

A close-up photograph of a scientist in a laboratory. The scientist is wearing a white lab coat, safety goggles, and purple nitrile gloves. They are holding a glass beaker with a red liquid inside. A pipette is being used to add a drop of clear liquid to the beaker. The background is slightly blurred, showing other lab equipment and a bright light source.

Regulatory
compliance
made easy

FedEx[®]
Express



To meet its unique industry requirements, FedEx Express has a quality system designed specifically for the healthcare industry. No matter what occurs, the FedEx Quality Management System (QMS) provides a detailed audit trail throughout your shipment's journey.

The FedEx Quality Assurance (QA) team offers full service solutions to address customers' specific market needs. Given the high number of customers (67%) who require Good Distribution Practice (GDP) and Good Manufacturing Practice (GMP), FedEx Express has an entire QA department and series of processes dedicated to these essential quality systems.

Through QMS, your regulated shipments undergo a rigorous process including Standard Operating Procedures (SOPs), thermal mapping, shipping lane and container/packaging review, corrective and preventative actions (CAPAs), hard-copy temperature documentation, deviation reporting and contingency intervention controlled by monitoring. The QA team also has the expertise you need for temperature-sensitive shipments with protocols, calibration reports and temperature-data probes.

Quality Assurance is crucial to customers' regulatory compliance.

[Require GDP and GMP](#)

Sixty-seven percent of customers responded that they require GDP and GMP in a FedEx Express Voice of the Customer survey conducted with the pharmaceutical companies across 6 key markets in 2016.





FedEx Quality Management System

FedEx QMS ensures consistent results for your shipments with trained personnel who can process monitoring, controls and audits. QMS supports your regulatory compliance, including but not limited to the following national and international guidance documents:

- WHO Technical Report Series, No.961, 2011 (Annex 9)
- EU guidelines to GDP of Medicinal Products for Human Use
- US Food and Drug Administration (FDA) Quality System Regulation (21 CFR, part 820)
- PIC/S Good Distribution Practices
- China Food and Drug Administration (CFDA) Good Supply Practice (GSP) for Pharmaceutical Products
- Ministry of Health Malaysia (MOH) Good Distribution Practice for Medical Devices (GDPMD)
- International Council for Harmonization (ICH) Q10, Pharmaceutical Quality System
- ISO9001:2008

Quality Agreements

The FedEx Quality Agreement helps ensure your complete understanding of the standards of care to be used on each of your shipments. Each Quality Agreement can be customized to include your specific requirements for quality systems and processes.

Documented components of FedEx QMS include:

- a Quality Manual
- Healthcare-specific Standard Operating Procedures (SOPs)
- a Quality Agreement

Contingencies and compliance are critical to the smooth delivery of your shipments. QMS gives you peace of mind through the following key operations:

- Document Control
- QMS Training Plan
- Change Control
- Deviation Reporting
- Corrective and Preventative Actions (CAPAs)
- QA Audits (internal, external)

Deviation Reporting

If an exception occurs, FedEx is ready to support your quality protocols, take corrective actions, and, upon your request, document every step in the process. The FedEx deviation reporting process includes identifying the issue, investigating the reason, a root cause analysis, and implementation of corrective actions, as applicable.



Customized Shipping Studies

Shipping temperature-sensitive and regulated products can be complex. FedEx Express has a team of quality and transportation experts who can work with you to support your compliance needs.

FedEx shipping studies provide you with customized protocols and analyzed data so that you can see the big picture of your shipping requirements every step of the way. We can provide a customized shipping study for you to qualify lanes, determine packaging used on FedEx Express and commercial airlines, perform facility temperature mapping, and/or conduct site qualification.

Dedicated Quality Assurance Professionals

The FedEx Quality Assurance Team manages all aspects of a shipment's document control, audit processes and post-shipment audits.

The FedEx Quality Assurance team of professionals includes the following roles:

- Quality Assurance Coordinators
- Document Control Administrators
- Validation Technologists
- Validation Engineers
- Quality and Validation Supervisors
- Quality and Validation Managers

[More info](#)

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