale with their growth as an organization and with the regulatory requirements.

Along with this realization, updates made to ISO 13485:2016 were a catalyst that led them to begin looking for a quality system that would allow them to monitor everything closely, keep tabs on every nonconformance and be able to easily find any SOP or instruction.

> ***"WE HAD THE REALIZATION THAT A PROFESSIONAL QUALITY MANAGEMENT SYSTEM WAS OUR FOUNDATION FOR SUCCESS AND THAT ULTIMATELY, WE NEEDED TO GO WITH AN ELECTRONIC SOLUTION."***
>
> Clive Seymour, CEO

## DISCOVERING GREENLIGHT GURU'S EQMS SOLUTION

Canterbury Scientific shopped around for an electronic QMS and found a couple of options, including Greenlight Guru. Clive says that in the end, Greenlight Guru beat out the other solutions they were looking at because:

| greenlight guru | *VS* OTHER SOLUTIONS CONSIDERED |
|---|---|
| ✓ Medical device (IVD) focused | ● Too big for their needs |
| ✓ Meets global regulatory needs | ● Complex to learn |
| ✓ Easy-to-use | ● Configuration required |
| ✓ Out-of-the-box | ● Expensive |
| ✓ Scalable | ● Effort required to work with different international requirements |
| ✓ Training management made easy | |

## STREAMLINED IMPLEMENTATION AND IMMEDIATE VALUE FROM AN MDQMS

Clive says he had anticipated they might find it challenging to migrate to Greenlight Guru but was pleasantly surprised at how smoothly it went.

Canterbury Scientific took a two-phase approach:

1. Moving SOPs, work instructions and relevant documents from their QMS to the online Greenlight Guru platform
2. Focus on an enhanced internal audit approach to systematically improve documentation and embed the system throughout all functions in the company.

The company found that uploading documents went seamlessly and that version control was in place **immediately**. They quickly established automated processes for their quality events and change orders.

A foreseen challenge was getting everyone trained and up-to-speed on the new system in place; however, their team was won over when they saw how easy everything was. Now, logging into Greenlight Guru is the first step in their daily routines.

greenlight guru

## SIMPLIFYING AUDITS AND CREATING NEW EFFICIENCIES

Canterbury Scientific has multiple auditing requirements through their customers and the regulatory bodies they conform with. “Now, internal audits are also much faster because you don’t have to look around for the documents. As an internal auditor, you can go in during a quiet afternoon, pull all the info you need, have meetings with those you need to talk to and get through it quickly. **Last year was the first time we were able to complete every single internal audit on time, before the end of the year.”**

During a regular working day, the team has found that Greenlight Guru significantly improves their quality processes with automated tracking and tasks. By providing online access in the lab, they can easily access information in-the-moment, make decisions more quickly and overall, save a lot of time.

## RECOMMENDING GREENLIGHT GURU: A FLEXIBLE, YET REGULATORY-COMPLIANT SYSTEM

Clive says they have and continue to recommend Greenlight Guru to other IVD companies. As a company, they have a mantra to “always go back to the regulation.” Greenlight Guru helps to keep the right information at their fingertips so that they maintain a quality focus.

“The system is logical and can be scaled to fit your existing processes,” he says. Canterbury Scientific appreciates the flexibility of the system while knowing that the workflows keep them aligned with the relevant regulations. “We are confident we aren’t making any errors as we go,” he says.

Importantly for companies like theirs, Greenlight Guru isn’t too overwhelming, unlike some of the general-purpose QMS vendors that serve both the medical device and pharmaceutical industries. Operating globally and maintaining compliance is now second nature for their team with a scalable, compliant solution in place.

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## INTERESTED IN IMPLEMENTING A SCALABLE QMS THAT STREAMLINES PRODUCTION, COMPLIANCE AND QUALITY?

GET IN TOUCH WITH GREENLIGHT GURU →