FDA QUALITY & REGULATORY CONSULTANTS

Your One Stop Shop for Global Quality & Regulatory Compliance

GLOBAL EXPERTISE | fdaqrc.com

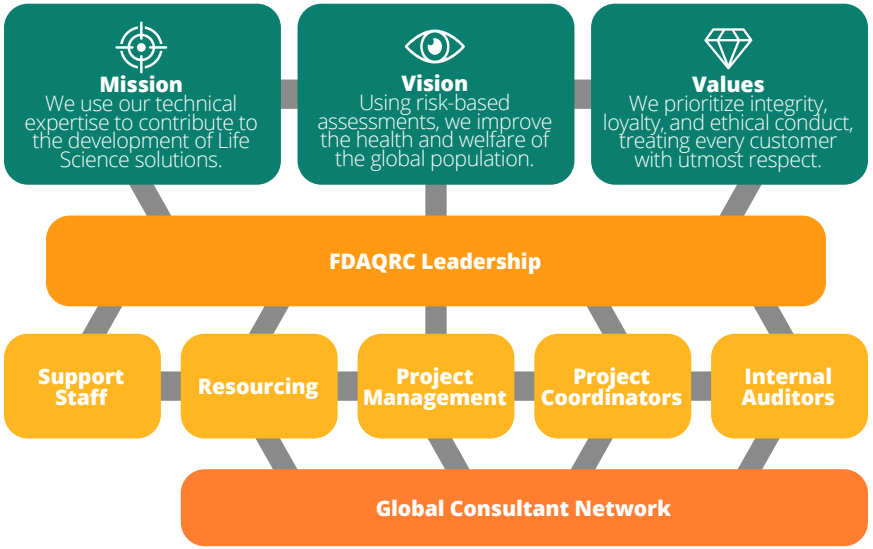
Your Worldwide Compliance Partner

Where Expertise Meets Excellence

FDA Quality and Regulatory Consultants (FDAQRC) is a leading provider of regulatory compliance solutions for pharmaceutical, biotech, and medical device companies globally. Our expert employees and consultants are experienced across all GxP areas to best suit client needs at any stage of the research and development process.

FDAQRC provides a range of services such as audits, mock inspections, GAP analysis, remediation services, recruitment, and more. Through our global consultant network, we pair our clients with experts for every project, regardless of location. FDAQRC has over 400 active consultants in over 50 countries. Our consultants go through a state-of-the-art vetting process, which allows us to personalize their consulting experience as well as ensure their expertise will align effectively with the specific requirements of each project.

- ☑ **Global Regulatory Compliance Leader**
- ☑ **Expertise Across GXP Areas**
- ☑ **Comprehensive Services**
- ☑ **Advanced Consultant Network**
- ☑ **Global Reach**
- ☑ **Personalized Consulting**
- ☑ **Excellence in Regulatory Compliance**
- ☑ **Tailored Solutions**
- ☑ **Client-Centric**
- ☑ **Trusted Partner**



OUR STORY

FDAQRC was founded by President Christopher Rush in 2009.

Rush is a former FDA employee. He saw a need in the industry to better match high quality auditors with regulatory projects for clients, which led to the founding of FDAQRC. The company was developed with the vision of helping others bring about medical innovations that can improve the global population's quality of life. FDAQRC focuses on using risk-based assessments to improve the health and welfare of the global population.

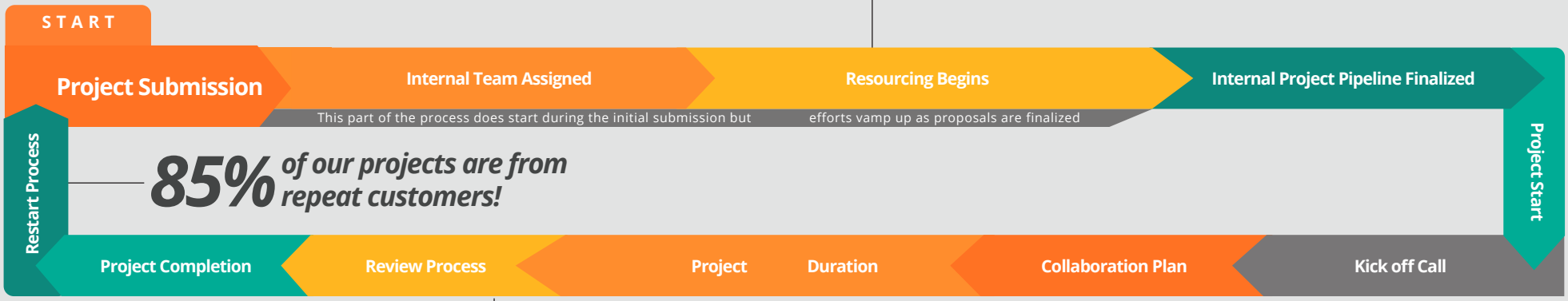
After establishing a reputation for excellent work, FDAQRC grew rapidly. From 2020 to 2021, the number of internal employees tripled. In 2022, two new departments were created to allow a more robust range of services to assist clients from start to finish.

Since 2009, FDAQRC has completed over 4,000 projects, and we currently have more than 400 consultants worldwide. Due to FDAQRC's reliability and high quality of work, 85% of existing clients return with new projects and requests.

Navigating Excellence

Our Process for Compliance Solutions

For comprehensive details on our consultant vetting and on boarding process, please refer to page 8.



FDAQRC takes the report review process seriously by ensuring every compliance solution undergoes a meticulous evaluation to maintain high quality standards.

"FDAQRC provides an outstanding service with very knowledgeable and expert auditors. The project manager and consultant's pleasant demeanors along with their extensive clinical and GCP expertise is greatly appreciated for our projects."

SENIOR DIRECTOR OF QUALITY ASSURANCE, 2021

FDAQRC is committed to excellence through communication and collaboration, ensuring every step of our process delivers the highest quality compliance solutions.

Our company model pairs Project Managers, Auditors, and consultants to our clients to offer the best compliance solution.

When a client submits a project, our dedicated resource team meticulously evaluates Consultant and Auditor profiles to find the perfect skill set and area of expertise to fit the project scope.

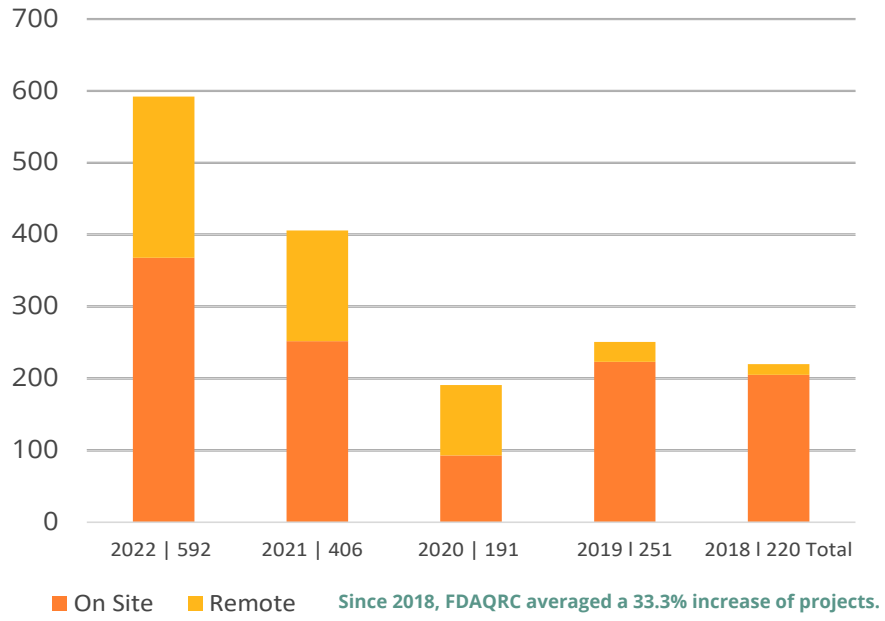
Throughout the entirety of a project, an FDAQRC Project Manager will oversee the process and both the client and consultant. Our Project Managers offer consultants support, collaborate on project deliverables, and communicate with the client to ensure everything exceeds client expectations.

FDAQRC's internal support staff such as Project Coordinators and Administrators, Human Resources, Marketing, and Information Technology, work tirelessly to allow our operations team to focus solely on their clients and consultants.

One Stop Shop

Your Path to Regulatory Compliance

Continuous Project Growth



Since 2018, FDAQRC averaged a 33.3% increase of projects.

At FDAQRC, our goal is to provide tailored solutions to address your unique project needs.

We excel in providing comprehensive support for projects in the realm of all GxP areas, including but not limited to, Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP).

We understand that your project's needs may evolve, and we are ready to assist you at any stage of your journey.

To meet client needs, we offer a wide range of capabilities. Our services include conducting various types of audits, such as investigator site audits (ISAs), vendor qualification audits, for-cause audits, CRO/CMO audits, mock FDA inspection audits, CSV compliance audits, and GAP analysis. We can assist in developing and enhancing quality systems to ensure compliance and operational efficiency.

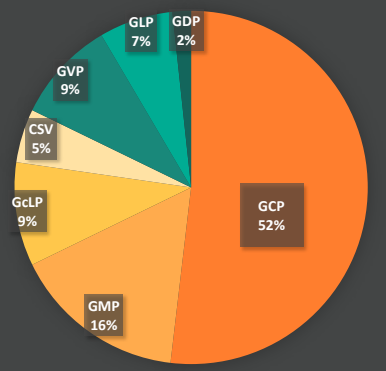
Our dedicated remediation department is ready to support clients who have received FDA warning letters or those seeking continuous improvement practices. We provide comprehensive training and consulting services to empower your team with the knowledge and skills necessary for regulatory compliance.

Our recruitment department is committed to sourcing top-quality candidates for your long-term, contract, and temporary positions, with a meticulous review process that includes screening resumes and conducting preliminary interviews to recommend experts with the right experience for each role.

Service Offerings

Clinical Trial Support
Compliance Audits
Computer System Compliance Audits
Consultancy Services
Data Management
Document Audits
Facility Assessments
Facility Walk through
GAP Analysis
Investigator Site Audits
Mock Inspections
Procedure/Process Audits
Post-Market Surveillance
PV Systems and Processing Audits
Quality Investigator Site Assessments
Quality Risk Management
QMS Consultancy
Regulatory Strategy and Submissions
Recruitment & Permanent Placement
Regulatory Intelligence
Regulatory Writing
Risk Assessment and Management
SOP Development
Supply Chain Audits
System Audits
Third-Party Audits
Training/Inspection Interviews
Trial Master File
Vendor Assessments
Vendor Audits
Validation Services

HOW OUR PROJECTS STACK UP:



Global Expertise

Experts Across all GxPs

At FDAQRC, we take immense pride in our exceptional global consultant network, a testament to our commitment to providing top-tier service in the quality and regulatory industry.

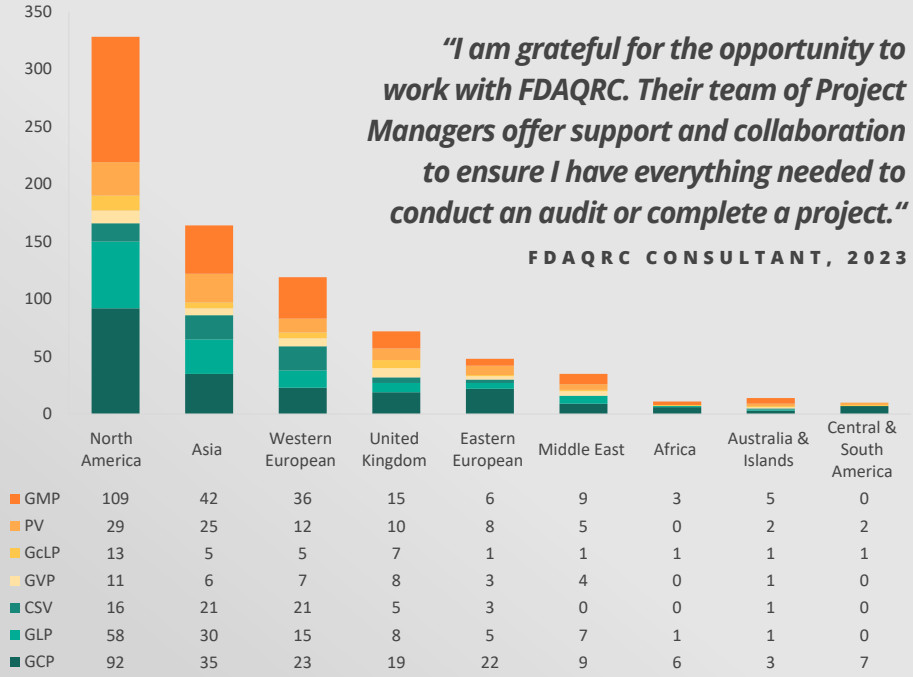
With over a decade of experience and a presence in more than 50 countries, we've cultivated a powerhouse team of active consultants covering the full spectrum of GxP areas. This enables us to address client needs across diverse industries and sectors. This allows FDAQRC to align our consultants' specializations and interests with your specific project needs.

We take great care in selecting highly qualified individuals to join our esteemed network by following our stringent internal requirements for consultants.

- ☑ **Detailed CV Submission:** Every potential consultant is invited to submit their CV. This step offers us valuable insights into their extensive experience and areas of expertise.
- ☑ **Personalized Evaluation:** An experienced FDAQRC Project Manager engages in a detailed interview with the consultant to gauge capabilities.
- ☑ **Reliable Reference Verification:** Our internal resource administrator conducts reference checks and validates the consultant's professional experience.

Over 400 Active Consultants

Our consultants are located in all global regions and have all different experience and backgrounds across all GxPs. We are known for hiring the best of the best, including former health authority employees.



"I am grateful for the opportunity to work with FDAQRC. Their team of Project Managers offer support and collaboration to ensure I have everything needed to conduct an audit or complete a project."

FDAQRC CONSULTANT, 2023

Stay Connected

Industry Insights and Updates

FDAQRC stays on top of the latest trends and industry developments. Our staff regularly attends training sessions and major industry events such as DIA's Global Annual Meeting, SQA, RQA, and more. At these events, we meet new like-minded individuals and strengthen our connection with existing clients and consultants. Our employees are known to present posters and presentations on cutting-edge topics, such as education bias, GMP continuous improvement, and deep dives into the pathways to consultancy.

FDAQRC regularly publishes Industry Insight articles regarding relevant topics in the bio-pharmaceutical and regulatory compliance industry.

FDAQRC stays active on a day-to-day basis on social medias which allows us to stay in touch with our clients, consultants and connections from around the world.

Follow along on our website and on LinkedIn to see all the things FDAQRC is up to.

FDA|QRC

We had multiple of our sites audited by FDAQRC prior to an FDA inspection.

Thanks to the detailed and diligent work of FDAQRC's consultants and Project Managers, when the FDA conducted their inspection, there were no findings. We appreciate the great collaboration and hard work from FDAQRC while managing our projects.

SENIOR MANAGER OF QUALITY SYSTEMS, 2022

Since 2009, FDAQRC has completed over 4,000 projects, and we currently have over 400 active consultants worldwide. Due to FDAQRC's reliability and high quality of work, over 85% of our clients continue to bring new projects and requests.

FDAQRC has experienced exponential growth since 2020. Our internal team has tripled, and our number of projects has increased by an average of 33.3% over five years. To manage this growth, we have promoted several employees to reward their dedication to FDAQRC.

We look forward to many years of continued growth.

FDA|QRC

Contact

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Consulting Opportunities | resourcing@fdaqrc.com

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