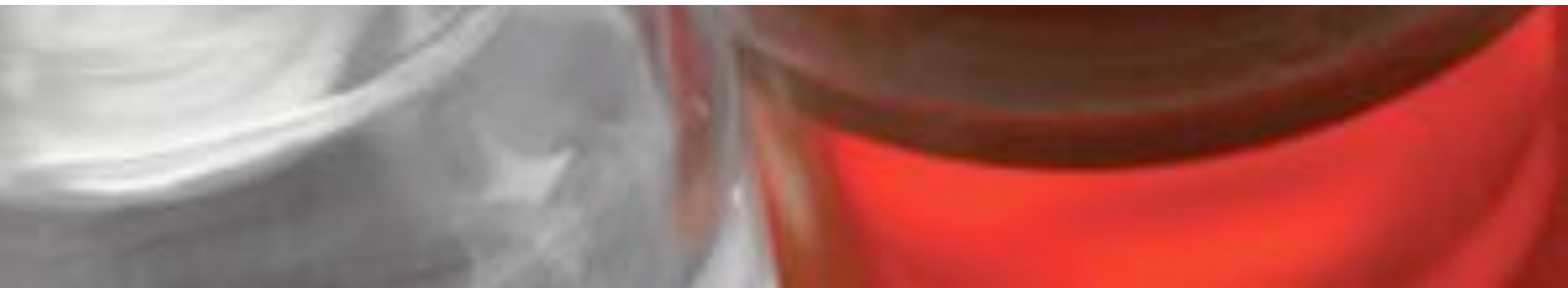
Excellence in pharma regulatory compliance

mcgee | pharma INTERNATIONAL



Welcome to McGee Pharma International where we value our clients as colleagues and work with them to achieve excellence in pharma regulatory compliance in the interest of public health and well-being.

Your partners in compliance

Contents

Compliance with Performance

At McGee Pharma International we focus on delivering complete peace of mind and regulatory compliance for the pharmaceutical industry, optimising performance in compliance with regulation and time and cost efficiencies including waste minimisation, brand reputation management and overall business performance.

We combine an extensive body of knowledge on regulations pertaining to the Pharmaceutical and Healthcare allied sectors with a unique business sense for delivering our service to the industry – delivering the right service for compliance and also excelling and achieving optimum performance in the delivery of the service.

History

Founded in 2004, we have over 100 years of experience in the area of pharmaceutical quality and regulatory compliance between our team of consultants and associates, which includes a number of former regulators. We engage our complementary skillsets to ensure a truly personal and customised experience for you, our client, supporting the needs of your team to attain and sustain regulatory compliance. We service an international client base working on projects across the globe, providing an expert perspective on both EU & US regulatory compliance.

Contact

We welcome all comments and feedback from our clients and would be delighted to hear from you.

We can be contacted at **info@mcgeepharma.com** or +353 1 846 4742

Ann McGee
Managing Director
and Principal Consultant

Stephen Smyth
HR & Operations Director

Personal and customised experience
for each client

GxP Services

We deliver our services across the product lifecycle from development through to discontinuation.

This facilitates innovation and continual improvement, and strengthens the link between pharmaceutical development and manufacturing activities (ICH Q10).

GLP
Good Laboratory Practice

GCP
Good Clinical Practice

GMP
Good Manufacturing Practice
including Good Practice for Tissues and Cells (GP)
and Good Engineering Practice (GEP)

GDP
Good Distribution Practice

MAH
Market Authorisation Holder compliance

GPvP
Good Pharmacovigilance Practice

GBP
Good Behavioural Practice

GPP
Good Pharmacy Practice

All product types are covered – including:

- Human and veterinary medicines
- Sterile (small and large molecules)
- Non-sterile (tablets, capsules, semisolids and liquids)
- API (Active Pharmaceutical Ingredient) (small and large molecules)
- Investigational Medicinal Products (IMPs)
- Blood products
- Tissue and cell based products
- Traditional herbal products
- Food supplements

Service	GLP	GCP	GMP	GDP	MAH	GPvP	GEP	GBP	GP	GPP
Mock Inspection/Audit Readiness	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Self inspection	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pharmaceutical Quality System design and improvement	✓	✓	✓	✓	✓	✓			✓	✓
Process understanding	✓		✓	✓					✓	
Consultative Advice	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Facility Design	✓		✓	✓			✓		✓	
Quality Management	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Quality Risk Management	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Vendor management & Evaluation	✓	✓	✓	✓	✓	✓	✓		✓	
Quality & Technical Agreements	✓	✓	✓	✓	✓	✓	✓	✓	✓	
Quality & Compliance support for Technology Transfer	✓		✓				✓			
Quality & Compliance in Process Validation	✓		✓				✓			
Quality & Compliance in Cleaning Validation	✓		✓							
Quality & Compliance support for Analytical Method Validation and Equipment Qualification	✓		✓				✓			
Training	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Managing change	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Measuring ROI	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Demystifying legislation	✓	✓	✓	✓	✓	✓	✓		✓	✓
Expert Opinion in Legal Cases	✓	✓	✓	✓	✓	✓			✓	✓
QP and RP services			✓	✓	✓	✓			✓	
Help Desk	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Key Services

Permanent Inspection Readiness

Aiming for Permanent Inspection Readiness (PIR)? We can assist you by:

- Reviewing the status of your open Deviation Investigations and working with you to close them out in an effective and compliant manner
- Reviewing your open Change Control proposals and assisting you in their approval, execution and close out
- Reviewing your CAPA log and assisting in management of the implementation of Corrective and Preventive Actions
- Reviewing your calibration and preventive maintenance programmes and record keeping to ensure they are up to date and ready for inspection
- Carrying out regular quick 'snapshot' GMP audits, raising and addressing GMP non compliances in 'real time' to ensure on-going PIR
- Participating in your self inspection programme, bringing fresh eyes to your inspection process and assisting you in completing audits as per your audit schedule
- Close out of external audit and inspection observations
- Working with you to bring your GMP training programme up to date
- Providing training for your SMEs (subject matter experts) so they are ready at all times to interact with a regulatory inspector

Mock Regulatory Auditing

The pharmaceutical regulatory environment is constantly evolving and the pharmaceutical & allied healthcare sectors must ensure compliance with the most current legislation and best practice standards. Aiming for 'inspection readiness' at all times is essential.

We can assist you by:

- Conducting mock regulatory inspections in all areas of best practice (GxP), taking a risk based approach in accordance with ICH Q9
- We will provide guidance on remediation activities in areas of GxP non-compliance, working with you to implement effective remedial action. This will give you an opportunity to rectify any regulatory compliance issues before they are observed by the inspector
- Training personnel on how to prepare for a successful regulatory inspection, including advice on the behavioural aspects, and mock inspection interviews with SMEs, including the 'Do's and Don'ts' of hosting and interacting with regulatory bodies

GxP Remediation & Improvement

Compliance with regulatory and best practice standards is a requirement for business continuity in the pharmaceutical sector. Legislation and best practice standards are continually evolving and regulators worldwide expect you to adapt your operations to take account of such developments.

McGee Pharma International provides advice and support in relation to GxP requirements for the development, manufacture, distribution, sale and supply of all pharmaceutical product types. This includes Active Pharmaceutical Ingredients (APIs), oral dosage forms, parenteral products, biotech products and products for clinical trials (IMPs).

We can assist you by:

Demystifying Legislation

- Helping you understand & interpret the legislation that applies to your pharmaceutical operations

Facility Design

- Evaluating the suitability of design of your facility, your unit processes, and the flow of people, materials and equipment

Process Understanding

- Performing process mapping to help you to gain a detailed understanding of your key business processes
- Identifying gaps in your systems and procedures that could impact on product quality, or regulatory compliance, and that could present potential quality compliance risks for your business

Quality Management

- Redefining your 'Quality Mission, Vision and Values', to reflect the concepts and principles of Quality Management
- Preparing a Quality Manual as per ICH Q10 describing your committment to Quality & Compliance and the implementation of an effective Pharmaceutical Quality System that is designed to achieve your stated Quality Objectives

Pharmaceutical Quality System (PQS)

- Designing a new Quality System to suit your business operations, incorporating QRM (Quality Risk Management) principles and procedures to ensure compliance with regulatory requirements and best practice standards, as per ICH Q10
- Identifying gaps in your Quality System from best practice standards
- Re-designing elements of your Quality System to meet your changing needs as your company grows
- Preparing documented policies and procedures covering your regulated activities

Managing Change

- Helping you to assess the potential impact of a change on your organisation
- Working with stakeholders to identify requirements and resolve potential problems, or conflicts before they happen
- Project managing each phase of the change, i.e. impact assessment; assessment, approval, execution, evaluation of the effective execution of the change, and facilitating the on-going monitoring of the effectiveness of the change

Compliance Help Desk

- We have a dedicated 'Compliance Help Desk' to respond to client queries on industry best practice and regulatory compliance across the product lifecycle from GLP through to MAH and GPvP

"Our company engaged the services of McGee Pharma International as part of a quality improvement programme of one of our Irish facilities. Ann and her team of consultants provided quality and regulatory compliance support to ensure compliance with the requirements of EU and FDA current Good Manufacturing Practice (cGMP).

The work carried out by Ann's team of consultants over the last 18 months has been impactful and has made a very positive difference to this facility's operations. I would highly recommend the services of McGee Pharma International for the provision of quality and regulatory compliance consultancy. I have found Ann and her team to be extremely professional and approachable throughout our interactions and wish them every success in the future.

Vice President EMEA Quality, Multinational Pharmaceutical Company
GMP

Quality Risk Management (QRM)

QRM allows you to understand and to manage your business and quality risks and is an essential component of your Quality System. We can assist in the development and roll-out of a QRM system within your organisation in compliance with ICH Q9 by:

Risk Assessment Methodology

- Using a risk based approach, helping you to translate quality & regulatory requirements into a practical philosophy for day to day operations
- Teaching you the tools to effectively identify, assess, control, review and manage your quality risks
- Design, develop and deliver training on QRM specific to your business operations

MAH Compliance

As pharmaceutical business models evolve and diversify, the regulatory expectations of the MAH (Marketing Authorisation Holder) are becoming increasingly demanding. Maintenance of the MA can often lie within a central regulatory office physically remote from the site of manufacture where QP certification and batch release to the market takes place. Ensuring the effective operation of a robustly designed Quality System for the MAH is imperative to achieving and sustaining regulatory compliance.

We can assist you by:

Demystifying Legislation

- Identifying and interpreting the pharmaceutical legislation that applies to you as an MAH

Pharmaceutical Quality System

- Designing and helping you implement highly effective systems and procedures for MAH compliance, incorporating QRM principles and tools

Quality & Technical Agreements

- Developing contractual Quality & Technical Agreements with your suppliers and 3rd parties; defining respective best practice (GxP) responsibilities for both parties ensuring effective MAH compliance

McGee Pharma International was engaged by Allergan Limited, UK to review the design and implementation of key systems and processes to evaluate MAH compliance and 'inspection readiness' in the areas of Healthcare Compliance (HCC), Medical Information and Regulatory Affairs. This project also included facilitation of risk assessments to support the company to develop a quality improvement action plan and performing mock inspection interviews with SMEs as part of the inspection readiness programme.

I found the consultants extremely professional throughout the project and their in-depth knowledge of regulatory requirements ensured their recommendations were insightful and pragmatic. I would highly recommend the services of McGee Pharma International

Senior Director, EU Regulatory Operations, Allergan Ltd, UK
MAH

Vendor Management

Suppliers & 3rd parties play a key role in today's modern pharmaceutical industry. As pharmaceutical companies continue to look further afield in search of economical vendors, the regulatory expectations for Quality Management of these vendors are increasing in response to the degree of the associated and increasing risks. Outsourced activities such as clinical trial management, manufacturing, analysis, warehousing and distribution are commonplace. Companies supplying raw materials & packaging supplies must also be assessed in terms of compliance and there must be a system in place for the on-going monitoring of suppliers.

We assist by:

Auditing

- As highly experienced and trained professional auditors, we assist by providing comprehensive tailored audits of your suppliers and 3rd parties both in developed and developing countries, in compliance with applicable good practice, for example GMP, GCP or GDP
- Providing 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, a document required for product registration

Quality & Technical Agreements

- Developing contractual Quality & Technical Agreements with your suppliers and 3rd parties; defining respective GxP responsibilities and ensuring effective vendor management

Pharmaceutical Quality System (PQS)

- Helping you implement highly effective systems and procedures for the initial evaluation and on-going monitoring of vendors to ensure compliant vendor oversight

Managing Change

- Project managing a change of supplier through the impact assessment, execution and post change evaluation phases of change management

> *"McGee Pharma International carried out GCP and GMP audits on key third party companies based in India on behalf of Eirgen Pharma.*
>
> *The audits were exceptionally thorough and wide ranging and have provided us with a detailed framework and set of recommendations which will form the basis of our management of these relationships into the future.*
>
> *In addition, the audit findings will form the basis of our pre-requisites for third parties on an on-going basis. I would highly recommend the services of McGee Pharma International.*

Technical Director, EirGen Pharma Ltd.
GCP and GMP

Validation

We assist you by providing guidance, assistance and support in all areas of validation compliance.

Commissioning and Qualification

We support you in the management of Commissioning and Qualification projects to:

- Ensure that the key milestones of the project are identified
- Ensure that the challenges to the commissioning and qualification process are recognised
- Ensure the application of Quality Risk Management to the process
- Ensure input from the Quality perspective from the beginning through to the end of the project

We provide guidance and support on preparation of documentation, including:

- Procedures
- Protocols
- Reports and the associated records of actions taken or conclusions reached, as part of commissioning and qualification activities

We assist you in ensuring that commissioning and qualification activities are completed effectively, efficiently and meet regulatory expectations and compliance.

Process Validation

We support you in the management of Process Validation projects, providing expert inputs to ensure:

- The application of Quality Risk Management to the process
- The provision of guidance and support on preparation of documentation
- Validation of the process is completed effectively, efficiently and meets regulatory expectations and compliance

Technology Transfer

We provide:

- Support in the management of Technology Transfer projects to ensure identification of key milestones, challenges and the application of Quality Risk Management to the process
- Guidance and support on preparation of documentation - written policies, procedures, protocols, reports and the associated records of actions taken or conclusions reached, as part of Technology Transfer activities

Cleaning Validation

We provide:

- Guidance and support on preparing Cleaning Policies, Validation Master Plans (VMPs), protocols and reports for Cleaning Validation in compliance with best practice standards
- Support in the management of Cleaning Validation projects to ensure identification of key milestones, challenges and the application of Quality Risk Management to the process

Analytical Method Validation

We provide:

- Guidance and support on preparing protocols for analytical method validation, execution of protocols and reporting in compliance with best practice standards
- Support in the application of Quality Risk Management to Analytical Method Validation in the context of technology transfer and outsourced activities

Pharmacovigilance

We provide:

- Assistance in interpreting developing regulatory requirements for Pharmacovigilance (PvP)
- Identifying gaps in your current systems and procedures from best practice standards for PvP
- Design and development of a Quality Management System to support your pharmacovigilance activities
- Development of operational procedures for pharmacovigilance in compliance with regulatory requirements and best practice standards for PvP

QP/RP services

- Provision of contract QP services in compliance with legislation for the manufacture and release of finished pharmaceuticals and GMP
- Provision of contract RP services in compliance with legislation for the wholesaling of medicinal products and GDP
- Provision of QP services in compliance with legislation for Pharmacovigilance

McGee Pharma International provided a first rate service to us when reviewing our current pharmacovigilance systems. Scoping out the work in advance was very helpful and ensured all aspects were fully addressed. The Review was very thorough and the time taken to explain regulatory expectations/requirements to personnel really helped to reinforce their understanding of same. The work carried out by McGee Pharma International has given the site an excellent platform upon which to improve our current systems. It was a pleasure working with Ann and her team and I look forward to working with McGee Pharma International on future site projects.

RA Manager, Genzyme Ireland Limited
GPvP

Expert Opinion in Legal Cases

- We advise on interpretation of EU pharmaceutical legislation across the product lifecycle and how this translates into best practice standards that govern day-to-day operations
- We prepare expert reports in litigation cases

> *RCSI appointed McGee Pharma International to carry out performance assessments in the area of Professional Competence Assurance in Pharmacy Practices. We found their in-depth knowledge of legislation and best practice standards on this topic to be exemplary. Their professionalism and commitment is outstanding and I would have no hesitation in using the services of McGee Pharma International again*
>
> Head of the School of Pharmacy, Royal College of Surgeons in Ireland
> GPP

Measuring ROI (Return on Investment)

Our team of experienced consultants can assist you in determining ROI arising from various improvement initiatives, for example:

- Training – evaluating baseline performance and improvements in personnel performance in the workplace following training, to demonstrate its cost effectiveness (e.g. financial savings through reduced deviations; reduced complaints; reduced lost time etc.)
- Performing ROI studies following mapping of a more complex process to demonstrate the cost effectiveness of having clarity on your process, within company and inter company, with the consequential reduction in product quality complaints, quality defects, returns and / or potential for recall

As a start-up Indian CRO we were looking for someone who could play the role of a friend, philosopher and guide and help to gear up our practices, systems and approach to be in line with International requirements of Good Laboratory Practices and Good Clinical Practices. Inspection carried out by McGee Pharma International was very much useful and beneficial from this perspective. It helped us not only identify the gaps between our desire and reality but the discussions with them helped appreciate and understand the issues from a fundamental perspective. Since the visit we succeeded in putting in place many of their suggestions and ideas and in the process emerged to become a GLOBAL STANDARD CRO

Director, CRBio, India
GLP and GCP

Training

We design, develop and deliver training courses on best practice topics that are customised to your specific needs.

- We design courses on best practice topics where regulatory compliance requirements are continually evolving
- Our courses include bespoke and public e-Learning seminars, tailored training courses, open courses and 1:2:1 mentoring
- All our training includes assessments for training effectiveness and we provide a training certificate to each participant on the successful completion of these assessments
- Our multinational clients find e-Learning works very effectively for delivering information and ensuring clarity of understanding. When combined with classroom face-to-face interaction, participants are challenged to translate their theoretical knowledge into practical application through workshops and case studies. This dual approach is effective and efficient in terms of both time and cost

E-learning

Our Award winning e-Learning Centre was developed in 2008 enhancing the global reach of our services and providing a flexible training solution for our clients.

We specialise in building e-Learning into a programme of training that is delivered using multiple mechanisms, suited to our client's needs. E-Learning is a very effective and efficient means of delivering information. Followed by classroom training, we challenge participants to translate their theoretical knowledge into practical application through workshops and case studies. This combined approach is also a time efficient and cost effective way to deliver training.

Using baseline and follow-up on-line questionnaires, our e-Learning Centre allows us to conduct competency evaluations immediately following training to assess how much the participants have actually learned. We can perform ROI studies following our training to evaluate improvement in personnel performance in the workplace through measuring, for example, reduction in deviations and complaints and reduced lost time.

E-training provides an opportunity for companies to train their personnel and 3rd party suppliers in regulatory standards, regardless of their location, thus providing an ethical and environmentally friendly solution to training responsibilities at a global level.

Features include:

- Live, inter-active training to groups of people that can participate using their computers and phones at their desks
- Delivery of training using Power Point slides and other tools as required (e.g. interactive e-white board)
- Ability for participants to ask questions of the trainer in real time
- Group discussions on topics of particular interest
- We can record the training, either pre-recording or recording a live session, and this can be used to train additional staff. The benefit of the live training is that the participants can discuss questions or problems with the trainer in real-time. You can use recorded training sessions on multiple occasions

"When looking for a solution to ensure Best Practice for Janssen globally, I immediately thought of McGee Pharma International. Having worked with Ann on previous projects in Janssen in Ireland, I was confident that with Ann's previous experience as a regulator nationally and her involvement in influencing the development of best practice for the pharmaceutical industry at a European level, McGee Pharma International would be the best provider for our QP training requirements.

McGee Pharma International designed and delivered a customised 3 part training course on Roles and Responsibilities of the QP for Janssen which was delivered by a combination of e-Learning and a face-to-face workshop to Janssen personnel worldwide. The course was tailored to the specific needs of our team of QPs at Janssen. What particularly impressed us was that the e training provided a unique opportunity for our personnel to engage in live, online, interactive training in real time. Over 50 associates in different time zones around the world participated in this training. Our core objective was to ensure that QPs of Janssen and other quality associates in the global supply chain had a common understanding and best practice approach on European requirements. Ann and her team certainly delivered on our requirements in an extremely professional manner.

Senior Director Quality Operations, Janssen Pharmaceuticals Ltd
E-Learning

Service Delivery

Planning and Preparation

We believe that allocation of time for project planning and for preparation for project delivery is invaluable, providing the opportunity to scope out deliverables for each project and ascertain the most appropriate steps/procedures to ensure you receive maximum value when engaging our services.

Delivery

Following completion of the preparation phase, our project delivery is efficient, professional and relevant. We work with you on an agreed agenda and timeline that provides for the delivery of our services that is compatible with your team and processes.

Reporting (if applicable)

Within a two week period of delivery of the project, we will produce a comprehensive report of our observations and recommendations.

Observations and associated recommendations made in this report reflect current best practice standards to assist our clients in implementing an effective work programme.

We have developed this method of project management when working with clients over the past eight years as we have found that it provides them with both practical compliance and business solutions.

> *"Allergan Pharmaceuticals Ireland EuroCentre worked with McGee Pharma International to help to identify opportunities for improvement of our Quality Management System governing our European based GDP operations and to redesign some elements of the QMS to achieve the improvements that we wanted. Ann and her team provided a high level of expertise in a very professional, effective and efficient manner, providing us with solutions that are tailored to suit the needs of our business. We would highly recommend McGee Pharma International for this kind of work.*
>
> QA Manager, Allergan Pharmaceuticals Ireland, Eurocentre
> GDP

www.DesignPrintworks.ie

Suite 2, 1st Floor, Stafford House, Strand Road, Portmarnock, Co Dublin

T | +353 (0)1 846 4742 F | +353 (0)1 846 4898
E | info@mcgeepharma.com W | www.mcgeepharma.com

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your partners in compliance