CRQA

Clinical Research Quality Assurance

# Your Partners in GxP

# (GCP, GMP, GLP, GDP, GVP, 21 CFR Part 11)

CRQA
Clinical Research Quality Assurance

# WHAT IS QUALITY?

***"Quality needs to be built into every step of the clinical trials process", insists a leading US Food and Drug Administration (FDA) official.***

- The ICH GCP definition of 'audit' focuses on compliance assessment, and this is also an expectation of the regulatory authorities.

- All regulatory guidelines lay importance to Quality and there is a mention of need of QA in all CT regulations worldwide.

CRQA
Clinical Research Quality Assurance

# IMPORTANCE OF QA

- Quality assurance for clinical studies and pharmacovigilance the world over is a critical function.
- It takes on a greater level of criticality when such studies are conducted in a distant country and pharmacovigilance activities are being outsourced by MAH.
- Used effectively, external audits can reduce costs, maintain project schedules, and ensure regulatory compliance.
- Independent audit of a clinical trial can bring a unbiased perspective and new insights into the study.

CRQA
Clinical Research Quality Assurance

# WHY US?

- CRQA Auditors are independent and not on the payrolls of any CRO of pharmaceutical company.
- CRQA skilled and experienced auditors are able to pick up a minor inconsistency, deduce possible reasons, and then investigates, uncovering root cause (significant underlying issues).
- CRQA Auditors have handled wide exposure of various projects and in depth understanding of how and when things can go wrong.
- CRQA auditor is an out of box thinker as he is not related to any one in the CRO/ Sponsor's group.

CRQA
Clinical Research Quality Assurance

# WHO ARE WE?

- Established in 2010, we provide a full range of quality assurance and audit services for clinical trials, pharmacovigilance and pharma industry in India and several other countries in Asian Region.

- Following each audit, comprehensive and confidential reports and audit certificates are produced according to CRQA standard operating procedures or client specifications.

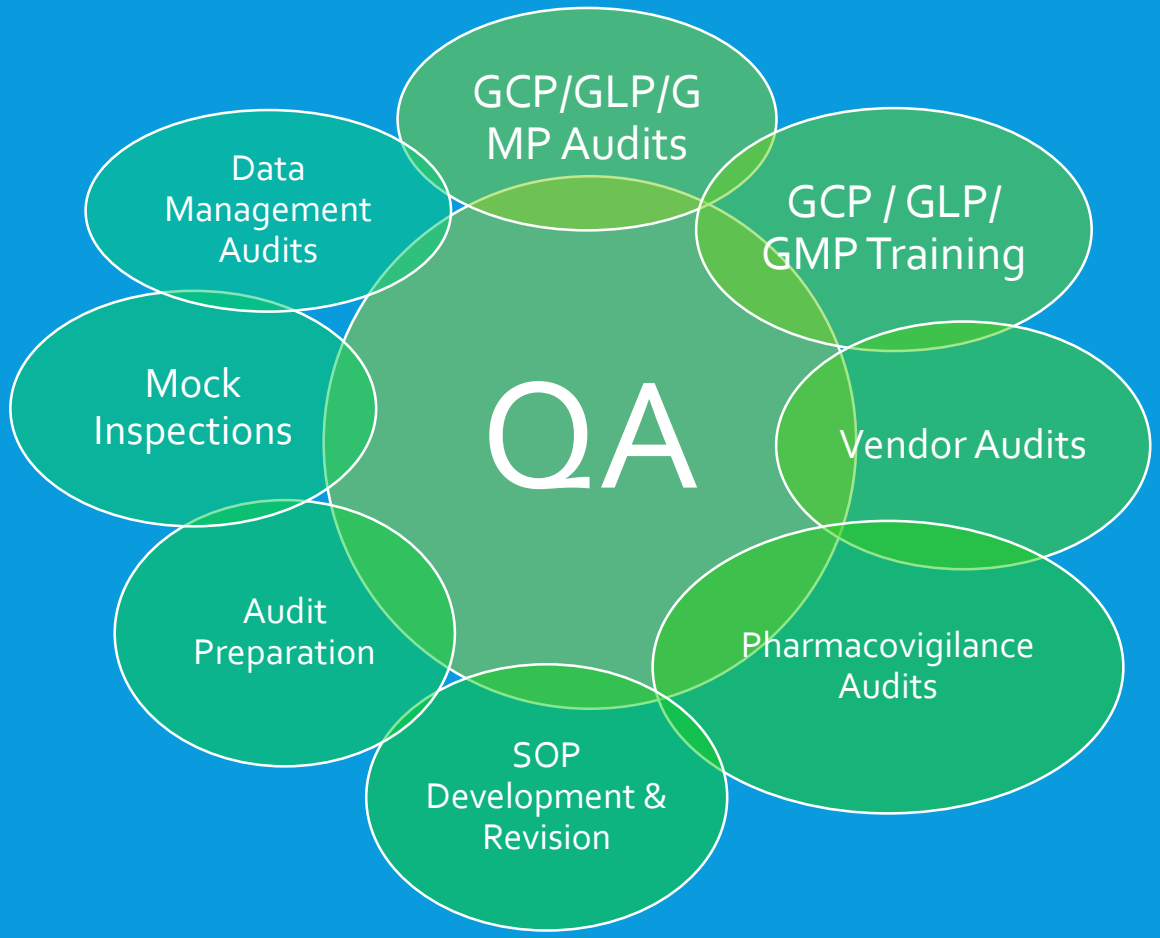
CRQA
Clinical Research Quality Assurance

# OUR AUDITING TEAM

- With over 120+ years of combined Audits experience, our group provides a full range of clinical audits from phase I to phase IV studies, including clinical data management & pharmacovigilance audits, cGMP, GLP on a global basis.
- The team comprises of experienced auditors who have a vast experience in the GxP regulated industry in conducting all types of audits, including GCP, GLP and cGMP.
- The group has gained experience in the audits, monitoring, project management, quality assurance, team building and training of clinical research professionals.
- Experience in setting up QA and Training unit and have prepared many sites for inspections and faced external audits in their career.

CRQA
Clinical Research Quality Assurance

# SERVICES WE OFFER



CRQA
Clinical Research Quality Assurance

# SPECTRUM OF ACTIVITY

| | |
|---|---|
| GCP Audits | • Site, IRB/IEC, Trial Master File Audits, Vendor, CRO. |
| SYSTEM AUDITS | • Vendor evaluation, Data Management, Investigational Product Management, Pharmacovigilance, Biological Samples Management, Ethics Management, Monitoring. |
| GLP AUDITS | • GLP audits of facilities, studies and reports, Assessment of laboratories for compliance with GLP regulations |
| TRAINING : | • GCP Auditing, GCP Certification, Quality Management System (QMS), How to conduct / face an audit, preparing for an audit/ inspection, basic and Advanced monitoring, How to create Audit Tools (audit plan, checklist, agenda, audit report), 21 CFR training etc. |
| SOP Development | • We develop SOPs, update them and also carry out a periodic SOP training of employees as per training matrix with evaluation. |
| GCP CONSULTANCY | • Advice on GCP issues and assist our clients in developing a quality strategy to minimize non-compliance. |

CRQA
Clinical Research Quality Assurance

# GCP AUDITSAUDITS

- **GCP AUDITS:**
  - **Investigator Sites,** IRB/IEC, Document Audits, Vendor, CRO (Phase I and/or BA/BE units)
  - For Cause Audits
- **Vendor Audits:**
  - Contract Research Organization Qualification Audits
  - Central Laboratory Audits
  - Clinical Trial Supply Audits
  - Independent Ethics Committee Audits
- **Clinical Data Management & Biostatistics Audits**

CRQA
Clinical Research Quality Assurance

# PHARMACOVIGILANCE AUDITS

- Global Pharmacovigilance audit
- MAH audit
- QPPV audit
- Company affiliates audit
- Business partner/Marketing partner audit
- Vendor/Service provider audit (Literature search, Case processing Unit, Translations, Vendor (PSUR/PABER/RMP/ADCO, etc.)
- Inspection/audit readiness

CRQA
Clinical Research Quality Assurance

# DATA MANAGEMENT AUDITS

- The audit program is designed to cover various aspects of clinical data management activities:

  -Database Set-up Audits
  -Data Management In-Trial Audits
  -Database Lock Audits
  -Process Audits
  -Biostatistics Audits

CRQA
Clinical Research Quality Assurance

# TRAININGS ON AUDITS AND REGULATORY INSPECTIONS

- CRQA provides training on audit preparedness for audits / inspections by sponsors and regulatory agencies.
- CRQA provides end to end training to the Clinical Data Management staff so that the Quality issues can be minimized.
- CRQA provides training to manage the Quality Issues and supports in Root Cause Analysis.

CRQA
Clinical Research Quality Assurance

# BA / BE

- Systems & Study Audits
- Bioanalytical Audits
- Study Monitoring
- Medical Monitoring

CRQA
Clinical Research Quality Assurance

# MOCK INSPECTIONS

- FDA, EMEA and now Indian regulatory authorities have made it mandatory to conduct clinical trial inspections for all the trials. With the latest development, not only sites, but Independent Ethics Committees, sponsors and CROs also have a high possibility of getting inspected.
- For you to handle inspections successfully, we are there to assist you.
- We shall make your site ready to face audits / inspections, handle findings and help you respond to the same in the best possible efficient manner.

CRQA
Clinical Research Quality Assurance

# SOPs REVIEW & DEVELOPMENT

- SOPs play a crucial role in Quality Assurance and it is therefore essential that they are understood and followed by all end-users.
- CRQA Services: SOP Writing, Training Matrix, Revision and Update.
- In a nut shell, we shall manage your SOPs completely.

CRQA
Clinical Research Quality Assurance

# PHARMA QUALITY MANAGEMENT SERVICES

- **Site Quality Audit Services** - This service will include Pre, Post or Regular Quality system audit of a site for the suitability of manufacturing & Testing/Release of the product at this site. This will generate a comprehensive report of the Audit covering the different critical functions performed at the site like, Stores, Quality control, Production, Stability Protocol/ Facility, Personnel Training, Equipment Maintenance, etc. functions to ensure the Quality Compliance of site towards manufacture & Testing / Release of the product from the site for sales.
- This Quality Audit of the Site will ensure compliance of each of the manufactured batch at the site and hence will save cost of recall & destruction of a non-compliant/ failed batch of product, cost of investigation and trouble shooting of the complaints, cost of losing image of the brand/Company.

CRQA
Clinical Research Quality Assurance

- **Product Registration Dossier Management -** PQMS will take up complete responsibility of Registration Dossier preparation, submission and query handling as per the Client needs and Formats. This will include CTD, Non-CTD, ACTD, any other format.
- **Independent Quality Audits (IQA)** – PQMS will carry out in-depth audit of the Quality control Laboratory function to help you receive various regulatory authorities Compliance.
- **Quality Document Management (QDM)** – PQMS can on-line Prepare & Review all Quality Documents like Batch Manufacturing & Packing records, Validation Protocols/ Reports, Stability Studies Report/Data compilation, any other Summary/ Report preparation as per your needs to significantly reduce your cost & time towards these mandatory regulatory tasks.

CRQA
Clinical Research Quality Assurance

- **Training** - Training to your people on any Quality topic as per your Training Calendar and Training Matter. This service will save your valuable Resources/Time towards Regulatory Compliance towards the Employee Training requirements. PQMS can take up Annual / Long-Term Contract for this Service.
- **cGMP workshops Organize workshops on cGMP** - This platform will offer a tailored training to your employees, which will be need based training and will target an Employee's job responsibilities

CRQA
Clinical Research Quality Assurance

# GMP SERVICES

- As a GMP consultant, help pharmaceuticals, health supplement, feed supplement, API, ayurvedic, and packing material companies develop and strengthen systems to achieve Good Manufacturing practices (GMP) compliance.
- GMP consultant for existing setup by analysing the gaps, fixing the gaps, training for continues improvement and follow-up.
- Supplier quality GMP audits for pharma/medical device industries, providing subject matter expertise, as well a focus in area deem as critical. Its include API, Raw materials, Packing materials, input devices etc.
- GMP Quality Inspection- auditing the facility quality system, validations and practices in accordance with cGMP norms, compile the report and recommendation.
- Follow-up audit on CAPAs and closed-out.

CRQA
Clinical Research Quality Assurance

# 21 CFR PART 11

## Compliance Training on 21 CFR Part 11

- At CRQA, we not only provide the highest quality compliance services, but we can also train your teams to proactively deal with compliance issues. Training can be conducted on-site, through WEBEx or at designated training centers. Participants will receive a Certificate of Training in 21 CFR Part 11, good for satisfying GxP training requirements.
- CRQA has conducted training sessions on several topics, including preparing for USFDA CSV Inspections, Automating CSV Processes, and 21 CFR Part 11 Compliance and Validation for Databases and Spreadsheets. CRQA can create or customize any training program to meet your needs. CRQA can provide any level of service, from teaching a single course to creating and managing your training department.

CRQA
Clinical Research Quality Assurance

# 21 CFR PART 11

## Part 11 Assessments and Compliance Assessments

- Part 11 Assessment are the first steps to controlling your systems. As the USFDA increases regulatory enforcement of 21 CFR 11, one of the most challenging issue for many companies is to know what technological and procedural controls their computer systems require in order to be in compliance.
- CRQA can assess all of your software, databases, and computer systems and identify what issues need to be addressed for compliance. Good control over your systems would allow you to expand your markets in the pharma industry.

CRQA
Clinical Research Quality Assurance

# COMPUTER SYSTEM VALIDATION

- Concept business development
- Planning & scoping
- Requirements & design
- Build
- Test
- Deploy
- Risk assessment level
- GAMP5 – CSV Framework for a configured product
- Audits & Inspections preparedness

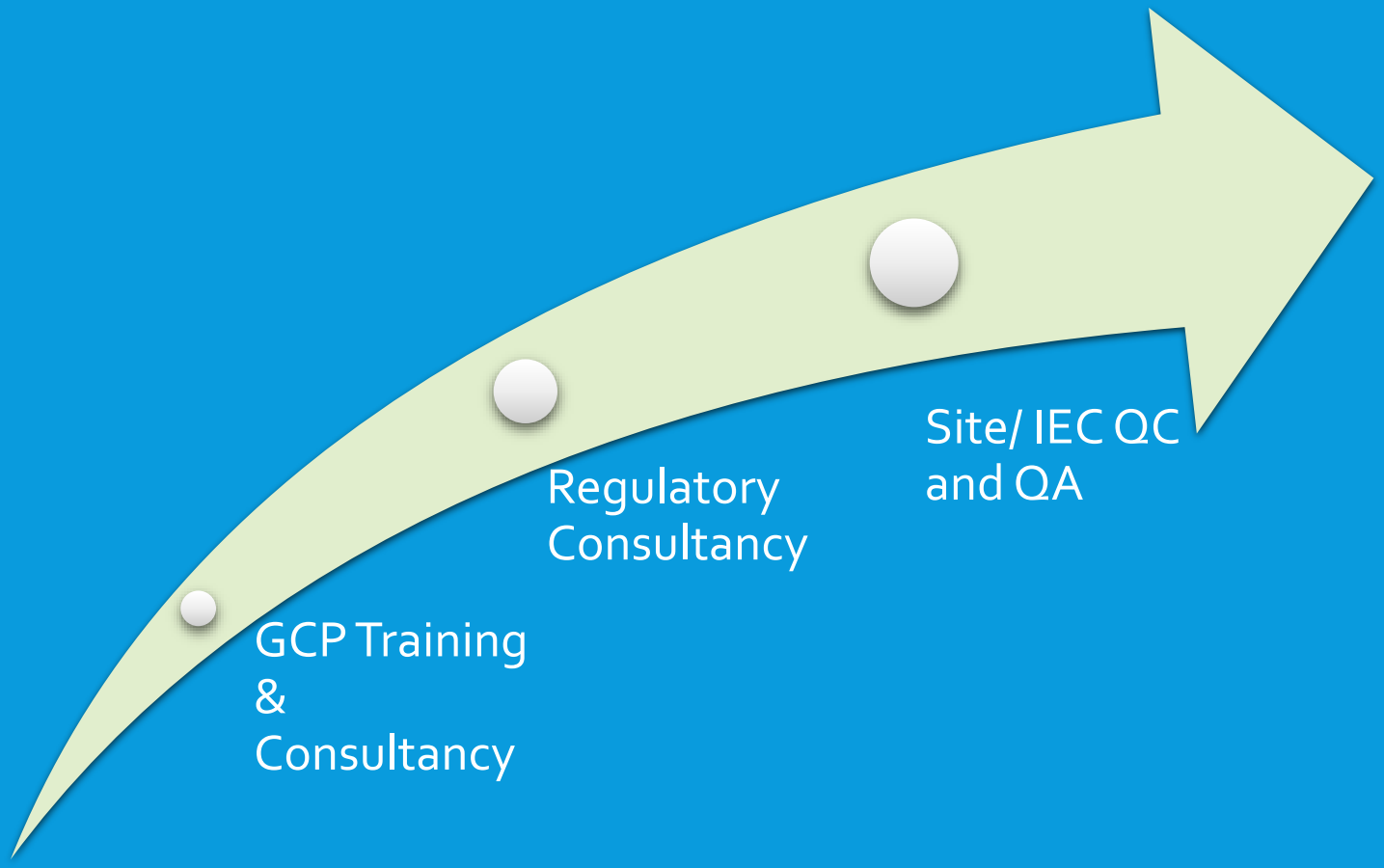
CRQA
Clinical Research Quality Assurance

# REGULATORY AFFAIRS SERVICES

- Review of client technical dossiers and developmental plans
- Research and interpretation of applicable local regulations
- Determination of regulatory status
- Review and support of manufacturing/GMP issues
- Pre-submission review of technical documents
- Critical writing and review of documentation
- Clinical trial applications and notifications
- Marketing Application Support

CRQA
Clinical Research Quality Assurance

# ADDITIONAL CAPABILITIES



CRQA
Clinical Research Quality Assurance

# GCP TRAINING BASIC & ADVANCED

- ICH GCP
- Indian GCP
- Regulations – FDA, EMA & Indian New Drugs & Clinical Trial Rules, 2019
- Ethical Considerations
- Roles & Responsibilities of Stakeholders
- Essential Documents
- Subject Recruitment & Retention
- Drug Safety Reporting
- Sponsor Audits
- Regulatory Inspections
- EC Accreditation

CRQA
Clinical Research Quality Assurance

# WHY CRQA?

- Strong experience in working with global organisations
- Head quartered in New Delhi NCR, India, with strong team of GxP qualified and experienced auditors with network of auditors in all major cities in India and other parts of the world.
- We have best pool of quality assurance professionals.
- Time & Lower Costs – we provide solutions at quicker turn around time and lower costs.
- Skilled and experienced auditors are able to pick up a minor inconsistency, deduce possible reasons, and then investigates, uncovering root cause (significant underlying issues).
- Out of box independent thinker and not related to any one in the CRO/ Sponsor's group.

CRQA
Clinical Research Quality Assurance

# KEY CLIENTS

- Our client list includes leading pharmaceutical and medical device companies, CROs, healthcare groups, healthcare NGOs, hospitals and healthcare consumer product companies.

- Client references would be provided upon request.

Thank you for your time and looking forward to hear from you


CRQA

C-101, First Floor,

Sector 2, NOIDA 201301, U.P. , India

www.crqa.in

bd@crqa.in

Mobile : +91 98100 68241