ProtaGene
Analytical Excellence

SOLUTION BRIEF

Antibody-Based Therapeutic Development Made Easy

Driven by the demand for advanced targeted drug therapies to address the global increase in cancers and autoimmune diseases, the antibody therapy market is continuing to thrive. Specifically, the anticipated worldwide compounded annual growth rate for monoclonal antibodies (mAbs) and antibody-drug conjugates (ADCs) through 2028 is more than 13 percent.[1]

While the future is promising, developers are challenged to effectively manage the analytical resources required to efficiently move the escalating number of needed new biological entities (NBEs), many of which address smaller patient populations, through the development pipeline. ProtaGene's comprehensive capabilities and expertise are positioned to help developers navigate the development process with dedicated CMC Molecule Managers and a long history of analytical excellence.

The Challenges

The rapidly expanding antibody therapeutics sector is accompanied by a range of notable complexities, including:

Limited In-house Analytical Capacity

Many pharmaceutical organizations' pipelines are flush with Immunoglobulin G-based monoclonal antibodies (IgG) targeting cancers and autoimmune diseases. The specificity of many of these therapeutics requires more candidates, often severely straining in-house analytical resources.

Accurate Capacity Planning

As understanding and methods improve, more NBEs than forecasted often advance to Phase III studies. While a good problem, late-phase Chemistry Manufacturing Control (CMC) requirements are more demanding of analytical resources, potentially becoming a bottleneck, delaying time-to-market.

Unpredictable Molecule Behavior Requires Specialized Expertise

While most antibody assays are platform in nature, some molecules don't play by the rules. These molecules typically require more analytical resources than planned, further increasing demands on analytical teams.

Insufficient Understanding of Acquired Assets

As larger pharma organizations secure early-phase candidates through licensing, acquisitions, or mergers, the analytical packages accompanying these assets are often incomplete, requiring unanticipated analytical resources.

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The Solutions

ProtaGene is a solutions-based analytical R & D partner with extensive expertise in advanced method development, early to late-stage characterization, GMP product testing, and complete analytical packages for an antibody therapy's entire lifecycle.

Expertise, Capabilities, and Capacity That Flex with Your Needs

Innovators often need access to extensive antibody therapeutic development experience, expertise, state-of-the-art capabilities, and scalable capacity. We provide scientific expertise and expanded capacity, allowing us to serve as a seamless extension of your analytical team.

Documentation and Regulatory Filing

Our comprehensive regulatory knowledge and dedication to quality in assay protocols and data management allow us to smoothly navigate assets through regulatory processes from pre-Investigational New Drug Application (IND)/Investigational Medicinal Product Dossier (IMPD) to Biologics License Application (BLA)/Marketing Authorization Application (MAA) with market approval.

State-of-the-Art Analytical Capabilities

ProtaGene offers a comprehensive set of platform methods for antibody therapeutics development. 95% of the assays we conduct are off-the-shelf.

However, we have experience with many antibody subtypes, including bispecific molecules and conjugates, allowing us to customize approaches for a given molecule when required.

Robust Analytical Capacity

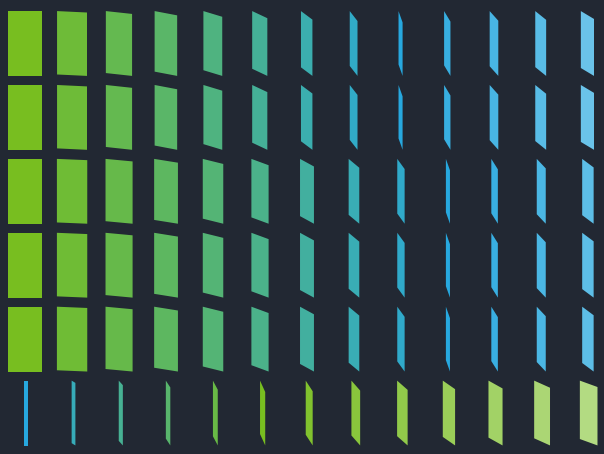
With state-of-the-art labs and advanced quality systems in Burlington, Massachusetts, USA, and Dortmund and Heilbronn, Germany, ProtaGene provides extended analytical capacity for our international clients.

Full Lifecycle Molecule Management

We manage the development of molecules, not merely individual projects. Our CMC Molecule Managers have strong technical backgrounds and a comprehensive understanding of the drug development process, serving as extensions of your analytical team from molecule to market.

Molecule Managers oversee the analytical data package needed for regulatory filings, provide timely and transparent insights relating to analytical trends negatively impacting critical quality attributes, and foresee project risks and analytical package gaps.

CMC Molecule Manager



"ProtaGene's team of CMC Molecule Managers are highly experienced, and our proactive approach allows us to lead projects and collaborations in a manner that serves as highly effective additions to our clients' analytical teams. Working hand-in-hand with our clients, we address critical challenges, create mitigation plans, and shepherd their molecules through the development process, shortening time to market."

André Abts,
Vice President Project Management CMC, ProtaGene

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Full Analytical Service Support from Research to Market

ProtaGene delivers customized full-service analytical packages to support each phase of development from Research to Market to successfully enable clients to achieve their product development aims. A flexible and experienced CMC Molecule Manager from our team coordinates each collaboration and facilitates rapid and seamless integration of results into purposeful data packages that fit smoothly into client workflows to support decision-making and regulatory filings.

Discover how ProtaGene can support your development programs and consult with our team today. Email us at info@protagene.com and let's start a conversation about your specific needs and how we can assist you in achieving your goals.

	Research and Preclinical	Clinical Development	Commercialization
AIMS	Selection of best development candidate	Definition of final analytical specification	Continuous market supply
	Production clone selection and platform process adaption	Process validation for market	Maintenance of analytical method panel
	Definition of Analytical Target Profile (ATP) and Critical Quality Attributes (CQA)	Extended Characterization of variants and impurities	Bridging studies for outdated methods post-market
	IND/IMPD for Phases I and II	BLA/MAA	Root cause investigations in case of out of specification (OOS) risks
Solutions	Developability assessment	Analytical support of Process Design Studies (PDS)	Continuous release testing
	Analytical process support	BLA/MAA enabling analytical packages including extended Forced Degradation Studies (FDS)	Analytical lifecycle management
	Complete analytical panel for release, stability and characterization	Release analytics and shelf life stability testing	Evaluation of process parameter influences on changed or trending product quality attributes
Specialty Expertise	Mass Spectrometry (MS) based structure-function-relation analysis	Analytical experiences for all kind of monoclonal antibody formats including bispecifics	Analytical release panel with MS as Multi-Attribute Method (MAM)
	CQA definition based on experience and *In vitro* analysis	Expertise in isolation and characterization of product-related variants and impurities	Release testing by Edman sequencing
	High throughput clone selection analysis	*In vivo* CQA analysis of Drug Substance (DS)/ Drug Product (DP) samples	Experiences with multi-site and multi-country method transfer

Reference:

1. https://www.gminsights.com/industry-analysis/antibody-therapy-market

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