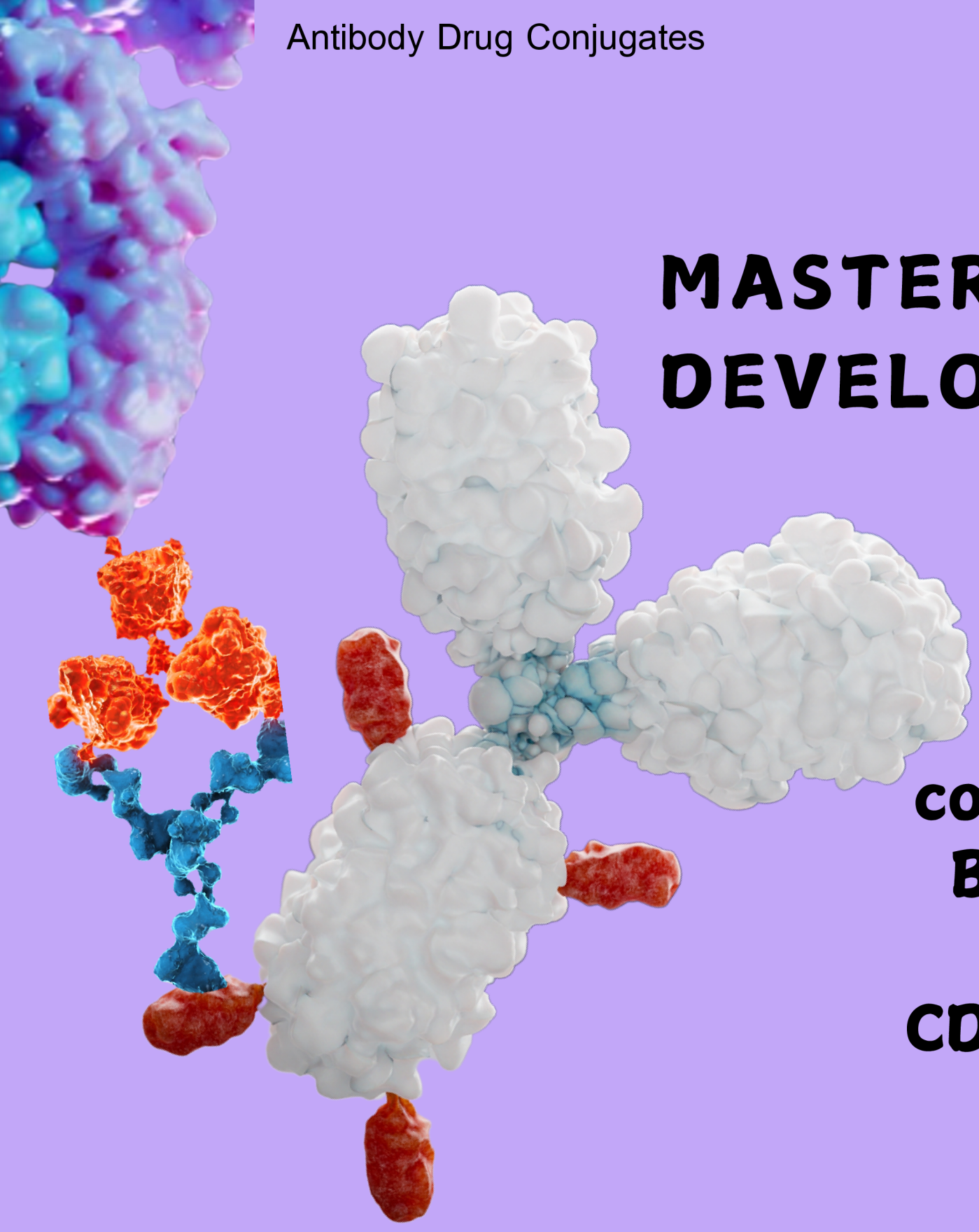
Antibody Drug Conjugates

DR.HOTHA'S
LIFE SCIENCES LLC



MASTERING ADC'S DEVELOPMENT

Essential considerations for Biotech Success with CDMO Partnerships

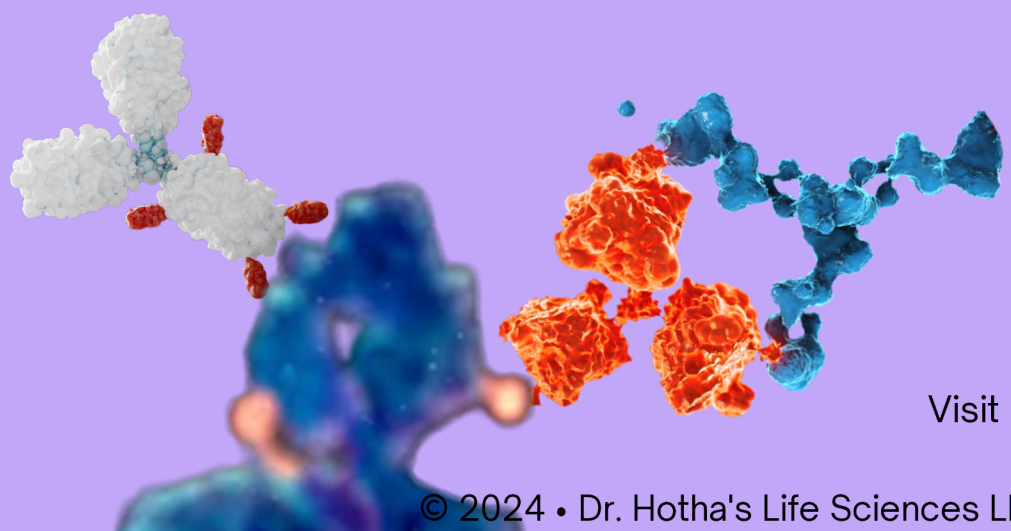
Kishore Hotha, PhD, MBA

Visit us: drhothas.com

Safety at the Core: Handling High-Potency Payloads with Care

Safe handling of ultra-potent cytotoxics with expert toxicology assessments.

ADC development involves handling highly cytotoxic payloads that demand strict safety measures. Partner with a CDMO equipped with safety certifications(ex: safebridge) and in-depth toxicology expertise to accurately assess exposure risks. Look for containment capabilities like isolators, negative-pressure rooms, and specialized training for personnel. This not only safeguards your team but ensures uninterrupted progress, keeping your project on track and compliant with regulatory requirements.

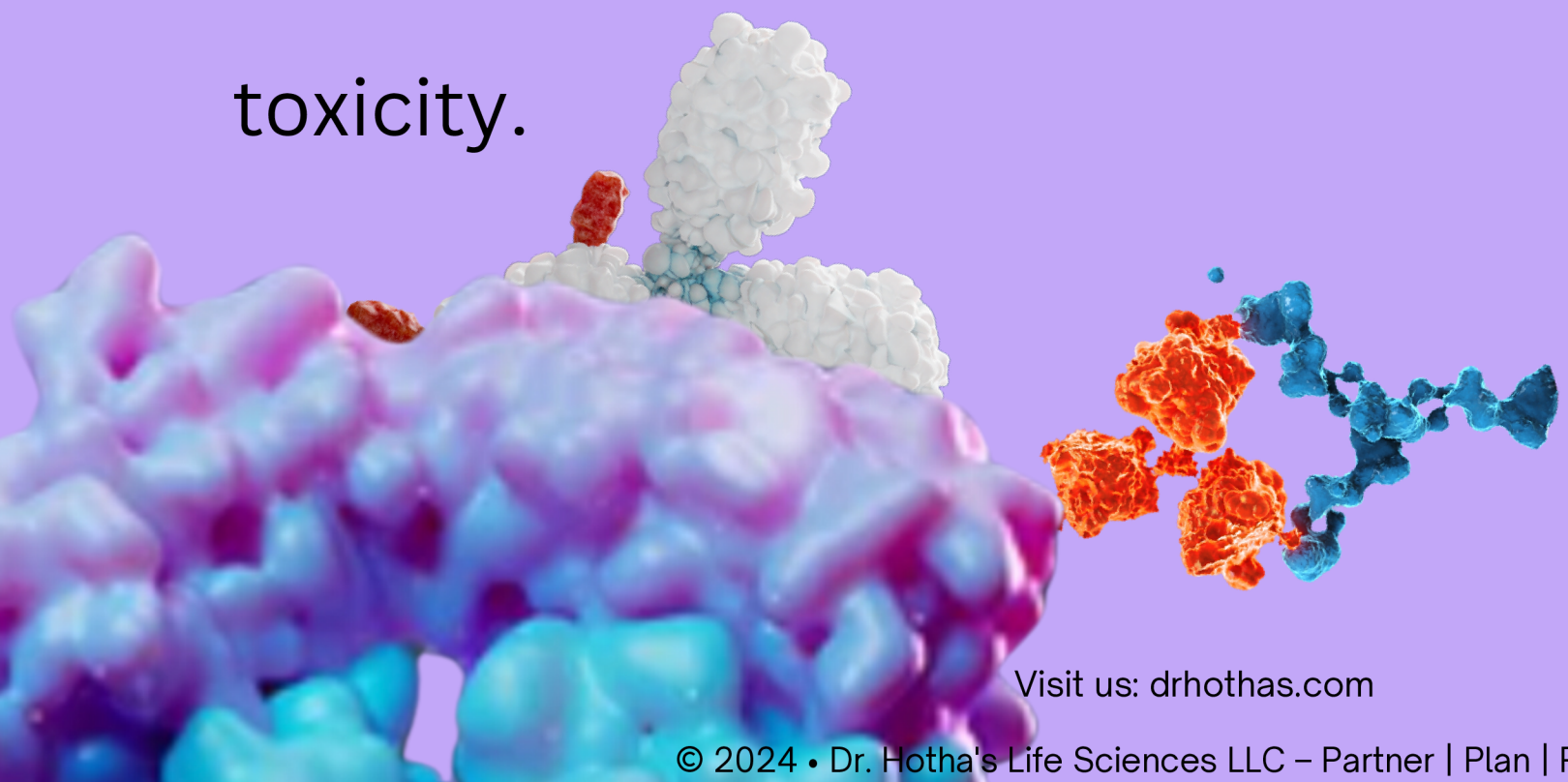


Visit us: drhothas.com

Bioconjugation Brilliance: Get DAR Right

Achieving a consistent Drug-to-Antibody Ratio (DAR).

Consistent DAR is crucial for the efficacy and safety of ADCs. Look for CDMOs skilled in site-specific conjugation methods, like cysteine conjugation, to minimize variability. Expertise in DAR assessment methods and bioconjugation processes ensures your ADC remains potent while reducing off-target toxicity.

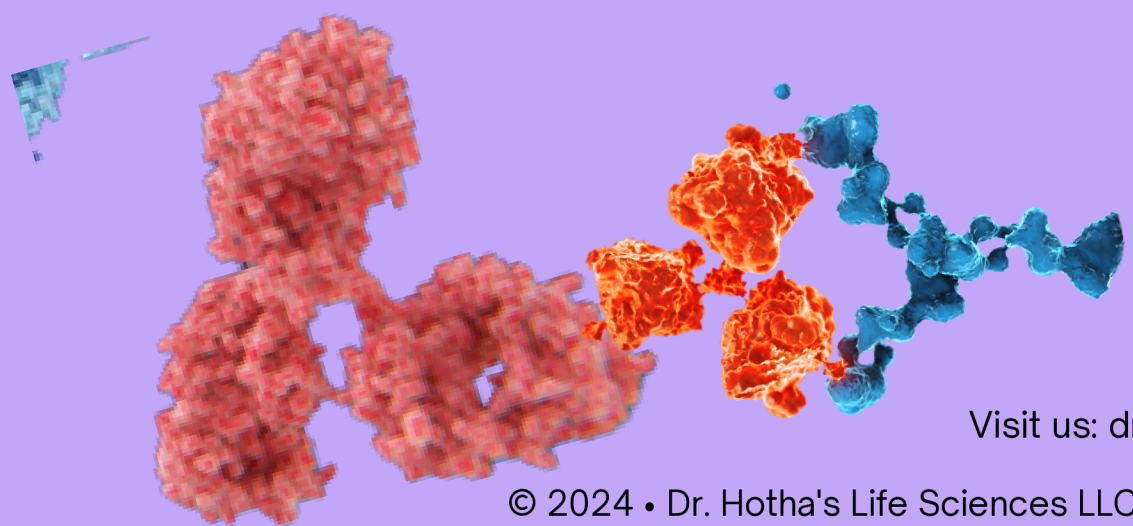


Visit us: drhothas.com

Build an Unbreakable Supply Chain

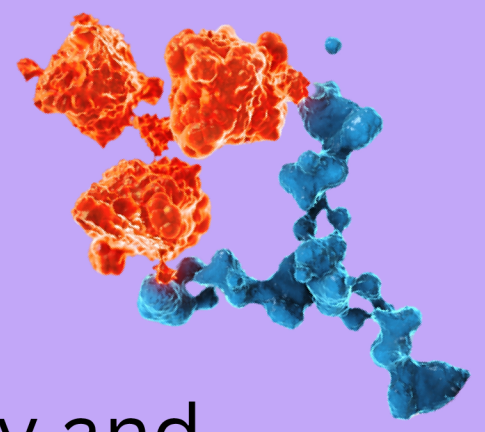
Securing key materials and avoiding delays.

ADCs rely on specialized components, from antibodies to cytotoxic payloads. A reliable CDMO will offer a robust supply chain with risk assessments and backup suppliers, ensuring no disruptions. Their expertise in managing the supply of critical raw materials can prevent costly delays, keeping your timelines intact.



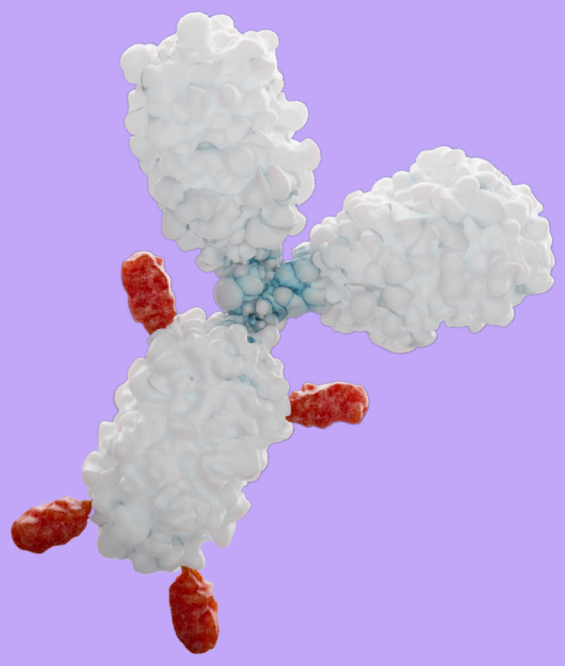
Visit us: drhothas.com

Linker Chemistry: The Key to Precision Release



Stability and selective payload release.

The linker in an ADC controls the stability and release of the cytotoxic payload at the target site. Cleavable or non-cleavable? Your CDMO should have expertise in synthesizing linkers tailored to your drug’s pharmacokinetics.



A proven track record in optimizing linker-payload interactions can make a significant difference in achieving the desired therapeutic outcomes.

Visit us: drhothas.com

Purification: Where Quality Meets Precision

Removing unwanted aggregates and free drug.

Purification is a major challenge due to the complex nature of ADCs. CDMOs with a proven ability in HIC and SEC techniques ensure high purity by effectively removing aggregates and unconjugated payloads.

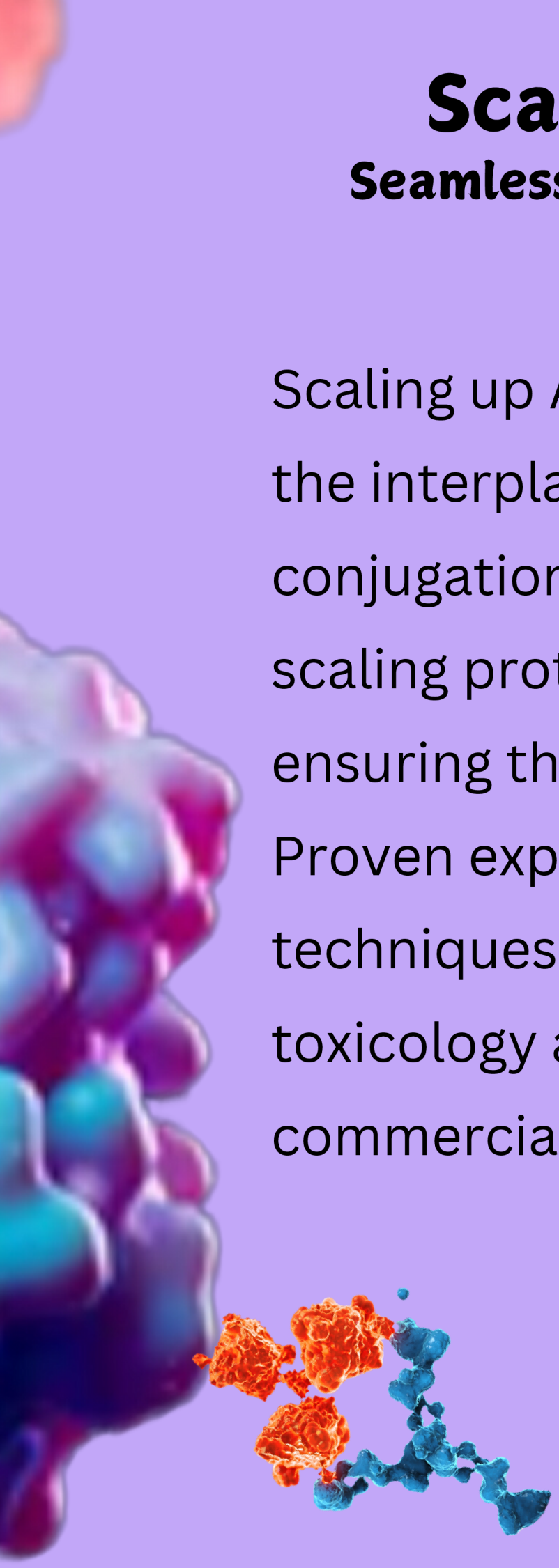
Their experience with purification methods translates into better product stability and safety profiles, vital for regulatory approval.

Visit us: drhothas.com

Scale Without Sacrifice

Seamlessly expanding from bench to batch

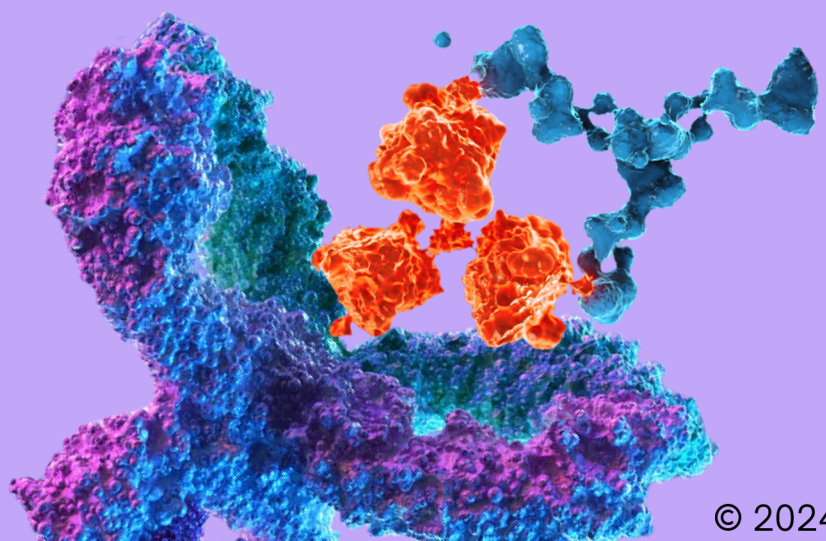
Scaling up ADC production is challenging due to the interplay of biologics and chemical conjugation. Choose a CDMO with validated scaling protocols and in-line monitoring systems, ensuring that product consistency is maintained. Proven experience with process intensification techniques and the ability to conduct scaled toxicology assessments is crucial for smooth commercial transitions.



Don’t Let Cold Chain Break the Chain

Keeping ADCs stable during transport.

ADCs often require strict temperature control to maintain stability and prevent degradation. A CDMO with validated cold chain logistics, temperature-monitored storage, and backup systems can ensure that your ADC reaches its destination intact, maintaining product integrity from production to clinical sites.

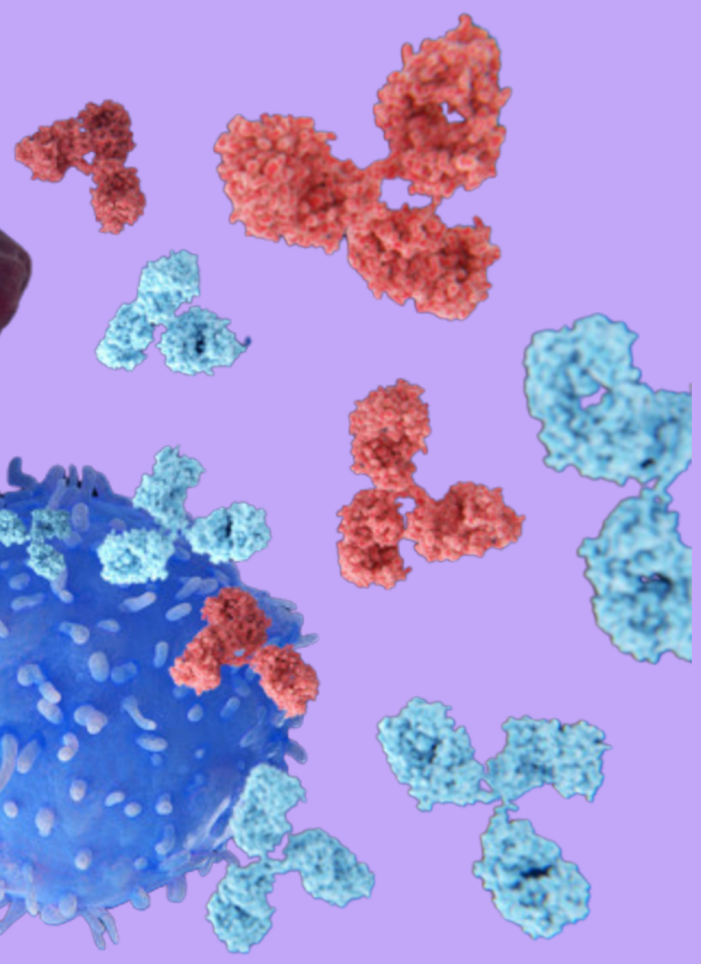


Visit us: drhothas.com

Master CMC for a Smoother Regulatory Ride

Optimizing conjugation conditions and toxicology for regulatory success.

A well-defined CMC strategy can smooth regulatory paths. CDMOs with expertise in toxicology assessments can help identify potential safety risks early on.



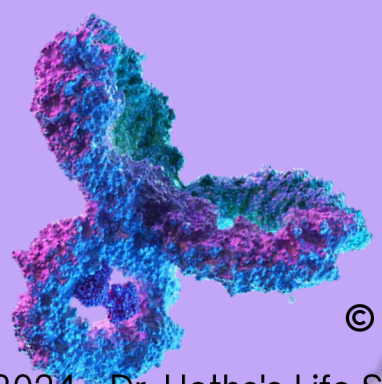
By optimizing pH, reaction times, and testing conditions, they ensure your CMC data aligns with regulatory expectations, accelerating IND submissions and ensuring faster approval times.

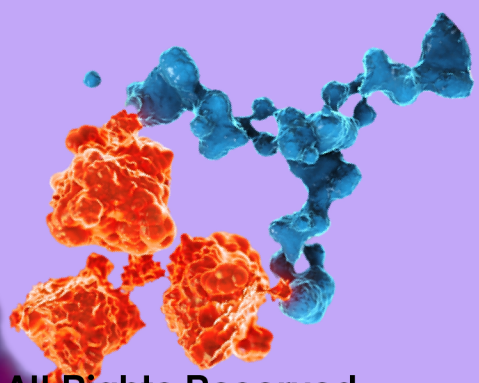
Visit us: drhothas.com

Analytical Powerhouse: Get the Right Data

Detailed characterization of ADCs.

ADCs are complex, requiring advanced analytical methods to monitor DAR, impurities, and potency. Partner with CDMOs that offer LC-MS/MS for mass analysis, HILIC for DAR profiling, and toxicological expertise to assess residual cytotoxics. This ensures that every batch meets Critical Quality Attributes (CQAs), keeping your product safe and effective.





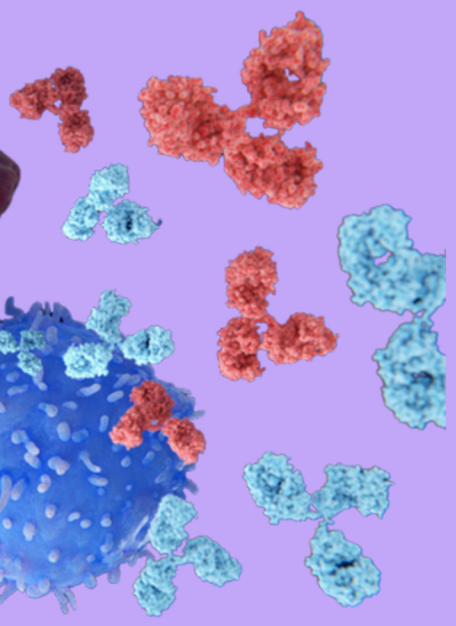
Visit us: drhothas.com

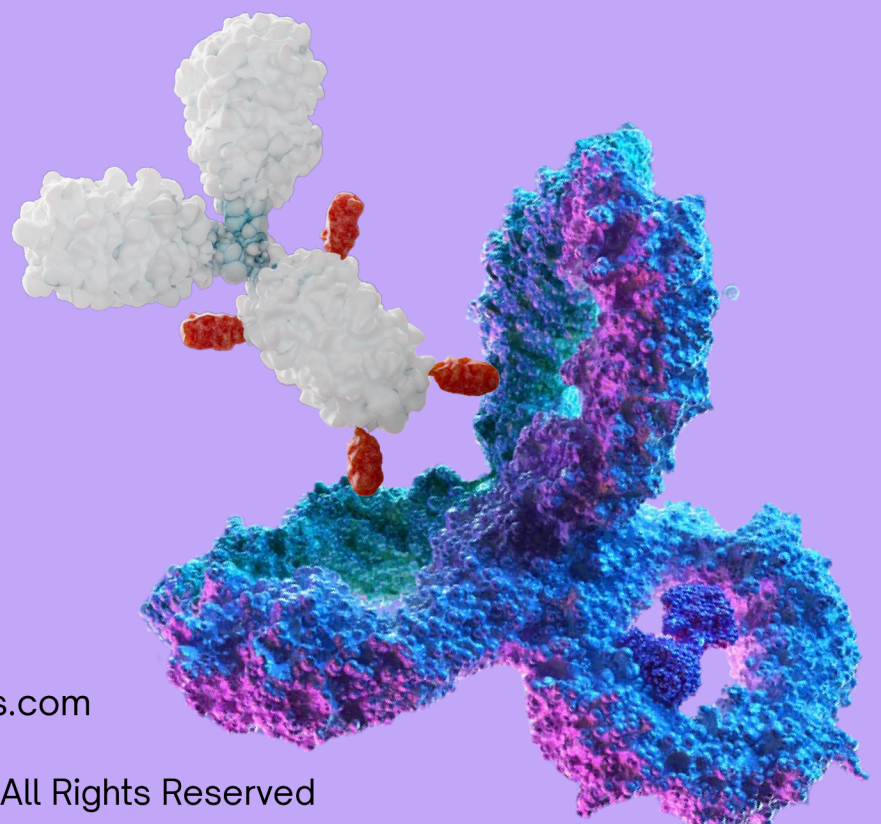
© 2024 • Dr. Hotha's Life Sciences LLC – Partner | Plan | Prosper • All Rights Reserved

Stay in Sync with the Regulatory Rhythm

Aligning early on global regulatory requirements

ADCs face unique regulatory challenges due to their hybrid nature. A CDMO experienced with FDA and EMA guidelines will guide you through stability studies, impurity analysis, and toxicology data. Early alignment on regulatory strategy avoids surprises during reviews, ensuring your IND or BLA stays on track.





Visit us: drhothas.com

DR.HOTHA'S
LIFE SCIENCES LLC

ABOUT US

Dr. Hotha's Life Sciences LLC is a Global biotech consulting firm specializing in comprehensive pharmaceutical and life sciences solutions. With more than two decades of expertise, we partner with clients to guide them through the entire drug development lifecycle—from early discovery to market entry. Our proficiency spans therapeutic areas, focusing on small and large molecules, ADCs, Oligonucleotides, and Peptides, ensuring successful outcomes for drug substances and products.

OUR MISSION

At Dr. Hotha's Life Sciences LLC, we transform complex challenges into clear, actionable strategies. Our mission is to simplify CMC drug development by providing bespoke solutions for regulatory submissions, including INDs, NDAs, and ANDAs. We are dedicated to delivering fast-to-clinic and fast-to-market strategies that maximize quality, accelerate project timelines, and meet stringent regulatory standards.

Mobile +1-978-501-4938
email: contact@drhothas.com

Visit us: drhothas.com

Complexity to Clarity Together
With a strong focus on early-phase to late-phase projects, Drug substances, and Drug products, we offer end-to-end consulting services that guide our clients through every development phase—from initial discovery to regulatory submission.

Our Approach:

Partner: We believe in solid collaborations. By partnering closely with our clients, we build tailored strategies that align with your unique goals and challenges.

Plan: We provide strategic planning that encompasses the entire development lifecycle. Whether navigating complex regulatory environments or optimizing lab operations, we ensure that your project is equipped for success.

Prosper: With our expertise and guidance, you can bring life-saving therapies to market faster, achieving sustainable growth and long-term success.