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KINGSMANN CONSULTANCY SERVICES

Thank you for taking interest in Kingsmann Consultancy Services. Kingsmann Consultancy (KC) is a leading business development-consulting firm serving the pharmaceutical, biotechnology, and medical device sectors worldwide.

KC is the top choice by many pharma and biotech companies for our consistency in delivering high quality, actionable business insight, and competitive intelligence.

It is our mission to help our pharma and biotech clients rapidly formulate winning strategies and tactics by providing the industry's most accurate business intelligence and market insight.

KC's expert team includes an extensive in-house staff: MDs, pharmacists, QPs, Ex MHRA Inspectors, auditors, nurses, scientists, and senior marketing and sales professionals.

KC's team is our client's competitive advantage, with contacts throughout Europe, Asia, and Africa thus our team is better able to serve our client's needs.

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MEET OUR EXECUTIVE STAFF

Colin Anthony Chambers – President & Co-Founder

Colin Chambers is a naturally outgoing ambitious quality professional with over 20 years of experience gained within the Pharmaceutical industry in manufacturing, research and clinical research arena. His excellent problem solving abilities are complimented by his proven track record of both managing and resolving technical problems.

Colin is a highly enthusiastic and self-motivated individual with excellent leadership skills. Completed qualified person training modules with David Begg and is an EU Qualified Person under the permanent provisions. Performed manufacturing audits, auditing to FDA CFR 210/ 211 and EU GMP regulations. Manufacturing oversight for US clinical studies, audited API and finished product manufacturers in the US (Boston and Spokane). Performed GMP gap analysis for US monograph products and has participated in several MHRA and FDA site inspections.

He has worked in many major and global pharmaceutical companies to ensure that all products have been manufactured in compliance with the EU marketing and manufacturing authorizations and with cGMP compliance. Perform duties in line with the Code of Practice for qualified persons in the pharmaceutical industry. Ensure that all principal manufacturing, packaging and testing processes have been validated. Assure the development, approval and implementation of standards, procedures and systems to maintain an effective and compliant quality management system. Assure the development, approval and implementation of standards, procedures and systems to maintain an effective and compliant quality management system.

Dr Naeem Khan – Technical Director & Co –Founder

Has extensive experience in pharmaceuticals. He has acted as a Consultant to various national and international pharmaceutical companies.

Experience Setting up of new Pharmaceutical Manufacturing facilities, development of QMS procedures, SMF, validation protocols Quality control procedures, contract manufacture documentation including technical agreements.

Set up API Plant to manufacture Paracetamol and Aspirin. Acted as consultant to API and other chemical manufacturers. Prepared feasibility reports, on various Pharmaceutical and chemical projects. Set up projects such as manufacture of Starch, Oral Glucose and Glucose Monohydrate from Rice, Carboxy Methyl Cellulose from cotton waste, extraction of Mint oil

and production of Menthol, extraction of essential oils such as Eucalyptus oil, Basil Oil and Rose Oil. Recovery of chemicals such as Methyl Chavicol from Basil Oil.

Acquired 56 Marketing authorisations in the UK and 32 Marketing authorisations in Holland for a UK company as well as acquisition and management of MHRA approved manufacturing unit.

Regulatory and GMP compliance of WDL, QMS and GMP compliance of manufacturing unit, Pharmacovigilance and other regulatory work relating to MEB and MHRA. Selection and audits of Drug Product and Drug Substance (API) manufacturers in India, China and other countries. Audit of CRO and management of BE study on Ibuprofen Suspension in India.

Managed three drug product manufacturers, from site transfer application through to MHRA GMP certification.

Developed Quality Management system, SOPs and other documentation, raw material procurement, production of batches, contract manufacture and other matters associated with a manufacturing unit for UK Pharmaceutical companies through to MHRA GMP certification.

Developed Quality Management System including SOPs, Validation Master Plan for a Canadian Veterinary Pharmaceutical company in preparation for Veterinary Medicine Directorate's GMP inspection. Based on the GMP compliance work, the company was granted GMP status. Have so far conducted over 80 compliance audits consisting of API manufacturers, Drug product manufacturers, Contract Laboratories, CRO and Surgical Instruments manufacturer. All audit reports approved by EU QP.

Miss Katie McLoughlin – Head of Regulatory Affairs

Katie has 10 years' experience working within the Pharmaceutical and Nutraceutical industry. Areas of expertise include Quality Control, Quality Assurance and Regulatory Affairs; ensuring GMP/GDP/GLP compliance. Katie has extensive experience working as the quality contact in tablet manufacturing for food supplements, traditional herbal medicines and veterinary medicines. Katie has developed and managed quality management systems and has been involved in numerous MHRA and FDA audits. She has established and maintained Product Licences for import and wholesale distribution; working closely with customers and regulatory authorities both in the U.K and internationally.

Mr Numair Khan – Head of Pharmacovigilance

A Good Clinical Practice certified, UK registered pharmacist. His wealth of experience covers Quality Assurance, Pharmacovigilance and regulatory affairs, the duties and scope of responsibilities include setting up, maintenance and the management of pharmacovigilance system, also developing and maintaining artwork for a company holding 36 UK marketing authorisations. He has been extensive involved with manufacturers in Oman, China and India, to ensure all products manufacturing and packaging are in line with marketing authorisation. He has established quality management system of company holding 20 licenses and overlooking responsible person activities for a major pharmaceutical company. He has been involved in preapproval inspection and gap analysis prior to the inspection by the regulatory agency.

OUR SERVICES

KC offers cost-effective solutions to the rapidly changing arena of Good Manufacturing and Good Distribution Practice.

ICH Q10 demonstrates industry and regulatory authorities' support of an effective pharmaceutical quality system to enhance the quality and availability of medicines around the world in the interest of public health. Implementation of ICH Q10 throughout the product lifecycle should facilitate *innovation* and *continual improvement* and strengthen the link between pharmaceutical development and manufacturing activities.

KC can deliver services across the whole product lifecycle including:

- Dossier Preparation and Review
- Acquisition of Marketing Authorisations
- Setup of GMP compliant facilities.
- Setting up quality systems and Standard Operating Procedures
- Auditing API, Medicinal Product manufacturers and Clinical Trial facilities for compliance with GMP
- Drawing up Technical Agreements with each contractor
- Good Manufacturing Practice documentation reviews
- Ongoing project reviews and problem solving
- Pre-inspection of facilities and GMP evaluation to regulatory agency FDA / MHRA standards with remedial plans
- Facility Design

QP Services:

- Batch release
- Audits
- Inspections

Quality Validation activities

- Facility Commissioning; Qualification, Validation
- Cleaning Validation
- Process Validation
- Computer systems and software validation
- Equipment validation

Quality Training

- We can provide tailored focused training to motivate and improve staff performance that is critical to a company's success and meets the professional development requirements of individuals.

Preparation and setting up of procedures and systems for MHRA, EU and FDA approval:

- KC can provide a pre-approval inspection or mock inspection and gap analysis prior to the inspection by the regulatory agency. Our team of auditors have experience of over 80 regulatory inspections undertaken by MHRA and FDA.

Pharmacovigilance support:

- Setting up quality systems to fulfil Marketing Authorisation Holders Pharmacovigilance obligations
- Weekly literature searching to identify potential adverse events related to Marketing Authorisation Holders products
- Collation, assessment, follow-up and reporting of spontaneous adverse reactions received by the Marketing Authorisation Holder
- Review of ASPRs
- Safety reviews
- Appropriate Qualified Person and Deputy Qualified Person for Pharmacovigilance including 24-hour cover

KC provides an advice and support service in relation to GxP requirements across the product lifecycle, from pharmaceutical product development to market and beyond for all pharmaceutical product types.

As the European Regulatory Authorities have accepted the use of 'third party audits' then through the use of our services we can ensure you will comply with your obligations under Article 46(f) of Directive 2001/83/EC. We can provide a customised audit report detailing all of the information required by your company's QP to facilitate a "Declaration of GMP Compliance" for your API suppliers and disposition of drug product, or provide the API QP Declaration on your behalf.

Wherever possible, confidentiality permitting, we would also consider the possibility for sharing audit reports to keep costs to a minimum.

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