Transition into the Pharmaceutical Industry

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The Pharmaceutical Industry

The UK is the 3rd largest exporter of pharmaceutical medicines and with world-class R&D facilities, the industry funds more healthcare-related research than every other source combined. There are opportunities for Physicians to join pharmaceutical companies, independent Clinical Research Organisations, (CROs) and regulatory bodies such as the MHRA.

The pharmaceutical industry offers a challenging, multi-disciplinary and commercial environment that requires high calibre Physicians who uphold the highest standards of their profession. Apart from selected areas of research, pharmaceutical medicine is involved in clinical evaluation programmes that support licensing and marketing requirements.

Moving from the NHS/Academia into the Pharmaceutical Industry

A career within the Pharmaceutical Industry is a fantastic career pathway for experienced Physicians wanting to operate in either a more commercial environment or to impact on wider patient populations at the cutting edge of medicine.
For Physicians, a great resource is The Faculty of Pharmaceutical Medicine. This is a professional membership body committed to advancing clinical medicine through the highest ethical standards and offers a great insight into the Pharmaceutical Industry for Physicians. As a Physician you can also complete the Pharmaceutical Medicine Specialist Training to be recognised by the GMC as a Registered Pharmaceutical Physician.

Transition into the industry is best achieved at SHO/Specialist Registrar level, or from an academic setting working on clinical trials. Pharmaceutical companies often look for candidates with current experience in therapeutic areas relevant to pharma company product portfolios.

Life Sciences organisations look for individuals who are passionate about healthcare and patient outcomes, have an analytical mindset and can operate in a dynamic work environment with a commercial mindset, particularly within Medical Affairs roles.

Pharmaceutical companies look closely at a candidate's record of employment over the most recent 2-3 years and generally require a minimum of 4 years post graduate experience. Medics with a recent history of short-term locum roles often find it difficult to move into the industry. Medics at Consultant level can be deemed too specialised by many pharma companies and often, like GPs, may find the move financially detrimental in the short-term. The caveat here is for Consultants who have strong therapeutic area expertise and who have acted as an investigator in clinical trials, who can often enter the pharmaceutical industry at an advanced level, particularly within Clinical Development. Some pharma companies and particularly CROs have job opportunities that require a strong clinical background with particular specialism and are prepared to offer a commensurate salary and benefits package.

Physicians join the pharmaceutical industry in “entry level” roles and are promoted to senior, leadership and progress to Medical Director level with increasing pharmaceutical and CRO industry experience. There is no definitive level of experience for promotion and much depends on the requirements laid down by each company for a specific role. As a guide, promotion to a senior role (Senior Medical Advisor) typically takes around 2-3 years and gaining ABPI Final Signatory status, a role such as a Medical Manager or Head of a Business Unit usually requires at least 3-5 years' experience and roles at Director level require several additional years' experience.

Medical Directors with wide-ranging experience and expertise sometimes elect to work on a freelance consultancy basis offering 'interim' services to one or more companies to help meet short-term or immediate needs.

Cpl Life Sciences run a webinar series on the career pathways available to Pharmaceutical Physicians and Pharmacists once they are in industry, allowing you to connect and network with leading figures within the Life Science industry that have progress into Senior Leadership posts.

Typical requirements for entry-to-industry level UK Physicians/Pharmacists

A career in the industry is an exciting prospect for any Doctor who wishes to develop a career as a Pharmaceutical Physician. Within pharmaceutical companies, Physicians will generally be employed in one of three fields; Medical Affairs, Clinical Research/Development or Pharmacovigilance.

Hybrid or crossover roles can exist depending on the size and structure of the company and in a small business, a single physician may be responsible for all three key functions. Although less frequently available, there are also opportunities for Physicians in Regulatory Affairs, Medical Education and Pharmacoeconomics.

Desirable candidates will often meet the following requirements:

- Full GMC registration.
- Usually at least four years in clinical practice and/or strong academic experience.
- For Physicians wanting to work in Clinical Research, previous clinical trials experience as an Investigator or Sub-Investigator is usually preferred, but not essential. If candidates lack trial experience, recent, 'hands-on' clinical experience is strongly preferred.
- For roles in Medical Affairs, strong therapy area alignment and/or commercial acumen is highly desirable.

Although patient contact may be infrequent or non-existent, pharmaceutical physicians are required to exercise their professional knowledge, skills and experience with due regard for the medico-legal and clinical implications of their decisions and all professionals in this field must carry appropriate professional indemnity. Regardless of the functional role, each day in the life of a Pharmaceutical Physician brings new and varying challenges, rarely are two days ever the same.

Type of roles and what to expect:

Clinical Research Physicians

This is the role most people are familiar with when thinking about Physicians in the Pharmaceutical Industry. CRPs are usually office based and will generally be office hours, from Monday to Fri
day with the occasional on call shift.. The role of a Clinical Research Physician will usually cover Phase I, or Phases II – III development.

Phase I work is conducted in units sometimes described as 'Patient Recruitment Centres'. These are separate from the units where Phase II-IV trials are carried out. Roles in Phase I involve the screening, care and supervision of volunteers taking part in research studies.

Roles in Phases II-III involve designing and writing protocols for clinical trials and Investigator brochures, liaising with Investigators in primary/secondary care, medical monitoring of ongoing clinical trials, providing medical advice to scientific and other internal/external groups, obtaining funding and making presentations to senior management and providing input to final study reports before submission to regulatory bodies for new drug licensing. Having access to global information on any drug, the Clinical Research Physician is able to advise trial Investigators and advance products through development if clinical trials indicate it is safe to proceed.

Clinical Research Physicians are also employed by CROs and in this role, the work involves providing medical input and advice to sites, Investigators, CRO personnel and the sponsor company alike. You will also be tasked with things such as medical monitoring, attending Investigator meetings, representing the CRO at Bid Defence meetings to win business for the company and acting as consultant to the sponsor pharma company.

Clinical Research Physician roles require participation in study team meetings and liaison with drug safety and regulatory colleagues. Some days might be spent in hospitals or at GP surgeries or meeting with Investigators to gain their input to protocols you are writing to discuss clinical trial progress. Attending and presenting information at Investigator meetings is also a key component.

Some of the tasks you can expect to encounter day-to-day are;

Protocols

- Writing and reviewing protocols for UK/regional/global studies
- Input into draft protocols
- With Clinical Research Associates, assessing feasibility and determining provisional patient numbers
- Sending draft protocols to key investigators in the therapeutic area(s)
- Setting up and running meetings to discuss feasibility etc

Site evaluation

- Identifying, evaluating and selecting qualified investigators and investigator sites
- Reviewing site facilities, site staff involvement, ability to enrol patients
- On completion of site visits, getting study team agreement on participating sites

Reviewing

- Case Report Forms
- Output from study meetings
- Medical queries, e.g. inclusion /exclusion criteria, concomitant medications
- GCP issues
- Significant laboratory /ECG values
- Adverse events
- ICD and updates to the Risk Profile

Becoming familiar and keeping up-to-date with

- Product(s) pharmaceutical/pharmacological properties and pre-clinical data
- Regulatory requirements specific to the product
- Disease area(s)
- Journals/publications
- Leading researchers, Key Opinion Leaders and centres of excellence

Input to

- Clinical Development Plan
- Preparation of ethical review submissions (including patient/volunteer consent/information materials)
- Preparation and submission of regulatory approvals
- Management of study budgets
- Clinical sections/analysis to product(s) Licence Application(s)
- Publication of trial results at conferences and in journals
- Implementation of pre-launch disease awareness programmes and other activities
- Key Opinion Leader/Advisory Board activities

Pharmacovigilance (Drug Safety) Physicians

Pharmacovigilance (also known as drug safety) is a role that, in comparison to the drug life process, runs throughout. It can involve early assets, through to late-stage assets and post marketed products. A prescribing Physician is familiar with The Summary of Product Characteristics (SmPC) packaged with medicines. They contain the current understanding of the drug safety profile together with a well-expressed quantification of the potential risks that will be experienced by the described patient population in the given indications for treatment. The information comes from existing pharmacological knowledge, pre- clinical and drug development trials and also from wider experience gained with a larger exposure to patients in the marketplace. Known in the industry as “Pharmacovigilance” its purpose is to collect, collate and evaluate information about suspected adverse reactions. This can be an aspect of the Clinical Research Physician role but due to its importance and increasingly high profile, most companies will have a separate department to assess and monitor the safety of products on the market and those in development.

These positions are office based and require close liaison with clinical research, regulatory, medical information and marketing departments to feedback on-going findings and trends, carry out medical assessments, prepare aggregate Periodic Safety Update Reports (PSUR’s) and carry out Surveillance and Epidemiology studies and Benefit/Risk estimations.

This role is data orientated, assessing, and interpreting adverse event information to track trends so that the on-going safety of the company’s products is maintained. Usually, you have responsibility for products in a specific therapy area but in a small company you could have responsibility for the safety profiles of several compounds. Reports need to be prepared and submitted according to standard operating procedures and the role demands good IT/database skills.

Some of the tasks you can expect to encounter day-to-day are;

Adverse Events

- Handling spontaneous cases from sales representatives, Health Care Professionals, patients, other company employees, market research, database analysis etc
- Handling Clinical Trial Cases (Serious Adverse Events)
- Medical Review
- Entering into database
- Follow up

Surveillance Activities

- Signal detection
- Signal assessment
- Recommending label changes
- Proposing pharmacovigilance activities
- Answering regulatory enquiries

Risk Management

(a proactive, systematic and more evidence driven approach to evaluating safety)

- Pre-marketing risk assessment
- Anticipating conditions of use
- Quantifying identified and potential intrinsic/extrinsic risks
- Understanding the epidemiology of disease area(s)
- Benefit/Risk assessment

Input to

- Trial planning
- Safety specification
- Pharmacovigilance plan
- Risk Minimization Plan/Risk Map
- Medical review of individual cases
- Regulatory reports
- Periodic Safety Update Reports
- Reviews of Risk Management activities, Post Marketing Surveillance activities and Medical summaries of safety

Liaison

- Sales and Marketing
- Clinical Research Physicians and Medical Advisers
- Health Care Professionals
- Medical Information and Regulatory Affairs
- Regulatory bodies
- Manufacturing

Medical Affairs Physicians

Entry level roles for Physicians in Medical Affairs are often called Medical Advisors. Here, you will be responsible for contributing to and delivering elements of the medical affairs plan/strategy in a cross functional environment. It follows Clinical Development and sees you 'launching' the product that has, so far, seen success in the clinical trials.

The roles have a strong commercial focus and are involved with late Phase III drug development, but primarily Phase IV work. The work involves liaising with Key Opinion Leaders (KOLs) who are key prescribers, developing strategies for launch. This role will see you developing and signing off promotional materials that accurately portray product capability, competitor analysis, preparing the market for new products, post marketing surveillance, providing medical information, managing late phase clinical budgets, drafting protocols and analysing clinical reports.

A Medical Advisor is often responsible for creating a scientific knowledge base in the organisation in specific therapy areas and, in collaboration with the training department, ensuring the sales force receives initial and ongoing medical training so that they understand and convey the scientific benefits of a brand appropriately. A Medical Advisor also acts as an ABPI Guardian, providing medical governance to ensure the highest levels of compliance with the ABPI Code of Conduct.
Importantly, the Medical Advisor evolves to become the scientific expert on the molecule. This means that they are ultimately able to recognise and recommend marketing opportunities for new disease indications and evaluate products that might be licensed-in to add to the product portfolio for a given therapeutic area.

Medical Advisors need to be fast learners, agile thinkers and able to assimilate large volumes of data. The role presents many face-to-face challenges and requires doctors who enjoy a fast paced environment with ability to excel in communication/negotiation. Although Medical Advisor roles are office based, time is spent away from the desk travelling to meetings with KOLs and to attend or present at conferences and training sessions. You will often have working from home flexibility and some autonomy over your diary.
As a Medical Advisor you will also work cross-functionally. Internal liaison with colleagues in Clinical Research, Pharmacovigilance and Regulatory Affairs is very important but the real thrust of these jobs is medical input to the marketing strategy for products on, or due to go onto the market. Launching a new product is a highlight of many Medical Advisors' careers.

Again, here are some of the tasks you will come across day-to-day;

Becoming the Medical Expert for a product or group of products

- Strategic awareness of the Clinical Development Programme
- Involvement in late stage (Phase IIIb and IV) clinical trials
- Maintaining up to date knowledge of product(s), applications, issues
- Maintaining contact with Key Opinion Leaders in the medical field and Non- Government Organisations in assigned therapeutic area(s)
- Playing a key role in advisory boards
- Attending frequent meetings and conferences – often overseas
- Networking with potential Key Opinion Leaders and Health Care Professionals

Working with Sales & Marketing team(s)

- Taking a supervisory role
- Ensuring the sales force are up to date with the most recent publications/key issues
- Ensuring any adverse events are passed to the Pharmacovigilance Dept.
- Involvement with Regulatory strategies, issues before launch and life cycle management

Involvement with the Sales Team

- Training sales representatives in broad medical aspects of the company's products
- Answering queries
- Keeping the sales team up to date with new developments, issues and market opportunities

*For further insight into the pharmaceutical industry and potentially making the transition, please contact the **Medical** team at Cpl Life Sciences on +44 (0) 1189 522799 or e-mail info@onlymedics.com*