

10 QUALITY FACTS

1 ISO 9001:2015 CERTIFIED

PFSCM's Quality Management System (QMS) is ISO 9001:2015 certified. PFSCM's QMS received its initial ISO 9001:2008 certification in 2014, and the organization advanced to the latest ISO 9001:2015 standard in 2017, and renewed its ISO 9001:2015 certification in 2020.

2 QMS PRINCIPLES

PFSCM maintains the four global principles of a QMS: improving customer satisfaction, improving process integration, upholding evidence-based decisions and continuous improvement.

3 QMS ACTIVITIES

PFSCM's Quality Management comprises: document management, internal quality audit program, incident management, risk management, management review, QMS training and awareness and ISO certification audits.

4 SUPPLIER PREQUALIFICATION

PFSCM has a supplier prequalification program. The aim of the program is to expand PFSCM's pool of local suppliers for risk mitigation, and to develop sources of supply closer to demand to reduce supply chain costs, and minimize the environmental impact associated with global logistics.

5 EXPANDING LOCAL SUPPLIER BASE

Since the start of PFSCM's supplier prequalification program, the organization has audited over 100 suppliers. The majority of PFSCM's 39 current approved suppliers are based in Africa.

6 PRODUCT QA POLICY

PFSCM upholds a strict Product Quality (QA) Assurance policy that covers regulatory compliance, prequalification of products and suppliers, quality control, quality monitoring, complaints, deviations and recalls, and vigilance among other activities.

7 QUALITY SUPPLIERS

PFSCM only procures products that comply with defined quality requirements as prescribed in applicable QA policies, such as those that are either prequalified by the World Health Organization, approved by stringent regulatory authorities or the International Medical Device Regulatory Forum; and meet national regulatory requirements.

8 QUALITY CONTROL

PFSCM has an established automated online sampling and quality testing system through which products are flagged for quality testing to continuously monitor quality standards. We work with prequalified quality control laboratories for pre- and post-shipment inspection and sampling.

9 RISK MANAGEMENT

Risk management and risk-based thinking is embedded in all our processes and covers all areas of possible risk including strategic, operational, commercial regulatory, legal and financial. Risk management is critical when dealing with global health supply chain and the safety of patients and users of health products.

10 INCIDENT MANAGEMENT SYSTEM

PFSCM uses Jira Incident Management software to manage and maintain investigations and incidents. Data from the Incident Management System is used to analyze trends, and better implement future preventative measures.

