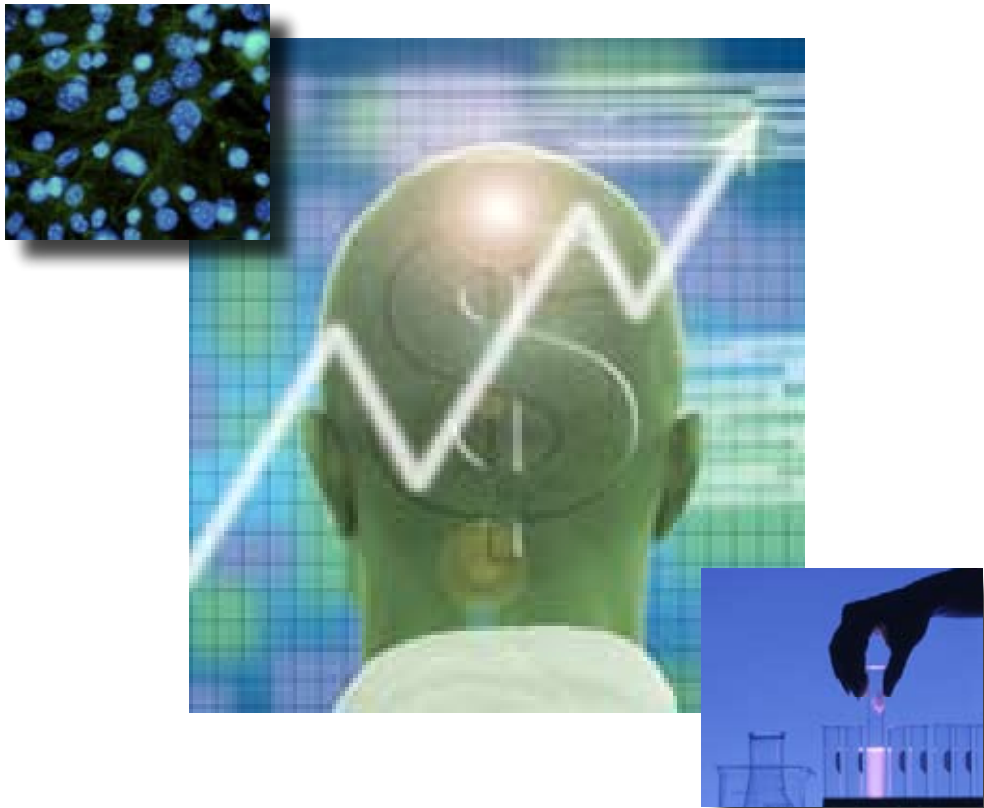




# Parenteau BioConsultants, LLC

*Your resource for winning life science*



(866) 722-0474 within the US, (617) 275-8845 outside the US  
[www.ParenteauBC.com](http://www.ParenteauBC.com)



Our mission is to help each client reduce the risk, time and cost of commercial bioscience through better evaluation, management and use of science and technology.

- Better product opportunities
- More productive pipelines
- On-target clinical strategies
- Stronger regulatory submissions
- Better investments and partnerships

Our technical specialty is in the evaluation, development and support of advanced biological products including advanced biologics, cell-based therapy and combination products.



**Look to Parenteau BioConsultants for expert help with:**

Scientific analysis and strategic R&D planning

Technology positioning

Expert review, technical writing and knowledge support

Technical advice in cell-based technologies

Opportunity Analysis

Due Diligence

R&D Management Coaching and Training

*Having faced and overcome many of the same challenges our clients now face, PBC is in a unique position to offer workable strategies, solutions and guidance that consider all aspects of a technology and business.*





## Why should a client seek our development advice and support?

Because few in biotechnology can claim the experience of bringing a new bioscience technology from scientific concept to commercialization that we can – enabling PBC to find workable solutions that properly balance a company's needs and limitations with what will be expected from clinicians, regulators and the marketplace.

The focus and effectiveness of an R&D effort is a major determinant of business risk.

There will always be challenges. How management approaches those challenges is pivotal.



At PBC we use both world-class scientific expertise and management experience to help clients avoid unnecessary hurdles, maximize their strengths and efficiently execute a development plan that results in a successful product and business.

## Clinical, Regulatory and Post-Market Support

Popular with clients, PBC's expert literature reviews and regulatory documents explain and substantiate a product's science, rationale, safety and clinical data in ways that gain the respect of regulators.

This is particularly important in the preclinical packaging of new biological technologies where the clarity of a sponsor's scientific arguments and supporting data can impact the start of a clinical trial, and even product approval.

Quality publications are also invaluable in creating the proper perception of a new technology or product in the marketplace.





*In 2009 Parenteau BioConsultants formed an alliance with BioRankings, LLC, a biostatistics firm specializing in biomedical analysis for investors and industry stakeholders. Combining our expertise allows us to offer a uniquely comprehensive and corroborative brand of life science due diligence.*

Our alliance helps both investors and companies minimize risk and increase the rewards of their efforts, investments and partnerships.

### Helping early stage companies validate their value proposition

Comparative effectiveness and increasing pricing pressure are changing biotech metrics from evidence of a talent for doing science, raising money and creating potential, to the ability to innovate and use science to generate products with a clinical significance the world's healthcare systems will pay for.

A due diligence audit can help companies better demonstrate their value to potential partners, buyers and investors.



## Determining the best opportunities within a crowded field of early technologies

With dramatic changes in the financial markets and the rising cost of bioscience development amounting to hundreds of millions of dollars invested in each product candidate, there is a pressing need for unbiased, comprehensive and corroborative due diligence that can guide private capital and public investment to the strongest life science opportunities.

A goal of the Parenteau BioConsultants and BioRankings alliance is to deliver a new brand of due diligence that can address this need.

Traditional analyses emphasize time-to-market, market potential and financials, yet a large part of time-to-market, value creation and risk is buried in the use and targeting of a technology and a company's current ability to manage its execution. The PBB Alliance analyzes key factors that will impact the likelihood of generating commercial value including:

- \* The likelihood of reaching therapeutic effectiveness based on science and statistical analysis of existing data in the space
- \* The comparative strength of a company's therapeutic target, approach and commercial strategy within a broad competitive landscape
- \* The company's life science management strategy – pivotal to value creation and competitive position

Lending credence to time-to-market estimates, market projections and financial estimates for more confident investment decisions



## Parenteau BioConsultants Co-founders

Nancy L. Parenteau, Ph.D. [nlp@parenteaubc.com](mailto:nlp@parenteaubc.com)



Dr. Parenteau is a biotechnology pioneer and award-winning biologist with over 20 years of experience as a senior industry executive from a Director of Research to CEO. She brings both direct research and management experience to the challenge of bioscience development, having built and managed top cross-disciplinary teams, while dealing with the business challenges of growing a company, and bringing a product to market.

Nancy has operated at technology's cutting edge throughout her career from her academic beginnings in monoclonal antibody research in its earliest days while at Georgetown, developing a novel ELISA assay commercialized while a Harvard post-doc, to pioneering the first living product to achieve clinical trial success and US FDA approval. Nancy's technology innovation and product achievements have been recognized with the prestigious "R&D 100" award in 1990 for a sophisticated *in vitro* test system and a "Best of Biotech" award in 2000 for a tissue engineered cell therapy that remains the leading cell therapy today after blood transfusion. She is listed in Who's Who in America and has served on the Chemical Sciences Roundtable of the National Research Council. She is an internationally recognized thought leader in *in vitro* biology and cell therapy.

Drawing from her successful experience as a scientific innovator, she co-founded Parenteau BioConsultants in September of 2005 to focus on analyzing, communicating, developing and supporting industry practices that can reduce the development risk of novel technology and increase the efficiency and effectiveness of bioscience R&D.

Janet Hardin Young, Ph.D. [jhy@parenteaubc.com](mailto:jhy@parenteaubc.com)



Trained as an immunologist at Georgia Tech and Harvard, Dr. Hardin Young has experience building and managing highly productive basic research, preclinical and clinical research teams. Jan has designed and implemented strategies for clinical immunological and safety testing, mechanism of action, establishment of bioequivalence, cell purity and biological assay design and validation, as well as post marketing clinical studies. She has worked on the safety assessment of biomaterials to complex cellular implants.

Her clinical testing strategy is now a benchmark for regulatory submissions in the field of cell therapy and tissue engineering having developed an overall strategy and validated clinical assays to demonstrate the safety of the first living cellular device to be approved by the US FDA and Canada.

Her broad bench to market experience has given her first-hand knowledge on how to make the most of basic and applied research; how to focus efforts to achieve the information needed for the regulatory approval process while minimizing testing and time to approval. She knows the importance of savvy preclinical development - that new technology needs new solutions and that even simple biological tests can be keys to success.

As a seasoned industry veteran and co-founder of Parenteau BioConsultants, Jan is committed to devising realistic strategies and providing the kind of input and support that can increase the success of innovative bioscience from bench to market.

Please visit our website to learn more about our online courses, podcasts, webinars and PBB alliance publications, many of them free.

<http://www.parenteaucbc.com>

To learn more about the Parenteau BioConsultants and BioRankings Alliance, visit <http://www.know-biotech.com>.

**Contact Information:**

We are located in New England and Texas and tap a consulting network that spans the US and UK.

Telephone: (866) 722-0474 for US clients  
(617-275-8845 for clients outside the US)

For general information please e-mail [info@parenteaucbc.com](mailto:info@parenteaucbc.com)

To discuss a project, please contact either Nancy or Jan by e-mail or phone.

To your success,  
Nancy Parenteau and Jan Hardin Young

