

## **Onyx Scientific Grows API GMP Synthesis Contract Chemistry Services**

*Expert in development stage API production, outsourcing chemistry services organisation Onyx Scientific, manufactures high value intermediates and APIs to GMP-compliant standards for both phase I and phase II clinical studies.*

*In addition to GMP synthesis and scale up, Onyx Scientifics' breadth of services include solid-form polymorph investigation, salt selection, custom synthesis, process development and lead optimization.*

April 8, 2010 (FPRC) -- Internationally renowned, contract research organisation Onyx Scientific, is pleased to announce the growth of its GMP synthesis services for development stage APIs (Active Pharmaceutical Ingredients).

Good manufacturing practice (GMP) compliance is an international requirement for the manufacture of medicinal products for human and veterinary use. Compliance ensures medicinal products are produced safely and correctly.

Among the first of its type to be approved by the UK Medicines and Healthcare Products Regulatory Agency (MHRA, equivalent to the US FDA), Onyx Scientific manufactures high value intermediates and APIs to GMP-compliant standards for both phase I and phase II clinical studies.

Commenting on the success behind their GMP growth, Onyx Scientifics' CEO Dr Tony Flinn credits the result to 'a highly responsive team of chemists, able to bring a GMP process down the cost curve by suggesting alternative chemical pathways to develop an API product. We excel at difficult-to-synthesise API chemistry. Quality driven GMP services, speed, and IP confidentiality differentiate us as a trusted outsourcing partner. Our world-class GMP capability is founded in state-of-the-art pharmaceutical science, process understanding, control methodologies and open communication - capabilities that position Onyx Scientific as well placed to serve major pharma in its transition to navigate the emerging 'patent-cliff' and 'off-patent APIs' and innovative biotech companies'.

Following a major round of capital expenditure in 2008, Onyx Scientifics UK based facility boasts dedicated GMP kilo laboratories for API production and flexible isolation rooms for intermediate scale GMP synthesis. The facility includes a class 100,000 clean room and a variety of vessel sizes up to 100 litres, enabling complete technology transfer to manufacturing scale and access to an extensive range of analytical services with expert regulatory guidance provided as standard.

The Onyx Scientific service model provides both dedicated FTE and fee-for-service resources, with full transparency and flexibility to switch resource on and off as needed even at short notice.

Recognised as the preferred CRO for pharmaceutical outsourcing, Onyx Scientific has developed and made over 60, individual, GMP-compliant APIs for European and US clients. They enjoy the enviable reputation as one of the hardest working chemistry service providers in the industry with best-in-class dedicated project management to harmonize:

Communications protocols  
Selection of the starting materials  
Mapping of critical manufacturing steps  
Process parameters and controls for product quality  
Capacity to reduce or remove impurities  
Assessment of process robustness  
Proof that methods are suitable for validation and scale up  
Identification and control of critical intermediates  
Certificates of analysis

In addition to GMP synthesis and scale up, Onyx Scientifics' breadth of services include solid-form polymorph investigation, salt selection, custom synthesis, process development and lead optimization.

MHRA certified and conforming to international GMP standards, Onyx Scientifics' state-of-the-art facility delivers peace-of-mind that all outsourced chemical services comply with Good Manufacturing Practice for the development of Active Pharmaceutical Ingredients.

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