



Agarose Bead
Technologies

Custom services
The perfect resin for your application



Custom chromatography resin development



The most suitable raw material is not always an off-the-shelf one. In the production of agarose chromatography resins, a lot of parameters have to be considered and they are usually fixed by the resin manufacturer, not the affinity resin creator or end user. The end user has to adapt his process, therefore sometimes accepting limited performance.

In view of this need for adaptable products and based on our technical expertise, Agarose Bead Technologies (ABT) works to combine high resolution and high capacity for custom chromatography resins which are tailored to each specific process requirement.

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We work in close collaboration with end users to design, develop, and manufacture the most suitable resin for each purpose.

Custom resin development includes the use of Design of Experiments (DoE) to define the resin-manufacturing process required for your purification needs. DoE screening includes pore size, bead size, binding capacity, and coupling chemistry to optimize performance for your biomolecule.

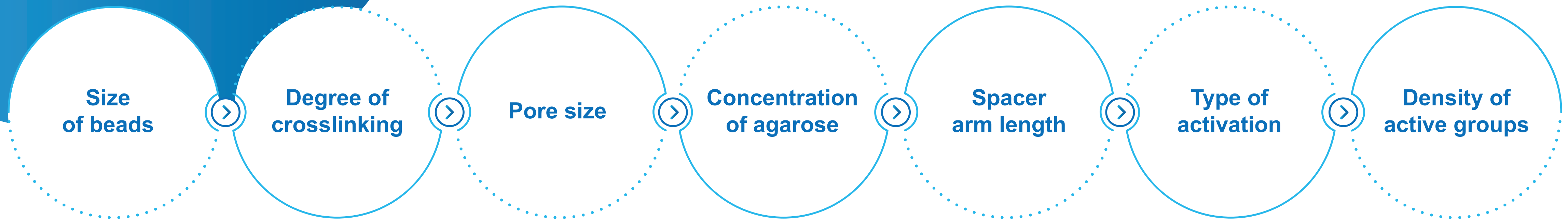
All process validation and regulatory requirements are fully supported by an ISO 9001:2015 Quality Management System.

A full service contractor



Parameters that can be specified are:

The product range for agarose resins on the market is driven by the most common R&D and production requirements. At ABT, we recognize that there are many specialized applications which are not currently served, and many separations which could be improved by a more appropriate bead. ABT offers customized resins to extend the range of performance by controlling certain parameters.



IN ORDER TO PRODUCE EXACTLY WHAT YOU REQUIRE,
OUR TEAM WILL WORK CLOSELY WITH YOURS AND
SHARE TECHNICAL DETAILS AS APPROPRIATE.

ABT's custom-made resins are now available to cover all of your purification needs (R&D to bioprocessing customers), making it possible for you to choose the specifications for your resin at an affordable price.


Custom services program



Phase 1

PROJECT STARTS.

Technical discussion and development plan definition



A custom manufacturing process requires a closer communication between manufacturer and customer. Therefore, to generate the needed trust, the process starts by signing a Non-Disclosure Agreement (NDA) to protect mutually information exchange.

In this phase, the Target Product Profile (TPP) would be defined by the customer and together with the team, would describe the scope of bead characteristics that will be examined to try and achieve the TPP. This is called the Development Plan. At this step the customer will provide information about the volume and timing requirements of the requested prototype as well as define the quality parameters.

Phase 2

EVALUATION OF THE VIABILITY.

Prototype & product's quotation



The information related to TPP and Development Plan will be evaluated by the team in charge of the project. All technical and economic aspects that would affect the project's viability will be evaluated at this stage.

If the project is viable, ABT would send the customer a quotation for the prototype (minimum quantity for trials) and a bulk price estimation. In addition, ABT will provide the customer's time frame information for the prototype.

A project team will be assigned to each project focusing on progressing projects at the suitable timing.

Custom services program



Phase 3 EVALUATION OF THE PROTOTYPE

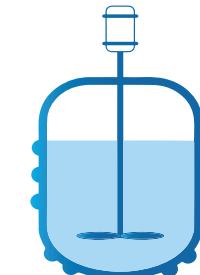


Once the phase 2 is approved, the prototype could be sent to the customer for its evaluation in 4-6 weeks*.

If the customer does not have the time/resources needed to test the prototype, ABT can quote this option as a service. Development timelines for launching a resin or using a resin in early clinical phases may be rapid. Outsourcing the preliminary testing to ensure the availability of the resin could be advantageous.

*Note: Depending on technical difficulty of prototype.

Phase 4 PRODUCT SCALE UP & QUALITY COMMITMENT



Scale up to the required lot size, process validation and developing the corresponding Regulatory Support File (RSF) are critical steps in custom resin use in manufacturing. Our quality system ISO 9001:2015 allows a quality assurance and provides the customer with traceability and batch-to-batch consistency.

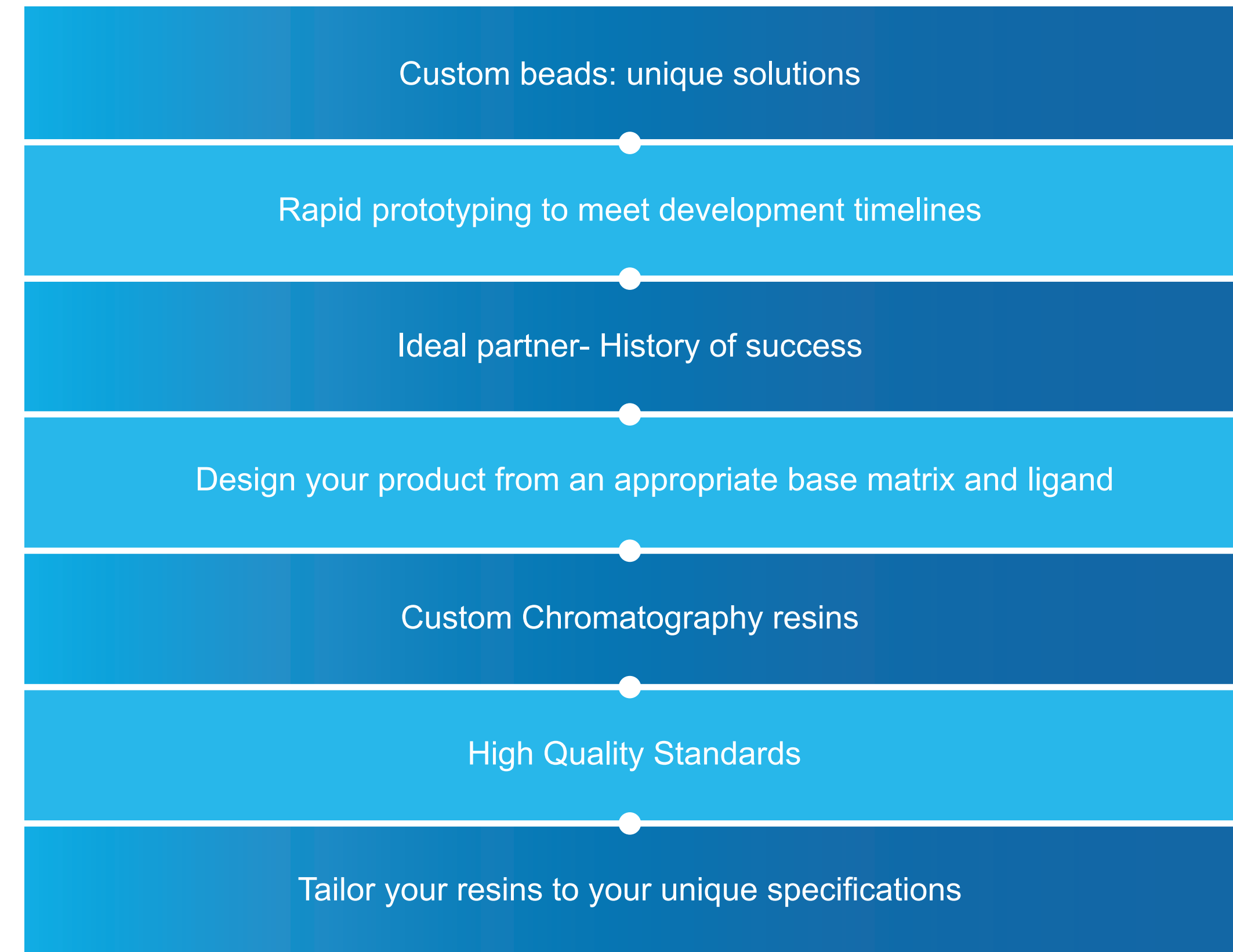
All customized resins will be manufactured following stringent quality standards to meet customer defined parameters. Once the agreed specifications are met, the product will be shipped with a certificate of analysis (CoA) stating all tested customer-specified parameters of product quality were met.



Key benefits

- Improved performance in critical manufacturing processes
- Improved purity, yield, capacity
- Partnership with resin manufacturer assuring product continuity and security of supply for affinity resin developers
- Custom resin costs can be less than sub-optimal performing commercial resins
- Suitable raw material for each application fields
- Increased resolution
- New application fields
- Improved final products and process optimizations:
 - Improved flow properties
 - Increased purity and/or yield
 - Increased binding capacity
 - Improved stability
- Competitive advantages versus competitors
- Cost and time savings

Key words





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