FDA QUALITY & REGULATORY CONSULTANTS

Setting the Standard in Global Quality & Regulatory Compliance

GLOBAL EXPERTISE | fdaqrc.com

EXPERTS ACROSS ALL GXPS

SERVICE OFFERINGS

Computer System Validation (CSV)

Good Clinical Laboratory Services (GcLP)

Good Clinical Practices (GCP)

Good Distribution Practices (GDP)

Good Laboratory Practices (GLP)

Good Manufacturing Practices (GMP)

Good Pharmacovigilance Practices (GVP)

Inspection Readiness Services (IR)

Qualified Persons (QP)

Quality Management System (QMS) Consulting

Recruitment Services

FDA|QRC

FDA QUALITY & REGULATORY CONSULTANTS

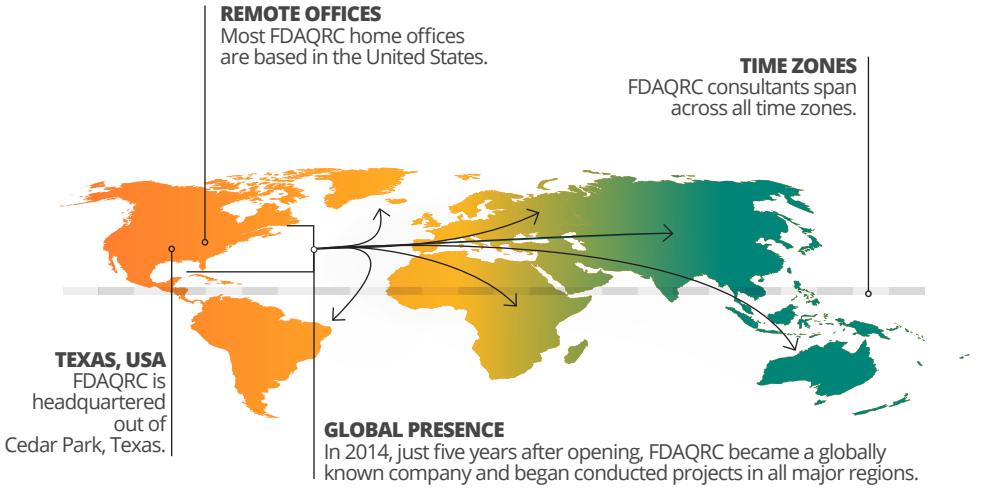
Your Worldwide Compliance Partner

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 all phases of product life cycle and development.

FDAQRC provides a range of services such as quality audits, mock inspections, gap assessments, 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 500 active consultants in every major region (70+ countries). Our consultants go through an extensive 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**
- ✓ **Personalized Consulting**
- ✓ **Excellence in Regulatory Compliance**
- ✓ **Tailored Solutions**
- ✓ **Client-Centric**
- ✓ **Trusted Partner**



OUR STORY

Company President, Christopher Rush founded FDAQRC in 2009, leveraging his experience as a former FDA investigator. Recognizing the industry's need for pairing top-tier auditors with regulatory projects, he established FDAQRC with a vision of advancing medical innovations for global well-being. The company prioritizes risk-based assessments to enhance the health and welfare of the global population.

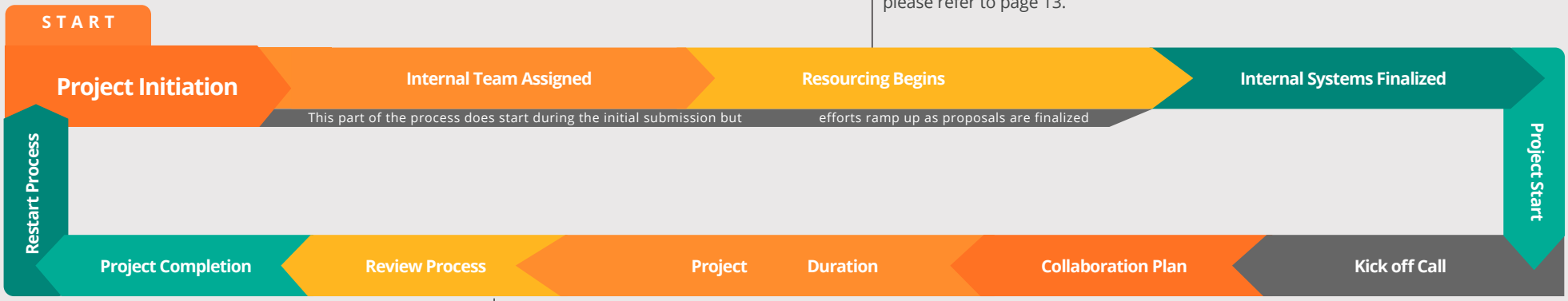
FDAQRC, renowned for its excellence, has undergone substantial growth since 2020. We tripled our internal workforce of Auditors and Project Managers and, in 2022, introduced Recruitment and Remediation departments, broadening our service offerings. Active enhancements in 2023 have elevated our Inspection Readiness Programs and Mock GMP and Mock GCP projects, making them our most sought-after services.

Since its inception in 2009, FDAQRC has successfully completed over 4,500 projects, boasting a network of more than 500 consultants worldwide in every major region (70+ countries). Our track record of reliability and exceptional work quality results in an impressive return rate of existing clients with new projects and requests.

Navigating Excellence

Our Process for Compliance Solutions

For comprehensive details on resourcing and our consultant vetting and onboarding process, please refer to page 13.



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

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 for both the client and consultant. Our Project Managers offer consultants support and logistics, collaborate on project deliverables, and communicate with the client to ensure everything exceeds 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.

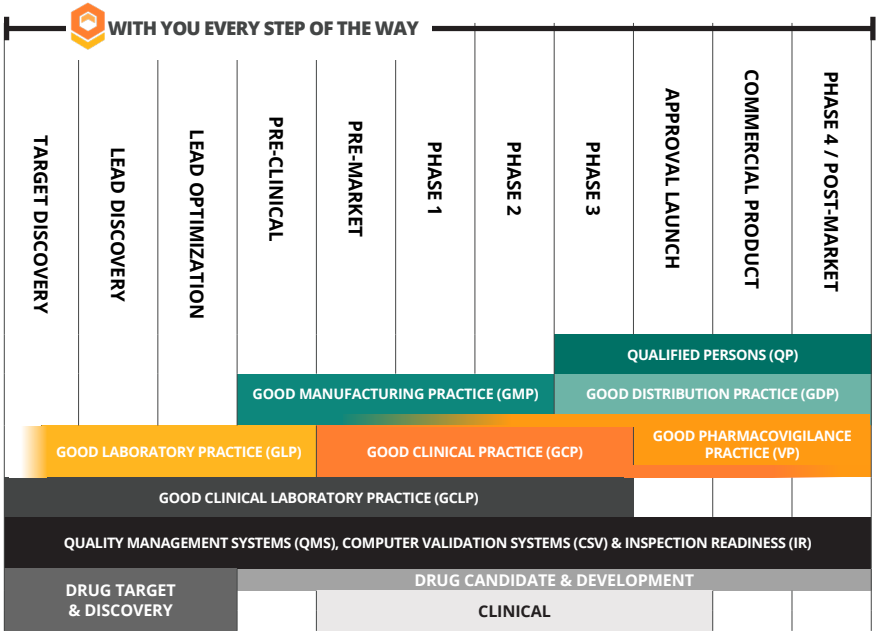
One Stop Shop

Your Path to Regulatory Compliance

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. 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 assessments. We can assist in developing and enhancing quality systems to ensure compliance and operational efficiency.



At FDAQRC, we embody a steadfast commitment to excellence, evident in our exceptional services tailored to enhance your regulatory compliance.

Our most requested offerings include:

GOOD CLINICAL PRACTICE

FDAQRC provides a wide range of services for Good Clinical Practice (GCP) projects in the pharmaceutical and biotech industries. Our employees and our global network of consultants are experienced professionals that can offer comprehensive solutions for Vendor Audits, Investigator Site Audits, For Cause Audits, Mock Pre-Inspection audits and more. Our team is here to ensure your clinical trials reflect the highest standards and industry best practices.

INSPECTION READINESS SERVICES

FDAQRC remains the foremost provider of tailored inspection readiness solutions. Our dedicated team specializes in preparing clients for inspections by FDA, MHRA, EMA, and other health regulatory agencies. Our experts excel in crafting personalized inspection readiness tracks that address each client's specific needs. With a team comprised of former inspector experts, we bring invaluable hands-on experience and regulatory insights. We are fully equipped to support you comprehensively in your preparations for upcoming agency inspections.

GOOD MANUFACTURING PRACTICES

FDAQRC continually showcases our unparalleled expertise in the sphere of Good Manufacturing Practice (GMP). Our GMP service offerings include Mock Pre-Inspection Audits, Vendor Audits, GAP Assessments, CMO Audits, and more. FDAQRC's project managers and auditors are highly qualified to ensure your GMP project processes excel in safety, quality, and consistency.

NEW SERVICES

As we evolve and expand our commitment to serving our clients with excellence, FDAQRC is thrilled to have introduced a few new services over the years that further enhance our comprehensive offerings, including:

REMEDIATION
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.

RECRUITMENT
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.

QUALIFIED PERSON (QP)
A Qualified Person is responsible for final verification of a drug or medical device coming into Europe. Our Qualified Person's Service is dedicated to assisting our clients with regulations, whether they are located in or interested in exportation of commercial biotech or pharmaceutical products to the United Kingdom and European market. FDAQRC provides highly vetted, certified QPs from our office in Europe.

Customize Your Experience

Experience Unparalleled Support

- TAILORED CUSTOMER SERVICE
- PROJECT MANAGEMENT MODEL
- GLOBAL EXPERIENCE & EXPERTISE
- SUPPORTIVE & COLLABORATIVE
- EFFICIENT & COMMUNICATIVE
- HISTORY OF REPEAT CUSTOMERS

At FDAQRC we are pleased to provide you with a tailored customer service experience through our project management model and global expertise.

We take pride in supporting our customers through their specific needs – no matter what stage they are in of their process.

FDAQRC is known for having a strong foundation with a good reputation and returning clientele.

Global Expertise

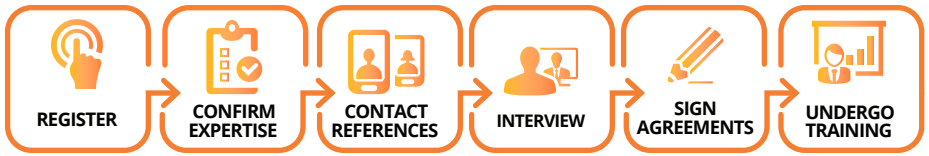
Experts Across all GxPs

FDAQRC proudly boasts a global consultant network, demonstrating our dedication to top-tier service in quality and regulatory. With a decade of experience in 70+ countries, our powerhouse team covers all GxP areas, addressing diverse industry needs.

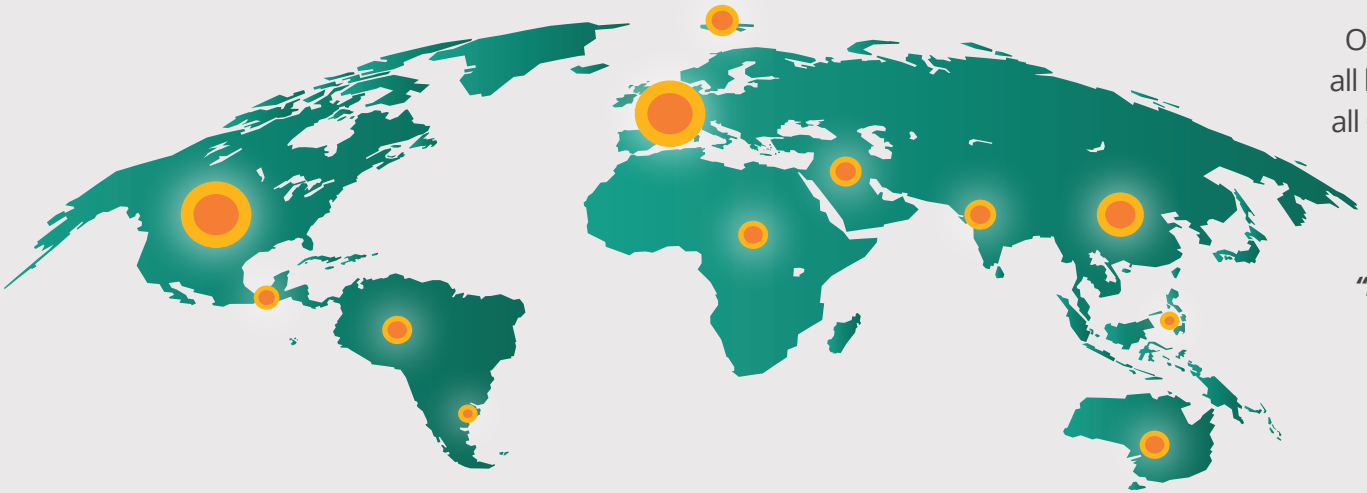
We take great care in selecting highly qualified individuals to join our esteemed network by following our stringent internal requirements for consultants.

- ✓ **Detailed CV & Writing Samples Submission:** Every potential consultant is invited to submit their CV, which must include writing samples. This step offers us valuable insights into their extensive experience and areas of expertise.
- ✓ **Reliable Evaluation and Reference Verification:** Our project management and resourcing team conducts in-depth interviews and reference checks for each consultant before completing the onboarding process.
- ✓ **Individualized Audit Resourcing Approach:** When a client submits a project, our resourcing department carefully reviews our global consultant networks to hand select consultants with the correct expertise and experience for the project. Clients only receive CVs of consultants who best match their project needs and timelines.

CONSULTANT VETTING & ONBOARDING PROCESS



FDAQRC CONSULTANT ASSIGNMENT ASSESSMENT



Over 500 Active Consultants

Our consultants are located in all global regions, and all have 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 offers 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 Drug Information Association (DIA) Global Annual Meeting, Society of Quality Assurance's (SQA) annual conference, Research Quality Assurance (RQA) conference, 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 media (LinkedIn and X) which allows us to stay in touch with our clients and consultants.

Scan here to explore FDAQRC Quick Links, featuring one-click access to our website, social media platforms, a contact form, and more.

FDA|QRC

"We had multiple 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

Since 2009, FDAQRC has completed over 4,500 projects, and we currently have over 500 active consultants worldwide. Due to FDAQRC's reliability and high quality of work, over 70% of our clients continue to bring new projects and requests.

FDAQRC has experienced exponential growth starting in 2020. Our internal team has tripled, and our number of projects has increased by an average of 33.3% each year. To manage this growth, we have promoted several employees to reward their dedication to FDAQRC and are always looking to bring on new talent. Please visit fdaqrc.com/careers to see our open roles.

We look forward to many years of continued growth.

FDA|QRC

Contact

Clients and General Inquires | info@fdaqrc.com

Consulting Opportunities | resourcing@fdaqrc.com

SCAN TO ACCESS FDAQRC QUICK LINKS

One-click access to our website, social medias, contact form and more.