

Information sheet

High Potency Handling

High Potency Drug Development & Manufacturing

Highly potent active pharmaceutical ingredients (HPAPIs) are becoming increasingly common in drug development pipelines, especially in the oncology sector, as researchers search for therapies with greater selectivity and pharmacological activity. However, HPAPIs present additional CMC challenges due to the containment requirements to protect both the operators and manufacturing facilities. Their production processes may also require greater precision and control due to the very small quantities of drug present in the final dosage form.

With over 30 years of experience in small molecule drug development, Quotient Sciences possesses the expertise to overcome the challenges that arise with HPAPIs. Our global facilities are configured with the necessary controls required for the handling and processing of these types of molecules and we offer our customers a complete, global end-to-end development solution from early phase formulation screening through clinical and commercial manufacturing.

High Potency Handling Capabilities & Support

Quotient offers a broad range of development and manufacturing services for HPAPIs from Preclinical through Phase III/Commercial Manufacturing:

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| › API Characterization and Pre-formulation Development | › Analytical Method Development |
| › Formulation Screening and Development | › Clinical Supplies Packaging and Global Distribution |
| › Stability Storage and Testing Services (ICH Storage Conditions) | › Commercial Product Manufacture |
| › Clinical Trial Manufacturing and QC Release (GMP) | › Development and Manufacturing of Intermediates and Finished Drug Products Containing HPAPIs with OELs as low as 0.01 µg/m3 |



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State-of-the-Art Facilities & Engineering Safety Controls

Quotient Sciences has heavily invested in specialized facilities in both the UK and US to provide the necessary containment, engineering controls and personnel protection needed to safely handle these types of compounds and to prevent cross-contamination. Our state-of-the-art manufacturing facilities have undergone multiple EH&S safety audits to ensure that they meet cGMP compliance standards and have been inspected by several major global regulatory agencies. Our risk management program includes ongoing environmental health monitoring and surrogate monitoring to ensure consistent control over our processes, facilities, cleaning procedures, and SOP's.

Quotient Sciences' Banding System

In order to protect the integrity of the drug product, as well as the safety of the environment and our personnel, we evaluate the potency of an API, by following the guidelines established by the Performance-Based-Level of Exposure Classification (PBLEC) system. A compound's categorization is risk-based and takes into consideration the safety/toxicology data available, which could be limited in the early stages of development, and aligns it with the appropriate occupational exposure range. At our global facilities, we are able to handle PBLEC levels 1 through to 5 dependent upon the type of compound, dosage form, manufacturing process and batch size required.

Key operational features include:

- > Multi-Purpose Manufacturing Facilities with Isolated, Single Pass HEPA filtration airflow
- > Interlocked Personnel and Materials Flow Airlocks
- > Flexible Containment Enclosures for Manufacturing Equipment
- > Walk-in Extract Booths in GMP Suites & Development Labs
- > Stationary & Portable Glove Boxes for Documentation
- > HEPA Vacuum and/or Dust Extract Arms for Dust Control
- > Highly Regimented Safety Protocols
- > Redundant Procedural Controls to Ensure Operator Safety
- > PPE's, Respiratory Protection and Specific Gowning/De-gowning Requirements
- > Air/Mist Showers for Decontamination



OEL Range	>1000 $\mu\text{g}/\text{m}^3$	100 – 1000 $\mu\text{g}/\text{m}^3$	10 – 100 $\mu\text{g}/\text{m}^3$	1 – 10 $\mu\text{g}/\text{m}^3$	<1 $\mu\text{g}/\text{m}^3$
PBLEC Category	1	2	3	4	5

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Quotient Sciences

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