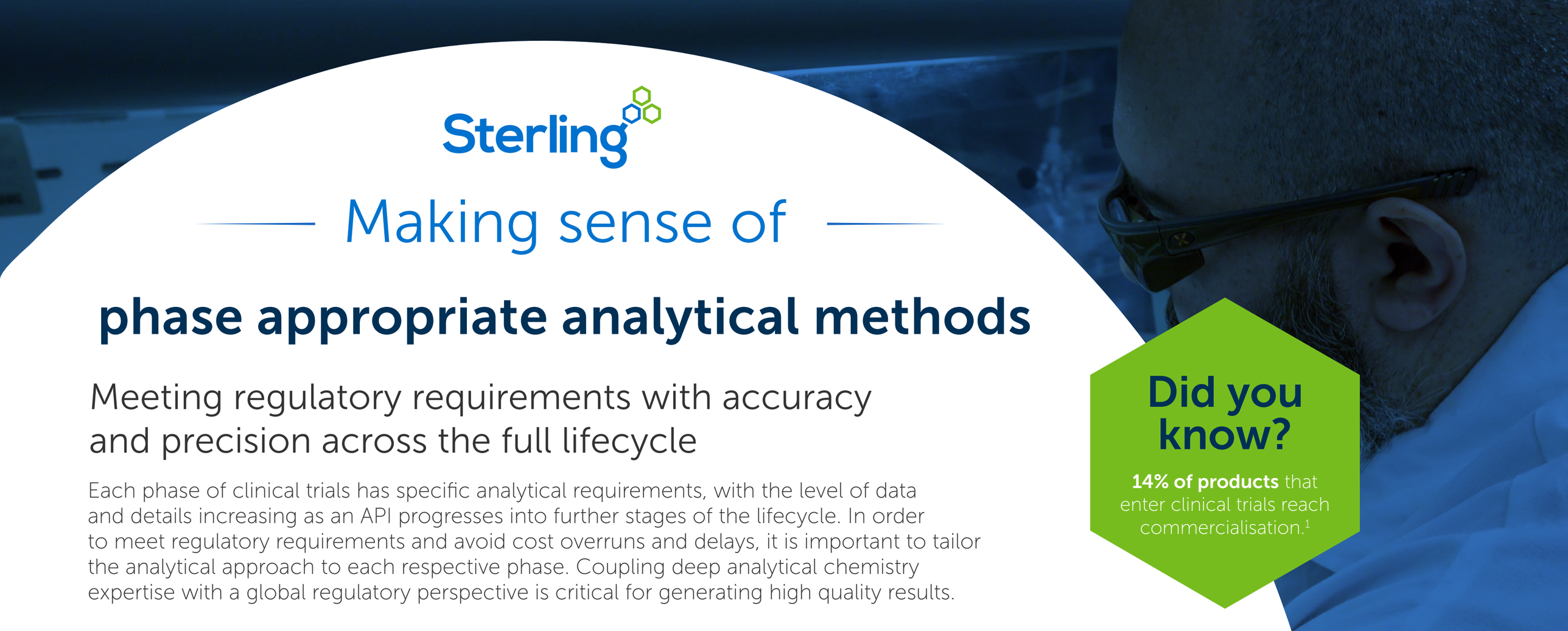
Making sense of

phase appropriate analytical methods

Meeting regulatory requirements with accuracy and precision across the full lifecycle

Each phase of clinical trials has specific analytical requirements, with the level of data and details increasing as an API progresses into further stages of the lifecycle. In order to meet regulatory requirements and avoid cost overruns and delays, it is important to tailor the analytical approach to each respective phase. Coupling deep analytical chemistry expertise with a global regulatory perspective is critical for generating high quality results.



Did you know?

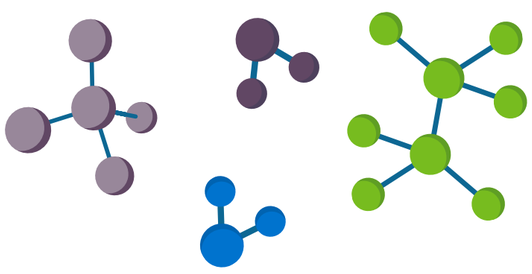
14% of products that enter clinical trials reach commercialisation.[1]

Analytical methods and the importance of a phase specific approach

Given that only a small proportion of products that enter clinical trials reach commercialisation, organisations want to avoid overspending on analytical work in the earliest phases of their project. However, they must also reach the core analytical validation criteria required at each stage, as well as generate quality results for their own benefit. **Having a stringent focus on the necessary quality and regulatory requirements at each phase can allow organisations to progress through clinical trials as efficiently as possible while ensuring regulatory compliance.**

How should you tailor your analytical approach at each phase?

To enhance efficiency, contain costs, and ensure regulatory success, a tailored approach to analytical method development is critical. **Let's take a closer look at each phase of the pharmaceutical lifecycle and the analytical standards that should be applied at each.**



Preclinical

Before clinical trials begin, there are no formalised data requirements from a regulatory standpoint. At this stage, it is important to achieve reliable results using scientifically sound analytical methods.

Phase I

During Phase I, official regulatory requirements begin, as the target molecule is given to small groups of healthy individuals. Analytical protocols and reports are formulated in a memo style and reviewed from more of a technical standpoint than a quality one. Methods should be scientifically sound and fit for purpose.

Phase II

Testing in Phase II is similar to Phase I, but becomes a more formal exercise. Specific analytical methods are defined in advance, and the protocols and reports go through a full quality assurance review. Testing during Phases I and II cover the core method validation characteristics, with more characteristics evaluated during Phase III and commercial level validations.

Phase III

In Phase III, the level of formality increases further, and organisations expect to reach commercialisation at this point. While only proof that methods can be validated is required, many organisations choose to perform full analytical validation at this phase to avoid repeating upon commercialisation. This phase involves a more formalised validation approach, including demonstrating method performance across an expanded range of validation characteristics.

Commercialisation

Full analytical validation is necessary once a product reaches commercialisation. Robustness testing is included to stress test the method by systematically altering method parameters to ensure the method performs under a broad range of operating and environmental conditions. Testing is performed by multiple analysts and multiple instruments to ensure accurate, reliable results can be achieved repeatedly as product reaches the market.

Collaborative partnership to exceed your analytical validation needs

At Sterling, we have experience performing analytical chemistry work for biotechnology and pharmaceutical organisations spanning different sizes and regions. As a result, we deliver the flexibility necessary to adhere to regulatory guidelines for all of our customers, while tailoring our validation approach to the customer's specific needs. Our familiarity with regulatory guidelines around the world and our expertise in analytical chemistry enable us to adapt our approach and make life easier for our customers.

Service

We pride ourselves on being easy to do business with, removing layers of complexity, maximising flexibility and adaptability to your requirements, and doing what we say we will do, again and again.

Passion

We promise to treat your molecule as our own, drive progress by continually exploring new and emerging capabilities, and do the right thing for our people and planet.

Science

We combine our expertise in complex and hazardous chemistry, our world-class facilities and our full-lifecycle capabilities to place scientific excellence at the core of every solution we deliver.

Are you ready to elevate analytical method development?
Visit www.sterlingpharmasolutions.com to learn more.

1. Hale, C. New MIT Study Puts Clinical Research Success Rate at 14 Percent. 5 February 2018. WCG CenterWatch. Retrieved from https://cms.centerwatch.com/articles/12702-new-mit-study-puts-clinical-research-success-rate-at-14-percent