



**Penn Pharmaceutical Services**  
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## QP RELEASE SERVICES



# PENN PHARMACEUTICAL SERVICES

WITH YOU EVERY STEP OF THE WAY

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



At Penn we believe flexibility is imperative. That's why you can choose to use our highly effective QP Release service in support of all our development services or as a 'stand-alone' consultancy. This approach has been particularly successful for our customers located in Japan, USA and Australasia following the implementation of the EU Clinical Directive.

Combined with our assistance to API manufacturers and purchasers preparing to meet the needs of the EU API directive 2004/27/EC, Penn offers the most comprehensive QP service anywhere.

With six resident QPs conversant with the latest regulations, clients are assured of expert and rapid QP Release Services that cover drugs and devices for clinical and commercial use.



## QP RELEASE SERVICES

### PEOPLE

Meet the team who can deliver a complementary service to other CMC activities or stand-alone QP consultancy. Penn's 6 QPs have varied backgrounds but all have undergone the rigorous training and UK approval mechanism to become fully qualified QPs.

With extensive experience in all areas of pharmaceutical development, Penn can truly offer a QP who will understand your needs whether your product is in development, commercialised, traditional or is novel in its nature.

### CORE SERVICES

Penn offers you an extensive QP Release service which includes:

- *Familiarisation audits for our customers prior to EU importation and provision of supporting reports*
- *European testing facilities and Qualified Person release for non-EU products*
- *Initial diagnostic services to determine importation parameters and how the EU legislation will affect our client's development programmes*
- *Review of Clinical Trial Applications*
- *An online QP service for worldwide access to QP professionals for rapid response to general or specific queries*
- *6 QPs on site all performing routine releases based on documentation as defined in your Technical Agreement*

## ACHIEVEMENTS

Penn's QPs audit more than 30 manufacturing sites per year. Combined with our high quality CMC consultancy service they have helped clients move product into the EU within days of the initial request. This flexibility and reaction time has saved our customers considerable potential lost time on the development of their products.

Also, our Analytical Development group works closely with our QPs to ensure any analytical testing required when moving product across international borders will satisfy the regulatory authorities.

## THE COMPLETE SERVICE

At Penn Pharmaceuticals we can truly offer you a QP service reflects our international track record and credibility. If you would like to add further value to your business, choose another of our services:

- CMC CONSULTANCY
- FORMULATION DEVELOPMENT
- ANALYTICAL DEVELOPMENT
- CLINICAL TRIAL SUPPLY
- CONTRACT MANUFACTURING

## YOUR NEXT STEP

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

**PENN – WITH YOU EVERY STEP OF THE WAY**