SOHAM KELA

O-602 Aarohi Crest
Gala Gymkhana Road,
South Bopal,
Ahmedabad – 380058
Gujarat – India

Phone No.: +91-9737815593
sohamkela93@gmail.com

CAREER OBJECTIVE:

- Looking for a challenging career, where I can contribute my experience, my knowledge and my skills for the growth of an organization, team and self and gives an opportunity for better learning and to excel as a leader.

PROFESSIONAL EXPERIENCES

Department- Quality Assurance
Executive- Lambda Therapeutic Research Pvt. 24th May 2021 To continue

- Online QA Monitoring of study related as per the approved project specific plan, verify that the research team follows the approved protocol, amendment if any applicable SOPs.
- ICF process online monitoring & its back up verification.
- Review 20% study raw data generated & ensure that all the study documents are accurate, complete, timely and legible and submission of documents to QA in respected timeline.
- Preparation of QA reviews reports and co-ordination with the clinical for the timely response.
- Maintain up to date self-trainings and training records.
- Verification of staff training file and medical reports.
- Preparation and review of applicable SOPs.
- To perform QA activities according to the SOPs and applicable regulations.
- To take the guidance from reporting authority as per requirements.
- Assist RDH in taking appropriate action design to prevent recurrence of detected deviations.
- QA check of all the logbooks regarding project specific activities.
- TMF review
- MSR Audit
- IMP verification
- System Audit
- Vendor Audit
- Clinical Lab
- Clinical Study Report

Department- Quality Assurance
Senior Quality Control Executive, Synchron Research Centre December 2018 to 13th May 2021

QA Clinical:

- Online QA Monitoring of study related as per the approved project specific plan, verify that the research team follows the approved protocol, amendment if any applicable SOPs.
- ICF process online monitoring & its back up verification.
- Review 100% study raw data generated & ensure that all the study documents are accurate, complete, timely and legible and submission of documents to QA in respected timeline.

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- Assist RDH to monitor that site is prepared for conduction of trial.
- Preparation of QA reviews reports and co-ordination with the clinical for the timely response.
- Review the responses received for QA review observations and ensure the compliance.
- Communication with RDH regarding QA review findings and response.
- Maintenance of master list of instruments and generate instrument ID to new instrument.
- Tracking, review & Maintenance of calibration schedule records.
- Perform QA check of routine Maintenance of equipment's at clinical site.
- Maintain up to date self-trainings and training records.
- Training to QA & Clinical department staff members as and when required
- Verification of staff training file and medical reports.
- Assist to co-ordinate with QMS regarding generation and control of documents like ICFs, screening and study CRFs.
- Provide specific documents accountability to QMS requisition, labelling and distribution and archiving of logbooks.
- Preparation and review of applicable SOPs.
- To perform QA activities according to the SOPs and applicable regulations.
- To take the guidance from reporting authority as per requirements.
- Assist RDH in taking appropriate action design to prevent recurrence of detected deviations.
- QA check of all the logbooks regarding project specific activities.
- Handling the Audit of sponsor, monitors of clinical facilities and provide the documents as per the requirements.

QA (Bio Metrics and Data Management) (BDM)

- To ensure that the study documents like protocol and CRF, BSS, amendment for clinical studies are accurate and precise.
- Cross check and verification of translation of all required documents.
- QA check of randomization schedule
- QA check of Blood sampling sheet.
- QA check of clinical listings.
- QA check of final report and eCTD format of the final report.

Research Assistant, Lambda Research Therapeutic — May 2018 to December 2018

- Perform online quality checks of generated documents
- To monitor study related activities
- To perform Internal system audits
- ICD and Database audit of Daily work timeline.
- Co-ordinate with CPMA, Pharmacy, Screening for query resolution.
- Dispensing the drug in Pharmacy department and maintain the logbook entries.

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- Audit of raw data in MSR as per project timeline.

Research Officer, Accutest Research Lab, PVT October 2016 to May 2018

- Audit the Trail Master File of the project before initiation of the study.
- Audit the labels of sample separation.
- Online Document review of ICF and to send the observations to CRA department.
- As per sponsor requirement, to review and check all the activities related to dosing like.
- Monitoring study related activities
- Perform retrospective audit of ICF, Screening CRFs, TMF.
- Response and tracking of QA observation

EDUCATION:

MBA in Healthcare Management, **Pursuing**
Narsee Monjee Institute of Management Studies (NMIMS)

Bachelor of Pharmacy, Pharmacy, May 2016 **6.5 Credits**
K B Institute of Pharmaceutical Education and Research, Gandhinagar, Gujarat

TECHNICAL SKILLS

- Extensive knowledge of Microsoft Office
- Adobe Acrobat Software
- Excel
- Microsoft Word
- Power Point

STRENGTH

- Continuous desire to gain knowledge
- Integrity
- Adjusting Nature
- Strong Will Power
- Team Leader

ACHIVEMENTS

- 2nd prize in the dance competition held at college
- 3rd prize in table tennis tournament held at college
- Appeared in newspaper for social activity

CO-CURRICULAR ACTIVITIES:

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- State level Table Tennis Player
- Freelancer Photographer
- CEO at Muzistaan Production

SOCIAL SERVICE

MADAD TAMARI SEVA AMARI (Seva Foundation)

DECLARATION

I hereby declare that all statements made in this resume are true, complete and best of my knowledge and belief.

Soham Pratapkumar Kela