Title: GLP/GMP and QC services towards pharmaceutical and biotechnological industries

Dear colleagues,

On the subject of one of essential EMGEN aims towards creating and sustaining value by being recognized as a player in the international biopharmaceutical, genomics and biotechnological industry aiming at promoting health in the region as well as developing industrial liaison concepts based on EMGEN objectives, we would be pleased to announce you that a professional team consisting of key relevant scientists and professors in addition to brilliant experts from industrial sectors in the field of QC and GLP/GMP issues have been arranged and developed in the frame of EMGEN industrial liaison section as attached items. In this regard, the possibility of establishing related webinars, electronic workshops, applied workshop in Iran and other EMRO countries as well as relevant professional inspecting and consulting services are available based on your request in the framework of official agreements. Please kindly send your application regarding the mentioned aspects to EMHGBN@gmail.com to progress further stages.

Kind regards,
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GMP/GLP inspection services and training include the following: 1. Train, equip and prepare to get GMP/GLP certification and 2. Performing pre-inspection procedure and supervising entire relevant concepts towards achieving regional and international certificates, in the frame of:

Concepts of GMP/GLP	
Test facility organization and personnel in addition to Quality Assurance (QA) program	➢ Study director ➢ Responsibilities of the QA personnel ➢ Standard Operating Procedures (SOPs) ➢ Test facility means ➢ Sponsor means a person(s)
Facilities	➢ Test system facilities

	➢ Facilities for handling test and reference substances ➢ Archive facilities ➢ Waste disposal
Apparatus, materials and reagents	➢ Suitably locating ➢ Appropriate designing ➢ Adequate capacity ➢ Inspecting ➢ Cleaning ➢ Maintain ➢ Calibrating ➢ Not interfering ➢ Labeling ➢ Indicating ➢ Identity ➢ Concentrating ➢ Complete information managing
Test systems	➢ Physical ➢ Chemical ➢ Biological
Study	➢ Study means ➢ Study plan means ➢ Test system means ➢ Raw data means ➢ Specimen means
Test and reference substances	➢ Receipt, handling, Sampling and storage characterization for test substance means, reference substance (control substance) means , batch, vehicle (carrier) means and sample means
Standard operating procedures	➢ Test and Reference Substance Receipt, identification, labeling, handling, sampling, and storage ➢ Apparatus and Reagents ➢ Use, maintenance, cleaning, calibration of measuring apparatus and environmental control equipment; preparation of reagents ➢ Record Keeping, Reporting, Storage, and Retrieval Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerized data systems ➢ Test system (where appropriate) ➢ Room preparation and environmental room conditions for the test system ➢ Procedures for receipt, transfer, proper placement, characterization, identification and care of test system

	➢ Test system preparation, observations examinations, before, during and at termination of the study ➢ Handling of test system individuals found moribund or dead during the study ➢ Collection, identification and handling of specimens including necropsy and histopathology ➢ Quality Assurance Procedures Operation of quality assurance personnel in performing and reporting study audits, inspections, and final study report reviews ➢ Health and Safety Precautions. As required by national and/or international legislation or guideline
Performance of the study and reporting of study results	➢ Content of the Study Plan and Final Report ➢ Conduct of the Study Plan and Final Report
Storage , retention of records and materials	➢ The study plan, raw data, samples, specimens, and the final report of each study ➢ Summary of qualifications, training, experience and job descriptions of personnel ➢ Records and reports ➢ The historical file of Standard Operating Procedures. ➢ Preparation permits evaluation ➢ Samples and specimens ➢ Material indexing and archiving ➢ Considering confidential items

Training applied concepts as well as relevant key points regarding research applications in QC:

I. Elaborating, defining and refining quality specifications and appropriate analytical testing methods
II. Compiling the specifications for new chemical entities (NCEs) and drug products (DPs) containing compounds that are based closely on pharmacopeial monographs
III. Discovering new and applied fields of quality characterization to be established and applied for marketed drugs
IV. Developing industrial analytical techniques, modern biochemical and biological methods
V. Investigating developed applicable concepts on stability data, validation of analytical work, impurities, biotechnological quality and specifications for market and development products
VI. Updating Common Technical Document (CTD), defining the scope (but not the content) of a global dossier for Chemistry, Manufacturing, Control (CMC)
VII. Discovering new approaches in direction of translating good manufacturing practice (GMP) principles into daily practice in addition to finding applied ways of research and development (R&D)

VIII. Finding applied concepts in the fields of pharmaceutical management and organization theory, supervision theory, leadership traits, behavior science and introduction to project management

IX. Investigating recent approaches in quality improvement of analytical laboratories, laboratory health and safety, identification and evaluation of hazards, chemical hygiene programs, waste management, GMP regulations and auditing

- **Theoretical and practical training of computer based applications in QC and data analysis:**

I. Finding recent approaches for documentation in all areas of QC requires

II. Improving state-of-the-art laboratory information management system (LIMS)

III. Expanding concepts of a paperless laboratory

IV. Developing strategies on industrial harmonisation of approaches to serve pharmaceutical market

V. Applying new concept – chip technology in pharmaceutical industries

VI. Expanding closer analytical networking within drug manufacturing companies

VII. Advanced biostatistics

VIII. Instrumental analysis based on computational approches

IX. Designing and performing statistical process control, quality control charts, process capability analysis, acceptance sampling plans and military standards