

Gmp Synthesis Chemistry Services CRO, Onyx Scientific, Reports Increased Small Scale Production for Phase I and II Clinical Studies

Onyx Scientific manufacture high value intermediates and APIs to GMP-compliant standards for both phase I and phase II clinical studies.

September 2, 2010 (FPRC) -- Internationally renowned, contract research organisation Onyx Scientific, is pleased to announce the continued growth of its small-scale GMP custom synthesis services for development APIs (Active Pharmaceutical Ingredients)

Commenting on the growing success of its small-scale GMP synthesis services, CEO, Dr Tony Flinn says 'our success is due to open communication and a highly responsive scientific team, who are able to lower the cost of a GMP process by suggesting alternative chemical pathways to develop an API product'.

Denise Bowser, Commercial Director, Onyx Scientific adds, 'Newly patented APIs are driving the demand for quality GMP compliance and it's here we excel, in streamlining GMP-approved processes and difficult-to-synthesise APIs. Our compliance standards minimise impurities, reduce costs and significantly improve timelines for phase I and II clinical studies.

Denise adds. 'Onyx has earned the enviable reputation as one of the hardest working chemistry service providers with world-class GMP synthesis capability to harmonise:

- 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

Onyx Scientific's GMP kilo-lab facility boasts flexible isolation rooms, a class 100,000 clean-room and a variety of vessel sizes up to 100 litres enabling ultimate technology transfer to manufacturing scale and access to an extensive range of analytical services with expert GMP regulatory guidance provided as standard'.

In addition to GMP synthesis and scale-up, Onyx Scientific's breath of services include solid-form polymorph screening, salt selection, custom synthesis, process development and lead optimisation.

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

MHRA certified, Onyx Scientific's state-of-the-art facility conforms to international GMP standards for

the development and production of active pharmaceutical ingredients.

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