

# Commitment to World-Class Service Leads to Successful Recertification for Medical Products Manufacturer

## Background

Founded as a printing company in 1934, Connecticut's Beekley Corporation is a leading global supplier of niche medical and hospitality products. More than 90 years later, the company remains privately owned, with a 70 percent female, 104-person team operating two distinct divisions at the Beekley Growth & Innovation Center in Bristol, Connecticut.

Beekley Medical is a medical device manufacturer whose goal is 'to help positively impact patients' lives and improve clinical outcomes.'

Its team focuses on researching and developing simple, cost-effective, disposable medical imaging products for procedures including mammography, CT scans, MRIs, radiation therapy, and breast biopsies for over 8,000 customers worldwide.

Beekley prides itself on delivering world-class customer care through medical products that improve accuracy, communication, productivity, and patient care.

Prestige Lane Hospitality Brands produces specialty print products for hotels, resorts, and casinos to help improve customer service and increase revenues. The company is proud to have been repeatedly named one of Connecticut's "Best Places to Work."

Beekley Medical is certified in ISO 13485:2016, the Quality Management System standard for the design and manufacture of medical devices to ensure they meet regulatory and customer demands for safety and efficacy.

## Challenge

Recognizing the critical role its medical products play in patient care, Beekley Medical prioritizes rigorous

# Beekley Medical®

## Results for Beekley Medical:

Dozens of Beekley's Quality System Procedures were audited during the three-day IQA including:

- **Retained Sales: \$1,000,000**
- **Cost Savings: \$2,000**
- **Increased investments: \$209,500**
- **Unnecessary Investments Avoided: \$75,000**
- **Jobs retained: 5**



*"As a medical device manufacturer, it is imperative that we have qualified professionals conducting our internal audits to this stringent ISO 13485 standard, as this audit has a direct impact on the success of our recertification. Our consultant is very knowledgeable with a wealth of experience who we see as an important partner in our success. CONNSTEP has been a valuable resource to Beekley over the years and has provided great service and support to ensure we continue to achieve our goals."*

Kate Chase  
Director of Quality and Regulatory,  
Beekley Medical



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standards and proactive process improvements throughout the organization, driving both growth and exceptional service.

Beekley has maintained its ISO 13485 certification since 2003. To assess compliance with its Quality Management System in preparation for its recertification audit, Beekley's leadership team sought outside assistance to conduct its required Internal Quality Audit for 2023.

The IQA would measure the effectiveness of the company's QMS, identify any nonconformances, look for continual improvement opportunities, determine necessary corrective actions, and provide feedback to management on whether Beekley's QMS was being effectively and efficiently implemented.

### Solution

Building on their successful, multi-year relationship with CONNSTEP, Connecticut's MEP, Beekley engaged Business Development Advisor Prakaithip Romanow to facilitate their IQA.

A third-party CONNSTEP consultant was chosen to perform the audit process, providing an objective, outside view of Beekley's QMS and furnishing a roadmap for the company to help it prepare for ISO 13485 recertification.

The audit would focus on three key areas: Beekley's management and QMS functions, product R&D activities, and its production and supporting processes.

### Results

Dozens of Beekley's Quality System Procedures were audited during the three-day IQA including:

- Quality objectives
- Control of documents
- Planning of product realization
- Contamination control
- Reporting to regulatory authorities
- Design and development planning
- Cleanliness of product
- Purchasing information
- Control of nonconforming product

The auditor found the company's QMS was "effective in managing and attaining objectives/targets," and "exceeds minimal compliance required with continuous improvement activities interwoven with QMS processes."

The IQA did not result in any major QMS nonconformances. Any minor findings were immediately addressed by conducting a root cause analysis and taking corrective action to ensure updated processes met the QMS requirements moving forward. Beekley management took the opportunity to retroactively assess and update previous documentation to comply with the quality standard and provided employee training for the implementation of any new procedures.

The team evaluated the observations and improvement areas to pinpoint quick fixes, preventative strategies, and proactive solutions aimed at preventing future issues.

Implementing procedural change and taking proactive measures on items noted in the IQA report completed by the CONNSTEP consultant directly contributed to Beekley successfully retaining its quality certification by the Certification Body.



CONNSTEP, Inc. is a consulting firm strategically helping companies in Connecticut to grow their businesses and improve operational methodologies, leading to increased profitability, improved efficiencies, and creating sustainable competitive advantages in the marketplace.