

FDA Fact Sheets: Quality Systems

The Quality System (QS) regulation (21 CFR Part 820) is designed to ensure that manufacturers have procedures and processes in place to produce safe and effective devices. QS requirements cover topics including: quality management and organization, device design, equipment, purchasing and handling of components, production and process controls, packaging and labeling controls, distribution, installation, complaint handling, servicing, and recordkeeping.

The QS regulation generally applies to organizations that produce finished medical devices (and some accessories) for human use that are commercially distributed, and entities such as device remanufacturers and specification developers. Manufacturers subject to the QS regulation must ensure that all components satisfy quality requirements, even when third parties supply those components.

Some low-risk finished devices are exempt from QS requirements. Investigational medical devices are not subject to all quality requirements, but are subject to design controls.

The QS regulation describes general objectives rather than specific methods. Manufacturers need only comply with requirements that apply to their establishments and products. Even when the QS regulation specifies methods, manufacturers may substitute other methods that meet the intent of the QS regulation if they can justify the substitution.