QIAGEN Quality FAQs

Sample to Insight

Site Entity/Address	Product/ Services offered	Total Space	No. of staff	No. of shifts
QIAGEN GmbH Hilden Qiagen Str. 1, 40724 Hilden, Germany	Design & Development, Manufacturing, distribution, servicing and administration of instruments and reagents. Service for RNA / DNA isolation, genome amplification, PCR-& sequencing-analysis.	~91000 m² ~979,500 sq. ft.	~1360 FTE	3
QIAGEN Manchester Ltd. 2.0, Citylabs, 200 Hathersage Rd, Manchester M13 0BH	QIAGEN's Center of Excellence for development of companion diagnostics for personalized healthcare and MDx Center of Excellence.	~8949 m² ~96,300 sq. ft.	~350 FTE	1
QIAGEN Sciences LLC Germantown 19300 Germantown Rd, Germantown, MD 20874, United States	Instruments, IVD, Medical Devices Installation and service	~29260 m² ~315,000 sq. ft.	~280 FTE	2
QIAGEN Barcelona Carrer de Baldiri Reixac, 4, Les Corts, 08028 Barcelona, Spain	QIAstat-Dx commercialization and manufacturing	~2880 m² ~31,000 sq. ft.	~230 FTE	1
QIAGEN Gdansk Gdański Park Naukowo - Technologiczny, 3, Trzy Lipy, 80-172 Gdańsk, Poland	Enzyme Production	~3208 m² ~34,500 sq. ft.	~75 FTE	1
QIAGEN DNA Synthesis AB Vasteras Pressduktorgränd 6, 721 36 Västerås, Sweden	Oligonucleotide Synthesis	~3160 m² ~34,000 sq. ft.	~85 FTE	1
QIAGEN Sciences LLC Frederick 6951 Executive Way, Frederick, MD 21703, United States	NGS Portfolio Development	~7246 m² ~78,000 sq. ft.	~120 FTE	1
QIAGEN Beverly LLC 100 Cummings Center, Suite 407J, Beverly MA 01915, United States	Enzyme Production	~5760 m² ~62,000 sq. ft.	~60 FTE	1
QIAGEN China (Shanghai) Co., Ltd. Block 20, 88 Da Er Wen Road, Zhangjiang Hi-Tech Park, Pudong, Shanghai, 201203, China	LS/MDx Distribution	~1594 m² ~17,158 sq. ft.	~173 FTE	1

Certificates	
What certifications does QIAGEN hold?	All QIAGEN manufacturing sites are certified according to ISO 9001 / ISO 13485 / ISO 18385 / MDSAP / IVDR and/or have an FDA registration depending on their operational needs. Please see QIAGEN.com for more details: Quality Assurance. www.qiagen.com/us/knowledge-and-support/product-and-technical-support/quality-and-safety-data/quality-assurance
QMS	
Do you have a Quality Manual?	Yes
Do you have a Quality Policy?	Yes
Are Quality Objectives defined?	Yes
Do you have an Organizational Chart?	Yes
How are QMS (Quality Management System) records maintained?	Electronic QMS, Electronic Document Management system and ERP (Enterprise Resource Planning).
Are records retained/maintained?	Yes, dependent on record type. All quality records retained for minimum 15 years.
How often are management reviews conducted?	Twice per year
Do you allow customer audits?	Dependent upon contract
Do you have an internal audit program?	Yes
Is a Medical Device File available for each Medical Device?	Yes
Are Quality functions independent from manufacturing functions?	Yes
Are quality management representatives appointed by top management?	Yes
Document Control	
Do you have a process in place for control of documents/records?	Yes
Do you have a procedure for document storage/archival?	Yes
Is there a process of verification and approval for quality documents?	Yes
Are records maintained to provide traceability of materials and equipment?	Yes through Enterprise Resource Planning system and Regulatory Asset Management system
Deviation, CAPA and Complaints Management, Analysis of Data	
Is there a formal procedure in place to manage deviations?	Yes
Is there a formal procedure in place to manage non conformances?	Yes
Is there a formal procedure in place to manage CAPA Investigations?	Yes

Deviation, CAPA and Complaints Management, Analysis of Data	
Is there a formal procedure for handling and investigating customer complaints?	Yes
Is there a procedure for managing recalls?	Yes
Is there a procedure in place for any Out of Specification results?	Yes
Is there a procedure for analysis of data?	Yes
Change Management	
Is there a procedure in place to document, assess and control any changes that may directly or indirectly impact product or services?	Yes
Are customer notified or any significant changes that may impact the products/service rendered?	As specified in contract or quality agreement.
Supplier Assurance	
Is there a procedure for the selection, evaluation and monitoring of suppliers?	Yes
Do you have an approved suppliers list?	Yes
Do you audit your approved suppliers?	Yes, dependent on supplier criticality
Do you have quality agreements in place with approved suppliers?	Yes, dependent on supplier criticality
Do you have a system in place to review and assess changes made by your approved suppliers?	Yes
Training and Personnel	
Is there a procedure in place that governs the onboarding, initial training and ongoing training of company staff?	Yes
Are defined training requirements in place for all job roles within the business?	Yes
Do all personnel hold a training record to record training activity and status?	Yes
Computerised Systems	
Do you have a computerized system validation procedure?	Yes
Are the computerised systems validated?	Yes
Is there a disaster recovery plan in place for IT systems?	Yes
Is there a procedure in place governing the back up and recovery of data?	Yes
Is there a procedure in place governing the retention and archiving of data?	Yes

Risk Management	
How does QIAGEN integrate risk management?	QIAGEN uses standards, such as ISO 14971, as guidelines for all critical systems risk analysis
GMP Principles	
What GMP principles do QIAGEN manufacturing sites use?	QIAGEN manufacturing sites utilise standard GMP priniciples e.g., manufacturing and quality control according to written procedures, defined acceptance criteria, control of purchased materials, product anayltical quality control, and QA release.
Calibration	
Is there a process in place to control monitoring and measuring devices	Yes

Audits and inspections

As a certified manufacturer of IVD and Life Science products, QIAGEN's QMS undergoes regular audits by competent authorities and notified bodies.

QIAGEN values the recommendations and continuous improvements that can result from these audits. Additionally, QIAGEN closely monitors the audit nonconformance rate as an indicator of the compliance and effectiveness of its QMS.

Nonconformance refers to an event where a process, service, or product does not meet the required standards. This is measured by the number of nonconformances identified by a notified body or competent authority per auditor per day. A rate below 0.5 indicates that QIAGEN maintains an effective and efficient QMS.

Recalls

Due to our stringent quality management, recalls rarely occur. In the reporting year 2024, six recalls (U.S./EU FSCA) and no FDA Class I recalls were registered. In the event of a recall, all of our sites are subject to global procedures to avoid the further use of the affected product. We assure full traceability of each product to the final customer and can, therefore, notify customers directly in the event of a recall.

Required actions for recalls depend on the individual case. Actions can range from providing additional information to physically recalling a product. We have defined processes, responsibilities and improvement programs as required by regulating authorities to avoid the recurrence of recalls.

Complaint management

Regarding our processes for engaging with customers, for the most part, complaints in 2024 centered around product performance. Typically complaints are very specific to the customer's application. Consequently, QIAGEN's actions focused on identifying the root cause and avoid reoccurrence by effective corrective and preventive actions.

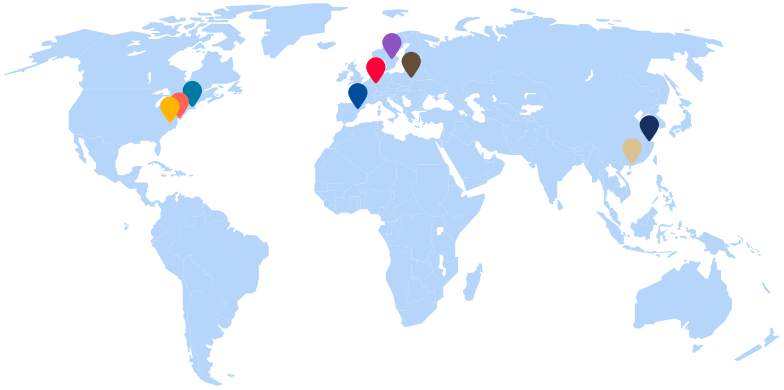
QIAGEN has established a global process to manage customer feedback. Central entry gate for technical customer interaction is our Tech-Service. Each support incident can be escalated to a complaint case if product performance may be impacted. Each complaint is investigated and appropriate corrections and corrective and preventive actions (CAPAs) are implemented. The overall complaint numbers are trended and evaluated.

The complaint management process is part of QIAGEN global CAPA process landscape that also includes Risk management, CAPA investigations, handling of non-conforming products, and management of deviations. All are feeding into a structured process to identify potential root causes and establish effective corrections and CAPAs. This process is part of QIAGENs global QMS and is overseen by the Global Quality Assurance team. The CAPA process as all other processes are trained to relevant employee groups at QIAGEN.

Our approach to quality

100% of manufacturing facilities are certified to ISO 9001 and/or ISO 13485 quality system standards

Global certifications at manufacturing sites



ISO 9001 and/or ISO 13485 Certified manufacturing sites

- **Hilden,** Germany
- **Barcelona,** Spain
- **Västerås,** Sweden
- **Germantown,** USA
- **Beverly,** USA
- **Frederick,** USA
- **Shenzhen,** China
- **Beijing,** China
- **Gdansk,** Poland

For more information, check out our QMS certificates **here**

Ordering	**www.qiagen.com/shop**
Technical Support	**www.support.qiagen.com**
Website	**www.qiagen.com**