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Commercial API Manufacturing

Onyx Scientific is a small molecule CDMO that offers commercial API manufacturing services ranging from low kilo quantities. We are ideally suited to meet the needs of a low volume drug substance (e.g. for orphan diseases), right up to the multi-tonne quantities required for high volume commercial supply.

Flexible and responsive to each client's individual requirements

Onyx Scientific (Sunderland, UK) manufactures small molecule APIs in our six MHRA-accredited Class 100,000 laboratories, with a flexible approach that is suited to today's complex materials.

Our US sister company, Pisgah Laboratories (North Carolina), is an FDA-accredited pilot facility in the US. Pisgah provides GMP manufacturing services across three multi-purpose GMP manufacturing suites up to 2,000 gallons / 8,000 litres and is ready to manufacture the larger quantities needed for many projects.

When scaling up a project, we offer dedicated scientists and rapid tech transfer between sites supporting our GMP manufacturing teams. Both sites have a proven track record of successfully validating processes at the required production scale and are fully supported by Onyx's quality assurance (QA) team that maintains the highest level of quality standards.

Onyx scientific, UK: Ideal for low volume commercial drug substance supply

Commercial Manufacturing Services

- Process development (QbD / DoE)
- Failure Mode and Effects Analysis (FMEA) investigations
- Analytical development
- Analytical validation
- Process validation
- Reference standard manufacture (API, intermediates and impurities)
- Commercial API manufacture, including controlled substances
- Process verification

Your molecule, our people - it's good chemistry

QbD / DoE

Quality by Design (QbD) brings a systematic approach to development. Statistical optimisation through Design of Experiments (DoE) is the main tool used to both optimise and understand the manufacturing process.

This data-driven method delivers better understanding of the manufacturing process, reducing the occurrence of batch failures, delivering proven and effective control, as well as bringing greater time and cost efficiencies.

By taking this approach we provide a robust process that will achieve a consistent and high level of quality suitable for process validation.

Pisgah Laboratories (North Carolina): For mid to high volume commercial drug substance supply.

Process Validation

Process validation is defined as the collection and evaluation of data, from the process design stage through commercial API manufacture, which establishes scientific evidence that a process is capable of consistently delivering quality product. Process qualification through a validation campaign is the method by which a process is shown to be under control and capable of reproducible commercial manufacturing.

A validation master plan is written at the start of the validation project and defines the scope and goals of the overall validation project. A pre-approved validation protocol is written per stage which details the pre-requisites required ahead of validation batches (e.g. Equipment DQ, IQ, OQ, analytical method validations) and the criteria that must be met for successful validation campaign. The results of the development and DoE work allow critical process parameters and their normal operating ranges / proven acceptable ranges to be defined with confidence.

The analytical targets identified during the development, DoE work and purge studies are also included as these will be used demonstrate that a process is under control. At least three consecutive validation batches are nominated, although a five-batch campaign is recommended to allow for commissioning, especially if the material has not been synthesised at this scale previously. A validation campaign is then carried out and completed successfully if the nominated batches achieve the pre-defined criteria. The key to success at this point is to ensure a thorough understanding of the process has been achieved in the earlier work.

Once validation is complete continued process verification is performed with trend analysis used to identify problems early and ensure the process stays under control.

Contact us

Commercial Director

Chris.Atherton@onyxipca.com
+44 (0)7733 370 732
+44 (0)191 516 6518

Sales UK/EU

Matthew.Coleman-Ware@onyxipca.com
+44 (0)7379 041 994

Sales US

Anthony.Harbour@onyxipca.com
+1 315-385-9666

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