DR. PAUL LAWRENCE

Director of Bioscience Research and Product Development

Biocogent, LLC

SPEAKER: Dr. Lawrence received his doctorate in molecular microbiology from Stony Brook University and before that obtained his bachelor of science degree in molecular biology from the University of New Mexico. During his career, he has conducted biological research in academia, industry, and for the United States government. He has conducted vaccine and anti-viral therapeutic research at Brookhaven National Laboratory and at the Plum Island Animal Disease Center. In industry, he has participated in contract biopharmaceutical research and development for the former Collaborative Bioalliance and Dow Chemical. Dr. Lawrence was also the Director of DNA Production for the anti-counterfeiting biotechnology company, Applied DNA Sciences. Currently, he is the Director of Bioscience Research and Product Development for the next generation skin care company Biocogent. Over the course of his career, Dr. Lawrence has published more than 15 research manuscripts and review articles as well as a textbook chapter.

TITLE: "Adapting Quality Assurance to Nucleic Acid Based Treatments"

ABSTRACT: The long-sought goal to utilize nucleic acids (DNA, RNA) for the treatment of multiple diseases and disorders is finally coming to fruition. DNA and RNA vaccines, RNA interference (RNAi) therapy, and CRISPR technologies, just to name a few, are being developed for use by a multitude of biotechnology and pharmaceutical companies worldwide. Indeed, the very first gene therapy for treatment of certain human cancers was licensed for use in August of this year. The very nature of DNA and RNA and their multiple forms requires new approaches to quality assurance that were not previously contemplated. This discussion will focus on DNA and RNA oligonucleotide drugs, short chemically synthesized nucleotides, of which there are no less than 150 that are currently undergoing clinical investigation in the United States alone. While the Food and Drug Administration (FDA) has released recommendations for the approval of oligonucleotide drugs, there is a lack of firm regulations. Moreover, the FDA and its European counterpart, the EMA, have failed to reach an agreement on how to approach oligonucleotide-based drugs. Furthermore, this discussion will address the multiple issues that should be contemplated when devising quality assurance protocols for oligonucleotide therapeutics, including: safety, efficacy, delivery, *in vivo* stability, and the dynamic range of mechanisms by which oligonucleotides act on the cellular level.