fusion pharma



Your Bespoke Regulatory Consultancy

What we offer

Your Bespoke Regulatory Consultancy



We enjoy collaborating with like-minded people and are certain that this is the foundation for our success.

Leah Heathman, Managing Director, Fusion Pharma

We are Regulatory Affairs experts who specialise in the UK and EU pharmaceutical arena.

We offer a bespoke consultancy service to our clients to obtain and maintain their product licences.

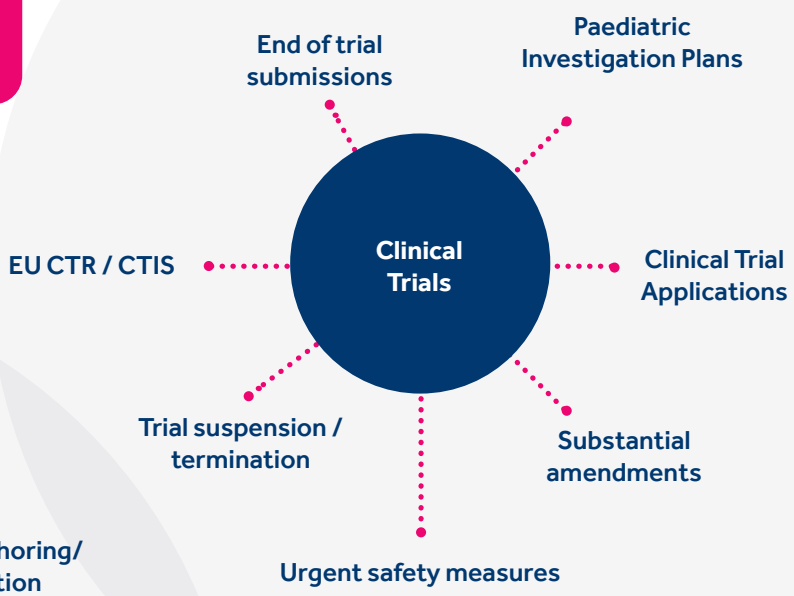
Consulting - utilise our wealth of Regulatory Affairs expertise for one-off projects or provision of a consultant to act as part of your team.

Full outsourcing - handover responsibility of your product portfolio to Fusion Pharma for all Regulatory Affairs activities.

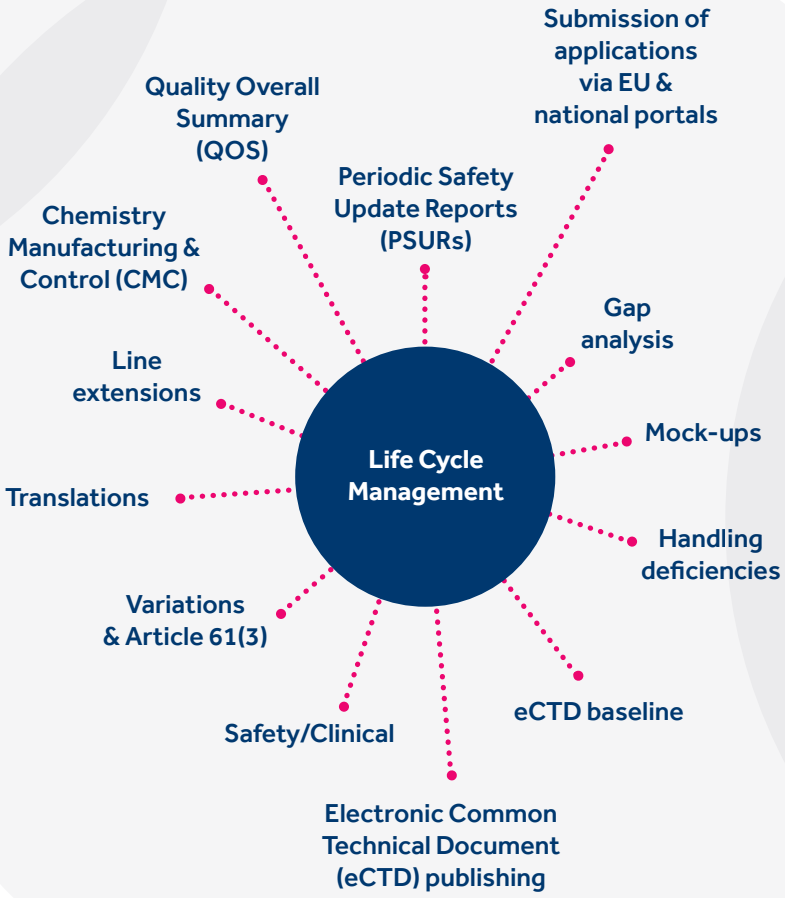
SME status - Fusion Pharma will manage your application towards gaining small and medium sized enterprise (SME) status with the MHRA and/or EMA.

We carry out a complimentary assessment for potential impact to Quality Assurance, Pharmacovigilance and Medical activities to determine if/when these functions need to be brought in to work cross-functionally.

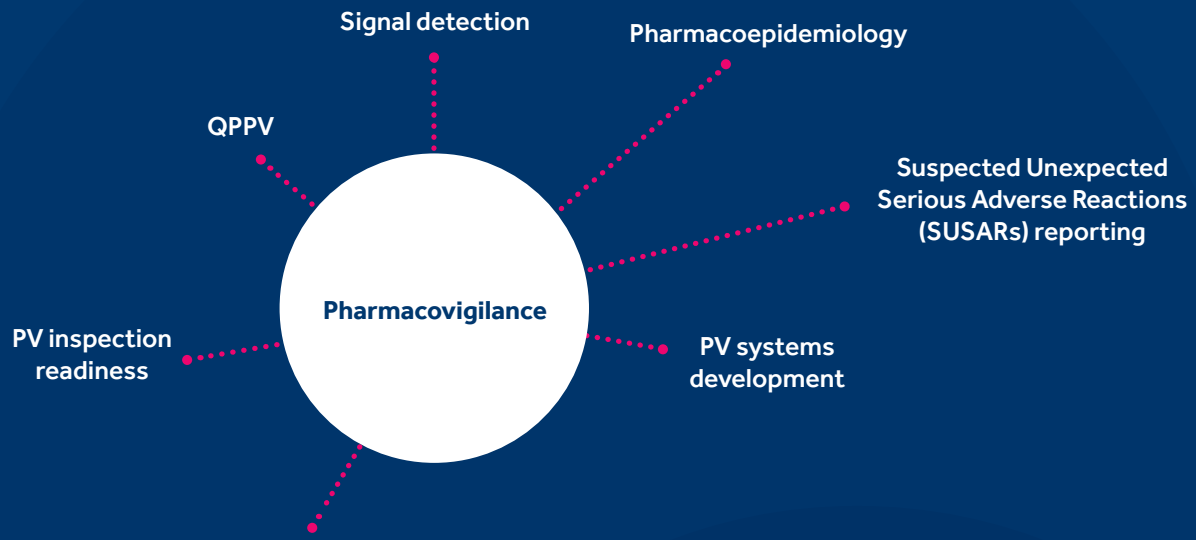
What we offer



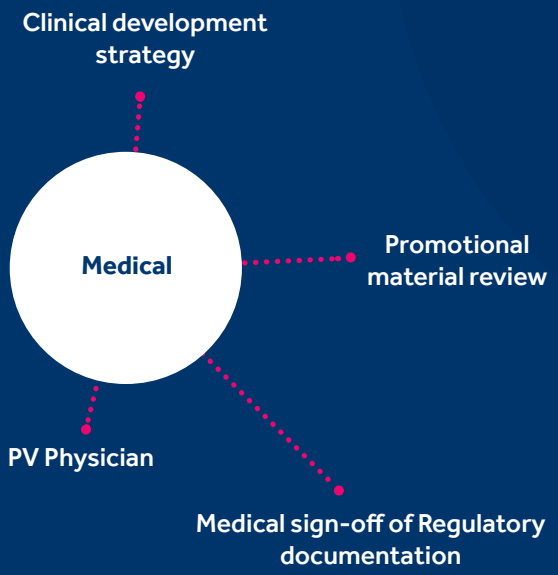




> **Fusion Pharma are skilled and trustworthy, experts in their field and I strongly recommend them.**
>
> *Steven Flynn, Associate Director, Britannia Pharmaceuticals*







Fusion Pharma is a great support for us, we use the resources provided by the team to help manage all aspects of our development, including Regulatory and Quality Assurance.

Andy Stafford, Managing Director, Oripharm

Full Outsourcing Model

We offer full outsourcing for all of your Regulatory Affairs activities.

Your full support package will include:

- A dedicated Project Manager
- Bespoke set of SOPs written to be aligned with parent company
- Monthly management meetings
- KPI reporting
- Access to our online project management tool for easy and transparent oversight
- Access to our SharePoint site for document storage and file share

1

Service review and agreement

- Service requirements
- Choose package / fees
- Contract
- Technical Agreement

2

Onboarding and Training

- Team introductions
- Write / sign SOPs
- Product training
- Handover of activities
- System access

3

Monthly Management Meetings

- Review of previous month's tasks
- Review of upcoming tasks
- KPI reporting

4

Annual Service Review

- Review of service
- Adapt package (if required)
- Audit

How we work

We like to be led by you and the needs of your business, we can adapt accordingly and be flexible to change.

We can either take work on within our team or if you prefer the 'contractor model', you can work with a dedicated team member to join your department for a period of time.

The benefit of working for Fusion is that our consultants are employed by us. This means that IR35 is not applicable to the way that we work and therefore there are no compliance risks (this affects UK only). Another advantage to using Fusion is that you bypass expensive recruitment agency fees!

Additional services

We support company growth and improve the functioning and compliance of existing teams through offering:

- Compliance audits
- Technical interviews for recruitment
- System selection
- SOP writing
- Training

We have excellent working relationships with global partners who are experts in the US, Australia and MENA regions to be able to support or create your global product strategy.

Rates

Our rates are competitive and are structured to reflect the level of experience required for the task. We can charge hourly or daily and can provide upfront estimates to help you budget ahead.

Next steps

We would be delighted to arrange a video call to introduce you to Fusion Pharma and sign a confidentiality agreement to discuss your requirements in more detail.

Following this, we can work quickly to agree and sign a contract and arrange a kick off meeting with your Project Manager.



We love hearing from you.

Here at Fusion Pharma we are more than happy to answer your questions. We offer a bespoke support package for your company and will spend time getting to know you and exactly what consultancy services you require.

Our office hours are 09:00 – 17:30
Monday to Friday.

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fusion pharma

Our service is bespoke and personable, we want you to access us like an extension to your team.

www.fusion-pharma-limited.com