Quality Policy Statement

Quality objectives

The Management and staff of Dynek Pty Ltd are fully committed to the successful implementation and maintenance of the Quality System as outlined in the Quality Manual to ensure quality is achieved in suture and non-suture products and are manufactured in accordance with the regulatory requirements for absorbable and non-absorbable sutures and the CE Mark if applicable.

Our objectives are to:

- Maintain a formal quality system that meets or exceeds the international quality standard ISO 13485 and the European Council Directive 93/42/EEC and later amendments concerning medical devices, and to monitor and measure the performance of the quality system through:
    - management review activities
    - implementation and periodic review of applicable external standards
    - undertaking external and internal audits;
- Comply to Australian Therapeutic Goods (Medical Devices) Regulation 2002, and to measure and monitor this compliance through:
    - management review activities
    - implementation and periodic review of applicable external standards
    - undertaking internal audits
    - undertaking external Therapeutic Goods Administration audits;
- Define the performance and activity requirements of all staff members through job specifications to ensure that employees are required to undertake their designated job requirements, as well as measuring and monitoring these job activity requirements through quality management system activities and staff performance reviews;
- Implement training of employees, and maintain records of training for all Standard Operating Procedures that are required to be performed by the employee to fulfil their required job specification, such that these can be monitored during internal audits and staff reviews;
- Undertake periodic assessments and reviews of suppliers to measure and monitor supplier performance levels to ensure continual high quality standards of the product;
- Implement and monitor continuous improvement actions related to the inspection of raw materials, "work in progress" product as well as finished goods, to maintain the high level of quality (and potentially improve) the product;
- Undertake and record the results of internal audits at defined time intervals to identify potential areas of improvement in the quality system;
- Measure and monitor Pyrogen levels of sample products to ensure that levels are within Dynek specification limits for 100% of products;

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- Measure and monitor pre-sterilization Bioburden levels of sample products to ensure that levels are within Dynek specification limits for 100% of products;
- Measure and monitor staff and manufacturing environment cleanliness and hygiene levels at defined routine periods to ensure staff and manufacturing environmental cleanliness and hygiene levels are within Dynek specification limits at all times;
- Measure, monitor and record Clean Room air particle counts through routine external monitoring and testing to ensure Clean Room air particle counts comply with Dynek manufacturing requirements;
- Measure and monitor the results of product performance testing (e.g. detach testing) to ensure that the specification of the final product complies with external standards as well as customer requirements;
- Measure. monitor and review manufacturing validation processes to ensure that the processes are still operating under the validated parameters;
- Implement continuous process improvements caused by any process variation and/or internal non-conformance, to ensure that any identified issue is resolved;
- Rectify any customer product query to determine the root cause, and measure and monitor customer product queries;
- Measure and monitor feedback from Post Market Surveillance from customers;
- Monitor any new and unforeseen risks identified from external searches of predicate devices;
- Periodically re-evaluate the Risks associated with the product to update the Risk Analysis management of the product to include any newly identified Risks;
- Periodically undertake clinical evaluation of products to monitor suitability of product for surgical procedures as outlined in Instructions For Use of the product, as well as to identify any new unforeseen issues found with predicate devices;

Quality aspirations

The Management and staff of Dynek Pty Ltd endeavour to achieve our Quality objectives by the utilization of our Standard Operation Procedures and Training Programs, and with forward thinking and a positive attitude to be the best that we can be.

Our aspirations are to:

- To be the customers' first choice, every time by focussing on customers' needs and develop products and services that meet and exceed their expectations;
- Promote an atmosphere of continuous process improvement and problem prevention, hence reduce customer product queries caused by process variation and internal non-conformances;
- Promote an environment that supports Department Managers and Team Leaders to ensure teamwork and quality at source;
- Develop sound relationships with suppliers, emphasising continuous improvement in product quality, delivery and service;
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Products

Dynek products are supplied either with or without needles (pre-cut lengths) of various types and sizes, with needles manufactured from stainless steel for internal and external surgery.

Non-absorbable and Absorbable

It is understood that the CE Mark does not cover Catgut; however, it is covered by the TGA (Therapeutic Goods Administration).

The main goal of Dynek Pty Ltd is to continue our expansion with exportation, and to achieve and maintain customer satisfaction and confidence in the products that we proudly produce under the Dynek label. Our aim is to reduce customer queries and internal non-conformances continuously.

Research and Development

To encourage research and development internally and externally by working with approved organisations to introduce new products and systems that will improve our current products and promote patient care.

Mr Peter Paraniuk
Quality Manager

Date: 6/07/2022

Mr Ralph Crook
Director

Date: 6/07/2022

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