Biointron Launches Comprehensive Antibody Developability Assessment Platform to Accelerate Biologic Drug Discovery

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Biointron, an antibody contract research organization, launched a new developability platform that helps drug developers identify manufacturing problems early, potentially saving millions by catching issues before late-stage clinical trials.

Biointron, a contract research organization specializing in antibody discovery, production, and optimization, launched its Antibody Developability Assessment Services to help drug developers catch potential problems before they turn into expensive failures. The platform combines high-throughput antibody production with a full panel of tests that check whether candidates can be manufactured at scale and remain stable throughout their shelf life, with results delivered in three to five days per assay.

To secure an Investigational New Drug (IND) approval, pharmaceutical companies typically must provide comprehensive chemistry, manufacturing, and controls (CMC) data demonstrating that their antibody

candidates are stable, pure, and can be manufactured consistently for clinical use. Late-stage development delays are often attributable to manufacturing and quality issues that just weren't caught in time. These challenges, including issues with product stability, impurity characterization, or process scalability, often only become apparent during large-scale manufacturing, highlighting the importance of early Antibody Developability Assessments to mitigate regulatory and operational risks. The antibody optimization services market hit approximately USD 3 billion in 2025 and keeps climbing by more than 8 percent annually, based on industry tracking data.

For more information visit https://www.biointron.com/

Biointron's platform tackles this challenge by systematically testing key factors that determine whether an antibody will succeed in manufacturing. The service evaluates thermal stability, self-interaction tendencies, hydrophobicity levels, aggregation risk, and non-specific binding characteristics. This helps biotech and pharmaceutical companies separate the winners from the long shots before they start writing big checks for preclinical work and clinical trials. The platform can analyze more than 3,000 monoclonal antibodies per batch using advanced instruments including Biacore, Carterra, and differential scanning fluorimetry systems.

Developability assessment is the systematic evaluation of an antibody candidate's biophysical and biochemical properties to determine its suitability for large-scale manufacturing and clinical administration. It's not enough for an antibody to hit its target well, it also needs to be stable enough to sit on a shelf, soluble enough to inject, and unlikely to trigger unwanted immune responses.

Biointron operates in the growing contract research services sector that supports antibody-based drug development. With an office in Cambridge, the company works with pharmaceutical companies, biotech firms, and academic research institutions across North America, Europe, and Asia. Since its founding in 2012, Biointron has maintained ISO 9001:2015 certification and delivered recombinant antibody production services to more than 3,000 biotech and pharmaceutical organizations worldwide.

Dr. Brady Wu, who leads Protein Sciences at Biointron, emphasizes that developability testing shouldn't require huge amounts of precious antibody material. The platform was designed with that in mind, each assay needs less than one milligram, and clients can choose which tests make sense for their particular candidates. Running tests in parallel speeds up timelines, while sequential testing conserves material when samples are limited. The toolkit spans everything from size-exclusion chromatography and capillary electrophoresis to specialized tests like affinity-capture self-interaction nanoparticle spectroscopy, hydrophobic interaction chromatography, dynamic light scattering, and various charge heterogeneity measurements.

The timing of this launch reflects broader trends in drug development, particularly the push to integrate

artificial intelligence with traditional lab work. Research groups have demonstrated that machine learning could eventually predict antibody manufacturability from sequence data alone, but only if the models have enough real experimental data to learn from. That's where high-throughput testing comes in, these platforms create the massive datasets that AI algorithms need to get smarter. As the technology gets better, companies might eventually need to run fewer physical tests during early discovery because the computer models will be able to flag problems before they hit the lab.

The company has invested in state-of-the-art characterization equipment that supports what's being called the AI era of biologics, tools that can handle large-scale screening with the precision that data-hungry machine learning models require. Biointron's service portfolio extends well beyond developability assessment to include affinity maturation, antibody humanization, and multiple antibody production options ranging from rapid high-throughput expression to full-scale manufacturing support. This breadth lets clients stay with one provider as their candidates move from discovery through the detailed manufacturing and quality work that regulators expect to see.

Biointron?s Cambridge office sits at the heart of one of the world's most active biotech ecosystems. The area has become home to numerous organizations specializing in different aspects of antibody therapeutics, from discovery to manufacturing to quality testing. This geographic concentration isn't accidental. It creates natural partnerships between contract research firms, drug developers, and universities, making it easier to tackle complex development challenges through collaboration rather than going it alone.

Companies developing more complex antibody formats, like bispecific antibodies that hit two targets at once or antibody-drug conjugates that deliver toxic payloads directly to cancer cells, face even tougher manufacturability challenges. These modified structures can introduce stability problems, solubility limitations, or aggregation tendencies that don't show up in standard antibodies. Early testing gives companies real choices. They can tweak the antibody structure to fix the problem, switch to a backup candidate that looks more promising, or at minimum go in with eyes wide open about the challenges ahead, all before spending millions on late-stage development.

The new service adds to Biointron's growing portfolio of solutions that cover the entire antibody development pathway, from initial discovery through manufacturing readiness. With production facilities in Shanghai, Nanjing, and Taizhou, Biointron can scale up or down depending on what a project needs.

ABOUT BIOINTRON

Founded in 2012 and certified to ISO 9001:2015, Biointron is a CRO specializing in antibody discovery, expression, and optimization services for biotech and pharmaceutical companies.

Biointron holds a leading position in the antibody expression service industry. From gene sequence to purified antibodies, our production only takes 2 weeks. We have delivered tens of thousands of recombinant antibodies for more than 3,000 biotech and pharma companies worldwide.

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