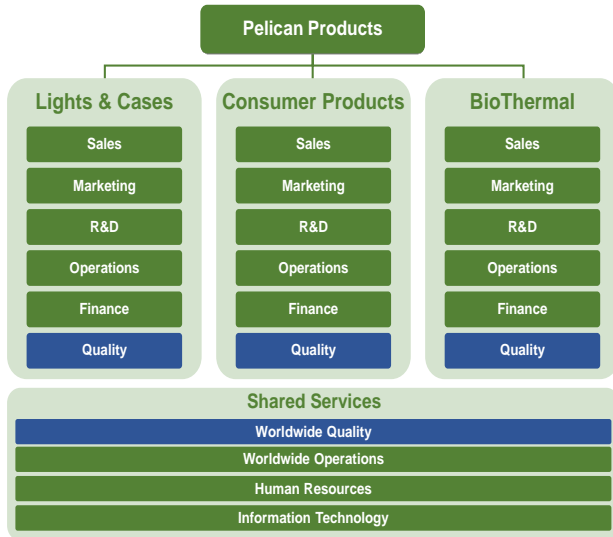


Roles/Responsibilities

The following people, functions, departments, or organizations have specific responsibilities within the quality system described by this document. An organization chart addendum to this quality manual, documents specific titles and the names of individuals filling these positions.



Management with Executive Responsibility ■

Committed to the development and implementation of the Quality System and maintaining its effectiveness by:

- appointing a Management Representative,
- communicating throughout the company the importance of meeting customer as well as statutory and regulatory requirements,
- ensuring the understanding and ownership of the Quality Policy throughout the company,
- ensuring that business goals and quality objectives are established,
- using management reviews to continuously evaluate the Quality System, and
- ensuring the availability of trained resources.

Management Representative ■

Ensures the Quality System is implemented and effective by ensuring:

- process, procedures, and instructions are established, implemented, and maintained,
- process and procedures are harmonized,
- management reviews are conducted, and
- the organization is aware of regulatory and statutory requirements.

QS Documentation Architecture



Level	Definition
Quality Manual (QM)	The Quality Manual defines policy, intent, and structure
Corporate Quality System Process (QSP)	QSP's define a sequence of procedures used across the company to fulfill the requirements of a specific portion of the quality system
Corp/BU/Site Standard Operating Procedure (SOP)	SOP's define the activities required to perform a specific procedure within a quality system process across the company, or within a specific business unit or site
BU/Site/Dept Work Instruction (WI)	WI's define the specific steps required to perform an activity within a business unit, site, or department
Quality Records	Quality Records are the outputs of quality system processes, procedures, and activities that provide objective evidence of compliance
Guidance	Non-binding information providing requirements clarification, rationale, or intent; or examples of possible compliance methods



Quality Manual

Quality Policy

Pelican is committed to continually improve our processes, satisfy applicable requirements, and actively engage our employees to provide unsurpassed customer value and satisfaction by delivering exceptional products and services.

Quality System Scope

Pelican Products, Inc. designs, develops, manufactures, supplies, and services high-performance case solutions and custom molded products, advanced portable lighting systems, and protective and thermal packaging globally. Our products and services are used in the most demanding markets, including firefighting, law enforcement, military, defense, aerospace, entertainment, industrial, transportation, life science, and consumer electronics.

Applicable Standards & Regulations

Standard / Regulation	Business Unit		
	Cases & Lights	Consumer	BioThermal
ISO 9001:2008	Y	Y	Y
ISO/IEC 80079-34	Y		
21 CFR Parts 210/211			Y ¹
ISO 14001:2004			Y ²
ISO/IEC 17025:2005			Y ²
OHSAS 18001:2007			Y ²

¹ BioThermal is not required to comply with FDA or other pharmaceutical regulations, but chooses to emulate some requirements where applicable

² BioThermal UK only



Quality Management System Process Model

The Quality Manual is the foundational framework by which Pelican Products enables continual optimization of products and services, customer satisfaction, business operation excellence, and compliance. This manual:

- establishes the quality policy that sets consistent expectations and responsibilities for the company,
- defines the scope of compliance with applicable regulatory, standards, industry, and business requirements,
- defines the roles and responsibilities for ensuring consistent process effectiveness, suitability, and adequacy, and
- describes the key processes of the quality system and their interaction, and identifies the documentation established for those processes.

