

Expertise Across Disciplines:

Meet the biotherapy professionals putting the CABP into practice

Introduction: Meeting the Moment in Biotherapies



THE CHALLENGE:

The biotherapies field has experienced significant growth. But despite many landmark discoveries and industry expansion, there is no unifying credential that signifies who is a true biotherapies expert.



THE SOLUTION:

AABB's Certified Advanced Biotherapies Professional (CABP) credentialing exam is specifically designed to fill this gap and provide a mark of distinction. The CABP validates that professionals — ranging from discovery researchers to manufacturing professionals, quality directors, regulatory specialists and practicing physicians — possess deep acumen and expertise in biotherapies. CABP recipients represent a pool of diverse, qualified and proficient professionals worldwide, ready to lead with confidence while advancing innovation, safety and quality across the field of biotherapies.





The CABP in the Field: Discovery, Preclinical and Translational Research



THE CHALLENGE:

Preclinical research conducted during early discovery stages is essential to the development of safe and effective biotherapies. It is where the scientific foundation for these therapies is established, from uncovering molecular targets to determining the most secure and clinically viable candidates for novel biotherapies. However, these early research and development stages are fraught with challenges that can impact clinical and commercial success down the line.



THE SOLUTION:

In this environment, leaders and experts must possess a thorough and unified knowledge base to help them balance the nuances of advanced biotherapies and shuttle innovative research through these early stages. The CABP credential is uniquely positioned to provide that validation.



Expert Highlight: Translational Research Linda Peltier, PhD, RN, CABPLaboratory Manager of the Cellular Therapy Laboratory Research Institute of McGill University Health Center

Linda Peltier represents a keystone in the essential bridge of translational research, responsible for supporting scientists as they shepherd their research into the clinical domain. Focused on blood-based therapies, her role requires not only an understanding of the fundamental science but also regulatory fluency and skills associated with patient care. With more than 20 years of experience, Peltier possesses a unique set of skills that make her uniquely qualified for her role. However, in the absence of standardized courses or evaluations associated with biotherapy development, her extensive expertise was hard to quantify. In the CABP credential, Peltier found a way to validate her knowledge in a constantly growing field.

66 If you are a CABP, it means you have a basic knowledge of the clinical bedside treatment in addition to the lab. That mix is required if you want to be able to find solutions when you have a problem. If you change or add something in the lab, you need to understand how it may impact your patients, and vice versa. It's not two separate things; it's a package deal. ??

Peltier also regularly works across disciplines and mentors others in her field. She's found that having the CABP credential further confirms her knowledge and competency to her peers. For her mentees, she sees the CABP exam and the material it covers as a guide for their training. If they're prepared to take the CABP exam after a few years in her lab, she'll know they're set up for success in the future.

66 Cellular therapies are the therapy of the future, but we're still at the beginning. It's a young field, and there's no one place where you can learn and evaluate the weak or strong points in your knowledge. The CABP exam gave me a view of where I'm situated. It allows me to say, 'I'm at that level.' ??





The CABP in the Field: Process Development & Manufacturing



THE CHALLENGE:

As biotherapies get closer to the clinic, speed and agility become critical. The teams working to develop processes, establish manufacturing flows and ensure quality must work with precision and urgency. In this environment, it's easy for individuals to become siloed, losing sight of the other elements of biotherapy development.



THE SOLUTION:

Having a credential that speaks to an individual's broader knowledge is highly valuable, particularly for managers hoping to hire well and advocate for their teams.



Expert Highlight: Manufacturing and CMC Amanda Conerty, CABP Executive Director, Manufacturing, Advocacy and Engagement Artiva Biotherapeutics

Experts in manufacturing are in the thick of drug development, and Amanda Conerty is no exception. As an executive director for a biotech company working on multiple cellular therapies in various stages of clinical trials, she oversees many specialized teams, including process development, analytical development, manufacturing, and materials management.

Managing such a dynamic group of individuals, each with a unique background and expertise, presents an interesting problem: it's close to impossible to rely on degrees and titles to encompass the skills they need to succeed. In fact, many individuals on Conerty's teams graduated from their degree programs before the development of modern cell and gene therapies. For individuals in manufacturing, Conerty found she couldn't point to a specific credential or degree program that confirmed her staff's expertise in cell therapy manufacturing. The CABP exam is the exception, with the right mix of rigor and comprehensive knowledge necessary to feel confident that CABPs know the field.

66 If you're in the hiring process and someone applies for a position and you see the CABP, you already know what level of background they're coming in with. > >

As a manager, Conerty also found her teams often suffered from the absence of a clear "ladder" for building their careers and preparing for their next big moves. To advocate for her teams, Conerty found a helpful partner in the CABP. If individuals on her team possess CABP, she knows it serves as an indicator of their extensive knowledge, beyond the domains indicated in their job descriptions.

66 There are career ladders and all these options for people in other fields, but not always for this one. The manufacturing lab team spends most of their time in manufacturing. They don't get high visibility, but they're so vital to the company. The CABP credential helps me showcase that expertise. I can say, 'look at these credentials they were able to get.' >>





The CABP in the Field: Process Development & Manufacturing



Expert Highlight: Quality Assurance & Supply Chain Siddarth Krishnan, MS, MBA, CABP
Associate Director, Supplier and Material Quality
ElevateBio

Siddarth Krishnan has more than 15 years of experience in the biotherapies field. While his current role is rooted in the nitty gritty of biotherapy manufacturing, he has also spent time in the research and development lab and the clinic. He found his way to the CABP exam when he realized his specialized roles had cut him off from the "bigger picture," leaving him largely siloed in his department. The CABP credential gave him a chance to show off his knowledge across teams and processes, providing proof of his broader expertise and experience.

**The science is advancing every day, and keeping track of the science is hard. You need an organization like AABB, and an exam like the CABP, to make individuals hold themselves accountable to a higher standard. **?

While the CABP is a feather in his cap, for Krishnan, validating his knowledge was just as much about proving it to himself as it was to his peers. In a field where everything is moving so quickly, acquiring a credential that is well-regarded as both robust and challenging was a boost to his confidence and an indicator that he's current with the latest innovations.

deal of confidence that I can draw on different, disparate pieces of information from different avenues of my career trajectory. All of those are relevant, regardless of where I am right now. 39





The CABP in the Field: Regulatory Affairs



THE CHALLENGE:

No biotherapy makes it to patients without the input of regulatory affairs. Operating in a fast-evolving field, the regulatory affairs community is particularly unique. Regulatory affairs professionals must possess a wide range of knowledge about biotherapies. Along with understanding the science, they require business acumen, an understanding of the legal and regulatory landscape and a connection to the patient element — particularly when working in rare disease or treatment areas with large unmet needs.



THE SOLUTION:

The CABP ensures that individuals in other disciplines can grasp the regulatory element of biotherapies, while also helping to create a standardized assessment of knowledge for professionals across the regulatory affairs field.



Expert Highlight: Regulatory Affairs

Jared Schuster, HTL(ASCP), CABP

Regulatory Affairs Specialist

NMDP (formerly known as the National Marrow Donor Program)

Jared Schuster didn't begin his career in regulatory affairs. In fact, he's spent time in almost every area of the biotherapy development lifecycle, including research, before finding himself in regulatory affairs. This unconventional progression isn't uncommon for people in this discipline, but it presents some unique challenges. In a world of PhDs and MDs, how do regulatory professionals with unconventional backgrounds make their expertise known? For Schuster, the CABP was part of the answer. While there are other regulatory certifications he could get, none adequately speak to the cell and gene niche on which he has focused. His CABP credential demonstrates the high caliber of experience and knowledge he possesses.

66 The CABP is really a mark of distinction that has retroactively validated the work that I've done and all of the experiences I've had that have led me to where I am. ??

As he's navigated through his career, the CABP fills in the gaps, showing everyone that the unconventional path he has taken has armed him with the diverse expertise he needs to succeed. It has also connected him to a community of other CABPs — a network of professionals with similar expertise levels, if not backgrounds.

66 The biggest thing it has done is identify who I can reach out to and talk to from a community perspective... Having those letters behind your name immediately tells me who the key opinion leaders or persons with expertise are that I can call on. ??





The CABP in the Field: In the Clinic



THE CHALLENGE:

The clinic is a pivotal stage in a biotherapy's lifecycle. Providers must work with novel therapies while treating highly vulnerable patients. Decisions made in the clinic directly influence a patient's outcome. Throughout the medical profession, board credentialing exams and extensive training programs are used to ensure medical professionals have the necessary training and experience. However, many clinical staff working in the biotherapies field likely completed their degrees years, if not decades, before the influx of biotherapies into the clinic.



THE SOLUTION:

In the absence of a standardized board exam for cell and gene therapies, practicing clinicians must use other means, like the CABP credential, to display to their peers and patients that they possess the expertise necessary to deliver the best standard of care.



Expert Highlight: Practicing Physician
Gaurav Gupta, MD, PhD, CABP
Transfusion Medicine and Cell Therapy Physician
Director, Apheresis Service
Memorial Sloan Kettering Cancer Center

Gaurav Gupta found himself in the world of transfusion medicine after his interest in immunology led him to the relatively new field of immunotherapy. In the medical field, where board exams and credentials are important indicators of experience and qualification, Gupta found that the world of biotherapies was largely uncharted. By studying for and taking the CABP exam, he set out to show his colleagues that he had a wealth of expertise beyond the clinical domain.

66 In transfusion medicine, you have a board certification, but historically, there hasn't been anything for the laboratory side of biotherapies. One of my key motivations for taking the CABP exam was to obtain a certification that demonstrates my competence in this field.

In addition to validating his expertise, taking the CABP exam also exposed Gupta to areas he had learned less about during his clinical training, such as regulatory and quality assurance. As a result of picking up more about these areas while studying, he found confidence when participating in wider discussions with colleagues. Because of his own experience, Gupta has also found the CABP credential a useful metric for assessing those around him, giving him confidence in his peers' expertise.

66 Knowing someone I'm working with has the CABP would definitely give me more confidence regarding their competency in the field. Particularly if I don't know them or haven't worked with them directly before.





The CABP in the Field: In the Clinic



Expert Highlight: Medical Director Kevin Land, MD, CABP Executive Medical Director, Biotherapies and Vice President of Clinical Services Vitalant

As an executive medical director with more than 30 years of experience, Kevin Land is looking to the future and the next generation of biotherapies professionals. Like many others in the field, his career has evolved with the science, and he views credentialing as an important aspect to evolving the careers of those he mentors. Specifically, he knows credentials like the CABP help him ensure he has adequately trained staff in the right places at the right time.

there, you need teams that are properly credentialed, accredited and experienced. If your lead staff has this credential, that means your team must really belong in this space. It lends credibility.

As someone who has seen the field grow, Land understands the high level of complexity required to get a therapy through manufacturing and clinical trials. He feels it's critical that his staff know more than just the mechanics of performing their jobs. The CABP credential ensures staff possess knowledge of the "why" or the big picture that is necessary to progress a career forward.

66The CABP is a great tool to get people to think beyond their day-to-day responsibilities and focus on something transformative, something that is a major step in their development as a professional... For people who have been in the field for a while, the CABP helps them show that they already have this knowledge. For the younger staff, it shows what they've learned and signals to us that they're ready for more.??





Conclusion



THE CHALLENGE:

The biotherapies field is on a course for continued growth and expansion. Across disciplines, domains, job titles and experiences, the field has been waiting for a credentialing exam that helps highlight those with the robust knowledge necessary to lead.



THE SOLUTION:

By evaluating professionals' knowledge across seven biotherapy domains, the CABP credential provides a standardized measure of knowledge, confidence in an individual's expertise and validation of that professional's abilities. Together, the CABPs represent a unique mix of experience, education and training, applied to advance innovation, safety and quality in the field.

How To Earn the CABP Credential?

The CABP credential is open to all experienced biotherapies professionals, including, but not limited to, researchers, medical directors, quality and regulatory specialists, and laboratorians. The process required ensures that individuals taking the exam meet candidacy requirements while maintaining a standard of rigor for the exam and certification.







Who is Eligible for the CABP Exam?

The infographic below gives you an overview of the eligibility requirements when applying for the CABP. Interested candidates can also **check AABB's CABP exam application online pre-approval questionnaire**.



★ Additional certifications may substitute for one (1) year of work experience.

What Does the CABP Exam Cover?

The CABP was built to cover the seven domains that are essential to mastery of the biotherapies field. Together, these domains cover knowledge ranging from manufacturing and development to the science and ethics of biotherapies.





