

## Quality and Regulatory Program

Ensuring MSD products and services fulfill customer needs and comply with applicable regulations and standards

# Ensuring quality and compliance

Thermo Fisher Scientific is the world leader in serving science, with revenues of \$23 billion and 70,000 employees globally. Our Mission is to enable our customers to make the world healthier, cleaner and safer. We help our customers accelerate life sciences research, solve complex analytical challenges, improve patient diagnostics and increase laboratory productivity.

Thermo Fisher Scientific supplies innovative solutions for microscopy and microanalysis to take customers from questions to usable data by combining high-resolution imaging with physical, elemental, chemical and electrical analysis across scales and modes—through the broadest sample types.

This program describes the Materials & Structural Analysis (MSD) Quality and Environmental Management System and demonstrates our commitment to continuous improvement and compliance with applicable product regulations and standards. It also describes the Quality and Environmental Management System framework, tools, and programs we have implemented to maintain and improve the System.

Our global Quality and Regulatory team works closely with all businesses (i.e. Life Science, Material Science, Semiconductor and Spectroscopy) and functions, ensuring our compliance with applicable quality assurance requirements:

- Our Management System follows the requirements of the international ISO 9001-2015 and ISO 14001-2015 standards. Our certifying body is DEKRA certification BV. Certificates are available on request.
- We have a documented Quality Management System that we call IMS (Integrated Management System). Our IMS begins with our Business Process Framework (BPF), where quality assurance requirements are documented.

## Scope:

The Management System applies to the following sites:

- Hillsboro, Oregon, USA
- Eindhoven, The Netherlands
- Brno, Czech Republic
- Bordeaux, France

For the purpose of the Quality Management System standard **ISO 9001:2015**, the following per-site scope is applicable (no exclusions apply):

1. **Hillsboro and Eindhoven:**  
Design, development, manufacture, installation and service support of focused ion beam and electron beam microscopes for industrial and science markets.
2. **Brno:**  
Design, development, manufacture, installation and service support of focused ion beam and electron beam microscopes and X-ray source-based instruments for industrial and science markets.
3. **Bordeaux:**  
Design, development and service support of application software for focused ion beam and electron beam microscopes for industrial and science markets.

For the purpose of the Environmental System standard **ISO 14001:2015**, the following per-site scope is applicable (no exclusions apply):

1. **Hillsboro and Eindhoven:**  
Design, development and manufacture of focused ion beam and electron beam microscopes for industrial and science markets.
2. **Brno:**  
Design, development and manufacture of focused ion beam and electron beam microscopes and X-ray source-based instruments for industrial and science markets.
3. **Bordeaux:** Not applicable.

# Management responsibility

Quality, Environment, Health and Safety (EHS) policies are established by top management. All employees are made aware of these policies via the Quality Manual, training sessions, a quality policy badge and EHS policy posters placed around the buildings.

Global Quality and Regulatory Affairs is led by the Global Q&R Director, who has been designated by management for the implementation, monitoring and continual improvement of the system in accordance with ISO 9001-2015 and ISO 14001-2015 standards.

Site Quality and EHS Managers ensure the promotion of awareness of quality, environmental and applicable customer requirements throughout the organization.

Thermo Fisher's Practical Process Improvement Program (PPI) empowers every employee to drive profitable growth by continuously improving safety, quality, productivity and customer allegiance.

Typical methods used are Key Performance Indicator (KPI) leadership, Customer Allegiance Score (CAS) program, Internal Audits, Corrective Action Preventive Action (CAPA), 8-step method for problem solving, Lean, Cause / Effect and Failure Mode and Effect Analysis (FMEA). These enable how we Plan, Do, Study and Act (PDSA) on risk and opportunities for the Quality and Environmental Management System. The implementation is assured by measuring quality, productivity and customer satisfaction.

For general surveillance monitoring of the Quality and Environmental Management System, the performance of the system is presented to senior leaders at each site and to divisional leaders. The Global Q&R Director reviews the Management System at planned intervals to ensure its continuing suitability, adequacy, compliance, effectiveness and resources to support these activities. These reviews include assessment of opportunities for improvement and the need for changes to the system(s), including the overall objectives.

# Quality policy

"We fulfill our Mission to enable our customers to make the world healthier, cleaner and safer by continuously improving the quality of our products and services and by ensuring global regulatory compliance."

## Our Company

We drive a continuous improvement culture that is enabled by Practical Process Improvement (PPI) and our company's Quality System

## Customers

Can rely on our products and services to consistently meet their specifications and requirements

## Colleagues

We take personal ownership to ensure our work meets customer requirements and is error-free from design through use

## Regulators

We operate at the highest ethical standards and meet or exceed all applicable regulatory requirements



Drive continuous improvement and profitable growth

# Environment, Health and Safety Policy

As a responsible corporate citizen, Thermo Fisher Scientific is committed to protecting the environment and the health and safety of our employees, customers and communities where we operate.

To this end, we will:

- Comply with all applicable environmental, health and safety laws, regulations and other related standards we may adopt and endorse.
- Implement sound environmental, health and safety management practices throughout our global organization, operations and activities.
- Operate in a manner that ensures a safe work environment, prevents pollution, minimizes our environmental impact and leads to improvements in the sustainability of our business enterprise.
- Continuously improve and periodically evaluate our environmental and health and safety performance and take necessary preventive and corrective measures.
- Communicate environmental and health and safety policies and programs to employees and key stakeholders.

All employees are responsible for delivering on these commitments. Leaders of individual groups, divisions, operating facilities and other functions retain ultimate responsibility for ensuring compliance and creating a culture of continuous improvement in our environmental and health and safety performance.

Further information on our current performance with respect to environmental sustainability can be found in our Environmental Sustainability Performance Document.

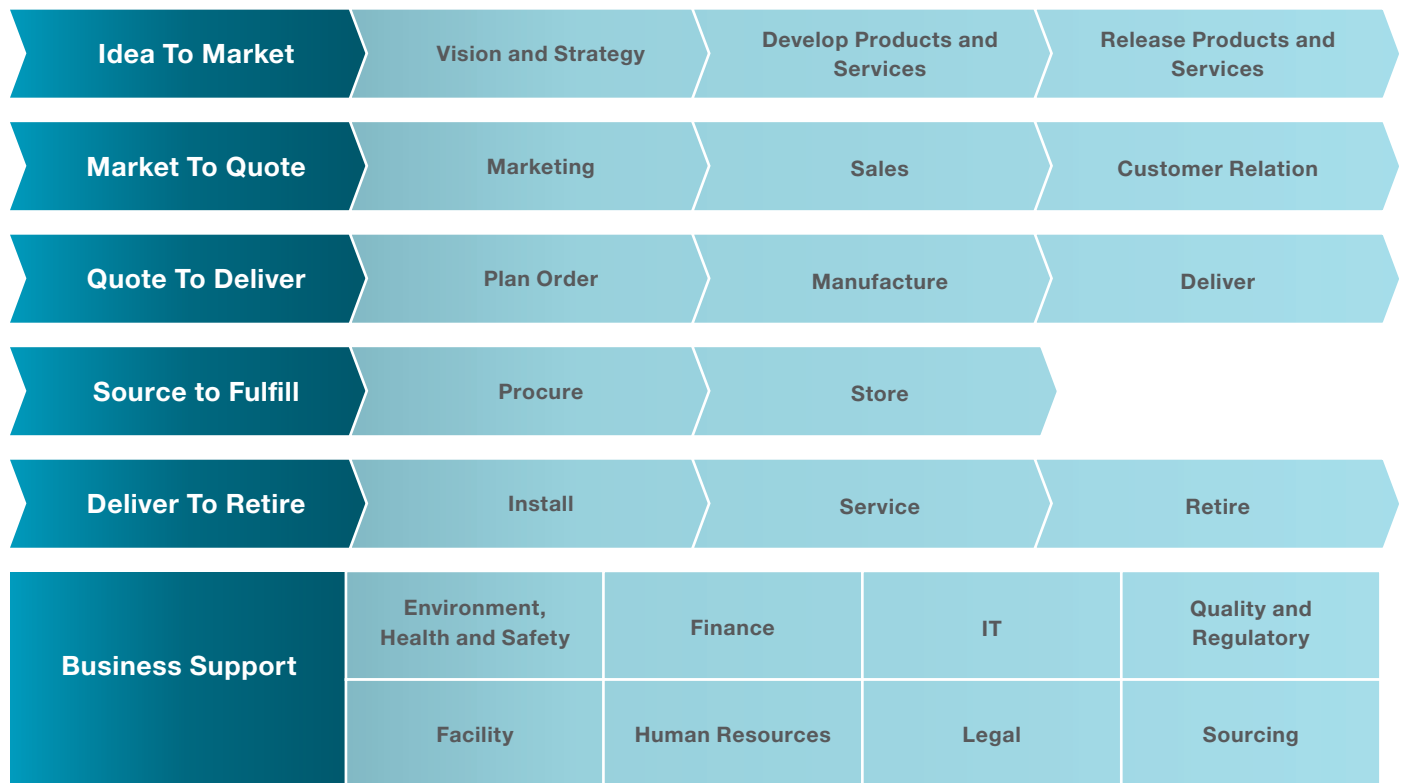


# Quality and Environmental Management System

We have investigated the organization's purpose, strategic direction and its internal and external context to determine the key business processes needed to achieve the intended results of the Management System as defined by ISO 9001-2015 and ISO 14001-2015 standards.

The Quality and Environmental Management System contains documents with information related to processes. These documents represent:

- Policies describing what must be complied with.
- Procedures describing specific activities as to how certain policies will be executed.
- Work Instructions providing further details in the execution of an activity as defined in a procedure where further specificity is identified for more complex tasks.



The processes above constitute our Business Process Framework (BPF). They are designed to interface with each other to form effective Value Streams. The process architecture and documented information assure that our products and services meet customer expectations.

Quality metrics (KPI) are identified to drive “perfect system health”, perfect design, perfect order and perfect service.

In monthly business reviews, metrics are being monitored against pre-set targets to drive continual improvement.

# Our commitment to quality

The quality and regulatory controls we have in place help us comply with requirements that give our customers confidence in our ability to consistently meet their needs. Some examples include:

- KPI leadership drives quality and continuous improvement in processes and products.
- Our products are designed and released in accordance with a systematic Product Management Process (PMP) as defined in our IMS.
- Our tooling and equipment used to manufacture our products follow a systematic calibration and preventive maintenance program.
- Our manufacturing teams maintain internal build quality and consistency. Test requirements are developed during new product development, as described in our IMS processes.
- Our manufacturing processes include both in-process and final tests to ensure we meet published systems specifications.
- Our manufacturing and installation processes include strict ESD (electrostatic discharge) and cleanliness protocols.
- Our technical training programs are comprehensive and continuous.
- Installations of our products at customer sites can include a third-party field evaluation by a Nationally Recognized Testing Lab (NRTL). Our products are CE marked and / or NRTL certified.
- Maintenance of our products at the customer site can be provided via service contracts by qualified Field Service Engineers.

## 4i Values

Thermo Fisher's 4i Values of Integrity, Intensity, Innovation and Involvement make up our culture and guide employee interactions—with our customers, suppliers and partners, and with each other. These four values are the foundation of our culture and are fundamental to our continued growth.



Integrity

Honor commitments, communicate openly and demonstrate the highest ethical standards

Intensity

Be determined to deliver results with speed, excellence and a passion to succeed

Innovation

Create value by transforming knowledge and ideas into differentiated products and services for our customers

Involvement

Make connections to work as one global team, embracing unique perspectives and treating others with dignity and respect

Find out more at [thermofisher.com/EM-Sales](https://thermofisher.com/EM-Sales)

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