Our passion for quality is a vital imperative for Dako and sets the foundation for driving our quality culture. Our Quality Management System serves as the guide for how Dako operates to ensure that high product quality and services are delivered to our customers. In this Quality Manual you will find a description of our most important quality processes.

We are continuously improving our Quality Management System and its effectiveness by:
- Conducting management reviews on a regular basis
- Communicating to relevant parties
- Ensuring relevant quality objectives
- Having an established quality policy
- Securing continuous suitability, adequacy and effectiveness.

It is the mission of our Quality Manual to assure product quality and patient safety for which we systematically address and apply risk management to the development and sustaining processes of our products.

This manual fully and correctly describes the Dako Quality Management System in practice. All company employees are bound to observe the principles and procedures described in the manual.

We are Passionate about Quality!

Contents

- Quality Policy .................................................. 6
- Quality Objectives .............................................. 7
- Quality System .................................................. 7
- QMS Processes .................................................. 9
- Quality Measures .............................................. 10
- Continuing a Tradition of Quality ......................... 11
- Compliance in a Regulated Environment ................. 14
- About Us ......................................................... 16
Quality Policy

The quality policy stems from a commitment to quality, that has been maintained for more than 45 years. **We are passionate about quality!**

The quality policy consists of three vital elements, the 3 Cs that speak of:

- **Customers** – Our customer focus
- **Compliance** – Our adherence to meet compliance
- **Culture** – Our quality culture

This is translated into practice by the 3 Ps:

- **Products and services**: Customer focus is addressed in the quality of our products and services, to meet and drive customer satisfaction.
- **Processes**: The compliance area is addressed by our processes, and our assurance to operate accordingly to meet external requirements and regulations.
- **People**: The quality culture is all about people and the way we take on responsibility to drive quality, fostering the spirit of continuous improvements. It’s in everything we do.

**Living our quality commitment! It’s in everything we do.**

Quality Objectives

It is our objective to constantly deliver Dako products and services of the right quality to fulfill the requirements from our customers, health authorities and regulatory bodies.

Any quality problem must be identified and solved rapidly and effectively, and the power of preventive action ensures quality to be continuously enhanced.

The effectiveness of our quality system serves as an enabler to fulfill this quality objective, assuring products to be safe, effective and reliable. The effectiveness of the quality system is also to be continuously improved, creating value for the customers and at all times in compliance with the regulatory requirements.
Quality System

The Dako quality system works at 3 levels:

**Level 1** is the Quality Manual (this document).

**Level 2** is the tactical level which describes the QMS processes (main processes) of the quality system. The QMS processes determine the what and why. The QMS processes describe Dako processes across the organization which means that the individual QMS process may cover several different parts of the organization.

**Level 3** is the operational level. This level describes how, when, where and who. The Technical Procedures (TP) are general QMS “how to do” procedures and the item related documents include work instruction, data sheets, Instructions for Use, Device Master Records, labels and Packet Inserts.
QMS Processes

Management Processes

- Quality Management Review
- Training & Education
- Project Management
- Risk Management
- Internal & External Audits
- Clinical & Other External Studies

Product Life Cycle Processes

- Design Control
- Procurement process
- Receiving Control
- Production
- Quality Control
- Inventory Control
- Order Management
- Distribution
- Service Provision
- Product Post Marked Performance

Supporting Processes

- Compliant Handling
- Validation
- Non Conformance Reporting
- Corrections and Clarifications
- MPR
- CAPA
- Change Control
- Document & Record Management
- IT Systems
- Facility Service

QMS processes are described in 2nd document level in the form of process descriptions. Cross-references to ISO 13485 as well as FDA are listed in a matrix document. The matrix also contains references to local (Dako Denmark or Dako North America) descriptions. As this matrix is a living document and is updated with each change to the detailed descriptions, it cannot be a fixed component of this manual.

Selected processes in the Dako Quality Management System have been outsourced to external parties, e.g. production of instruments, facility management, production (printing) of secondary packaging, instructions for use (IFU) and user manuals, translation of Instructions for Use and user manuals.
Management establishes quality measures to maintain the effectiveness of the Quality Management System. We measure our quality with regard to customers, compliance and culture. The customer focus is met by viewing customer satisfaction. Viewing this along with product complaints demonstrates the conformity of our products.

In order to ensure conformity of the Quality Management System we gauge our compliance with the results of internal and external audit programs. The corrective and preventive actions and Change Control processes ensure continuous improvements of product and processes.
Continuing a Tradition of Quality

When a person is confronted with a possible cancer diagnosis, a biopsy is performed and tissue is taken out. The tissue is tested in a pathology lab and a report is generated. The report confirms or rules out a cancer diagnosis and determines the ‘stages’ or to what extent the cancer has spread. Treatment options come with information on the size, shape and appearance of the tissue under a microscope. Dako tissue-based diagnostics are at the forefront of automated solutions helping pathologists to accurately diagnose cancer and determine the most effective treatment for cancer patients.

Founded in 1966 by Danish medical doctor Niels Harboe, Dako earned its reputation for innovation and quality by introducing the first conjugated antibodies for immunohistochemistry more than 45 years ago. Harboe realized the importance of obtaining a supply of antibodies for analytical purposes which had the same strength at all times. A discovery in early 1967 made it possible to standardize the strength of antibodies in a usable product. Soon antibodies became a useful tool for physicians, to the benefit of patients all over the world.

In 2012, Agilent Technologies acquired Dako, thus installing a cornerstone of Agilent’s sharpened focus on providing solutions to applied chemical, life science, and diagnostic markets. The addition of Dako products and competencies for cancer diagnostics expanded Agilent’s distinctive technology and commercial competencies, to better address the needs of research and clinical laboratories.

Agilent continues the commitment to quality that Niels Harboe commenced with the earliest of Dako solutions. Products such as pharmDx™, Special Stains, and Image Analysis have been established under the highest quality standards ISO 13485, ISO 9001 and FDA registered.
Part of Agilent Technologies since 2012, Dako solutions are used globally by hospital and research laboratories to make precise diagnoses and determine the most effective treatment for patients suffering from cancer.

**General information**

Dako is a legal subsidiary of Agilent Technologies Inc.

Dako tissue-based cancer diagnostics are manufactured at two sites: Glostrup, Denmark and Carpinteria, California, USA. The solutions are used within the business area of anatomic pathology.

**About Agilent Technologies**

Agilent Technologies Inc. (NYSE: A) is the world’s premier measurement company and a technology leader in chemical analysis, life sciences, diagnostics, electronics and communications. The company’s 20,600 employees serve customers in more than 100 countries. Agilent had revenues of $6.8 billion in fiscal 2013. Information about Agilent is available at www.agilent.com.

On Sept. 19, 2013, Agilent announced plans to separate into two publicly traded companies through a tax-free spinoff of its electronic measurement business. The new company is named Keysight Technologies, Inc. The separation is expected to be completed in early November 2014.