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## HIGH CONTAINMENT OPERATIONS FOR MANUFACTURE OF HIGHLY POTENT DRUGS



# PENN PHARMACEUTICAL SERVICES

WITH YOU EVERY STEP OF THE WAY

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



As one of the longest established pharmaceutical services companies, Penn has over 28 years of experience in providing integrated drug development, clinical trial supply and manufacturing services to the international healthcare industry.

Our wealth of knowledge and expertise allows us to provide a comprehensive, flexible and customised service to each client accelerating their route to market.



## DEDICATION

Always dedicated to answering the needs of the marketplace, Penn now offers High Containment Operations for the manufacture of highly potent drugs. There is a global shortage of High Containment Operations (HCO) manufacturing facilities for highly potent drugs despite a growing number of pharmaceuticals containing highly potent active ingredients including hormones, cytotoxic drugs, prostaglandins, retinoids, some antibiotics and some narcotic substances.

## CORE SERVICES

As defined by OELs (occupational exposure limits), it is estimated that approximately 40 to 45% of product OELs that are now being set by the pharmaceutical industry are at  $\leq 10$  mcg/cu.m. Penn's HCO facility offers high containment facilities to pharmaceutical companies conducting clinical trials requiring small scale batches of highly potent drugs. From this service clients can expect:

- *Class 100,000 containment manufacturing room – negative pressure, double airlock, single-pass HVAC, safe-change EU 13 HEPA filters*
- *Conforms to ISO Class 8 (100,000) BS EN ISO 14644-1 (1999) & EU GMP volume IV*
- *Closed manufacturing system*
- *Isolator for dispensing highly potent API*
- *ChargePoint valves for contained transfer of API (powder or solution) to a Zanchetta P10 one-pot high-shear mixer/granulator/dryer.*
- *Further contained transfers to milling & blending stages if necessary*
- *Contained transfer to tablet press*
- *Batch sizes up to 10L/3-6kg*
- *Validated to OEL  $> 1 < 10$  mcg/cu.m, OEB 4*
- *Primary packing in separate class 100,000 containment room*

## THE COMPLETE SERVICE

From our integrated single site facility based in the UK, we offer you a tailored, flexible and cost effective service that differentiates us from our competitors. Our facility meets the highest quality and regulatory standards and is licensed by the MHRA and is one of the few European sites inspected by the FDA. Whichever service combination you choose, you'll be guaranteed an individual experience at Penn.

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- FORMULATION DEVELOPMENT
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- CONTRACT MANUFACTURING
- QP RELEASE SERVICES

## YOUR NEXT STEP

No matter how large or small your needs, call +44 (0) 1495 711 222, 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**