Dr. Jeanne Novak
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Dr. Jeanne Novak received a Ph.D. in Experimental Pathology and a B.S. in Biology from the University of Utah. Dr. Novak conducted scientific research at United States Army Medical Research Institute of Infectious Diseases, Fort Detrick. Dr. Novak was an FDA staff member, where she most recently ultimately served as the BLA Project Manager for the Associate Director for Policy at Center for Biologics Evaluation and Research (CBER). In that role, Dr. Novak coordinated efforts for future implementation of a single Biologics License Application (BLA) for all CBER regulated products Her CBER experience included the review of product manufacture, preclinical data, clinical trial design, coordination and presentations at advisory committee meetings, and pre-approval inspections (PAIs). She was also consultant in the Quintiles Strategic Regulatory Division, prior to establishing Colorado BioReg/CBR International, a high-level strategic, product and clinical development consulting firm for the pharmaceutical and biotechnology industry. Colorado BioReg/CBR International provides detailed scientific and regulatory consulting, program and project management services, and staff training in the areas of FDA submissions, FDA interactions, FDA regulations/guidelines, cGMP compliance, GCP compliance and Quality Assurance.