

## About Hart Biologicals

Hart Biologicals are involved in all areas of coagulation and platelet aggregation and have built an extensive global network of distributors from South America to Asia.

As an agile, responsive company, Hart Biologicals react quickly to the needs of our partners and dedicate our expert teams to the execution of projects as they develop.

Our partners choose Hart Biologicals because we recognise that each customer has a different need, a different question, a different problem, which we address on an individual basis. We work with, rather than for, our partners to provide a highly personal level of support, help and advice.



## Partner With Us Contact Your Team



Quality



Accounts



Operations



Research



Servicing

E: [info@hartbio.co.uk](mailto:info@hartbio.co.uk)

T: +44 (0) 1429 271100

Learn more on our website:

[hartbio.co.uk](http://hartbio.co.uk)



## Partners in Haemostasis Testing Effective Reagent Solutions





Quality Assurance

# Committed to Quality

Hart Biologicals is certified to **ISO13485:2016**. We have extensive experience in executing the manufacturing process, from design to point of sale, within all relevant guidelines, including **EU IVDR** and **FDA CFR 820.2**. By working with Hart Biologicals you ensure that your products are ready for CE marking, and a rapid, safe launch onto the market.

Hart Biologicals has extensive experience of placing products onto the worldwide market. We can ensure all necessary registrations are in place to accelerate time to market for our partner's products.

Validation can be carried out on site, allowing a smooth transition from design, through to full-scale production. Documents to complete validation and comply with the IVD regulations can be provided by Hart Biologicals. Our QC department can also provide any required testing.

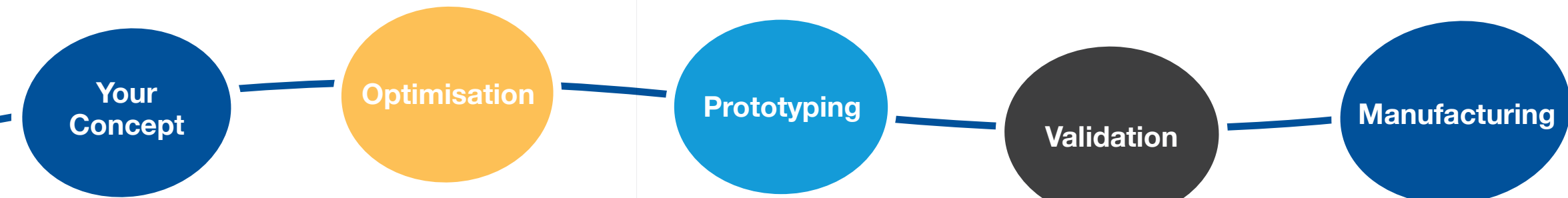
Our Quality department is dedicated to providing our partners with a bespoke service, working with you to ensure that all product and regulatory needs are met, and ensuring the correct documentation is available throughout the entire process.

**You can be confident that with our help, you will be able to demonstrate safe compliance within all necessary regulations, for all stages of the product life-cycle.**



# Bespoke, Responsive Solutions

Partner with us at any stage of your journey



Our solution-driven R&D team will work with you to define your problem or query, and capture specific project needs.

We'll work with you to optimise your design or concept, and adapt to your specific parameters, specifications and desires.

We work up from small-scale research batches to full-scale manufacturing and use our extensive product knowledge and scientific background to increase efficiency and reduce wastage during production.

Our expertise enables us to provide product validation, international regulatory support, and preliminary process and clinical validation activity, for full life-cycle support.

By working together, we can make things happen. Having a team of experts on hand to deliver your product is an investment in its future success.