



Penn Pharmaceutical Services
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CMC CONSULTANCY



PENN PHARMACEUTICAL SERVICES

WITH YOU EVERY STEP OF THE WAY

CMC CONSULTANCY
FORMULATION DEVELOPMENT
ANALYTICAL DEVELOPMENT
CLINICAL TRIAL SUPPLY
CONTRACT MANUFACTURING
QP RELEASE SERVICES



With over 25 years of CMC experience and highly expert staff, Penn can add a wealth of knowledge to your pharmaceutical development requirements from drug discovery to product commercialisation.

Our experts are fully conversant with current pharmaceutical regulatory strategies for both development and commercialisation. By tapping

into this resource as early as possible we can advise best practice and implement methods to help optimise your approach and minimise your costs.

Our established track record in all major pharmaceutical markets worldwide makes Penn the number one choice for all CMC needs irrespective of where our clients wish to develop their product.



CMC CONSULTANCY

PEOPLE

Meet the team who will ensure the most appropriate strategy is applied to your drug development process. Our most experienced scientific personnel and Qualified Persons will determine your requirements and plan your strategy with the assistance of Technical Specialists. The added bonus of a one site operation for all CMC activities ensures your project runs smoothly.

CORE SERVICES

Our CMC Consultants have a complete overview of all stages of the pharmaceutical development process and combined with our excellent operational regulatory inspection record, we can provide all the support on site that you may need including:

- *Technical exchange and commercial overview as part of a diagnostic assessment*
- *Production of a strategic development plan based on design, feasibility, potential regulatory issues and solutions*
- *Representation and expert review to answer questions from regulatory authorities*
- *Implementation of programmes and management of any third parties with regular client involvement*
- *Identification of possible regulatory issues and unnecessary resource commitment when involved at an early stage*
- *A flexible and proactive approach to support your development process*
- *Support for licensing and other commercial due diligence processes*

ACHIEVEMENTS

Penn has successfully advised numerous clients on their CMC strategy from API to commercial stages. For example we have provided:

- *Complete strategic CMC development plans*
- *Assistance in the production of DMFs*
- *CMC data collation for subsequent MHRA and FDA approvals*
- *Transfer of manufacturing and release methodologies*
- *Troubleshooting and solutions for scale up issues*
- *Support of PAIs*

WIDER SCOPE

As an independent provider of CMC Consultancy, Penn provides clients with complete security over confidential data and the client retains ownership throughout. As a value added tool in due diligence situations Penn's CMC Consultancy provides peace of mind for licensees, licensors and investors alike.

THE COMPLETE SERVICE

At Penn Pharmaceutical Services we offer you a tailored approach that differentiates us from our competitors. If you would like to add further value to your business, choose another of our services:

- **FORMULATION DEVELOPMENT**
- **ANALYTICAL DEVELOPMENT**
- **CLINICAL TRIAL SUPPLY**
- **CONTRACT MANUFACTURING**
- **QP RELEASE SERVICES**

YOUR NEXT STEP

No matter how large or small your needs, call +44 (0) 1495 713 607, email enquiries@pennpharm.co.uk or visit www.pennpharm.co.uk today to discuss your exact requirements.

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