



Dr. Dan Mamelak

Founder, Custom Biologics™

Our second Canadian Leader features Dan Mamelak. In a younger company, Dan demonstrates again that scientific excellence combined with vision, passion and great staff can produce a winning formula. Custom Biologics is breaking new territory and experiencing enormous recognition and success. Fred Haynes,

The process of creating effective pharmaceuticals from the initial discoveries at the laboratory bench to the practical and ethical demands of clinical trials and the eventual marketing of a successful therapeutic agent has always been fascinating to me. While at university, I can recall reading Barry Werth's, "The Billion-Dollar Molecule", which describes the entrepreneurial start-up of Vertex Pharmaceuticals and the challenges it faced applying sophisticated science to drug and business development. I knew then that this was the career for me.

Following my training and thesis work in protein biochemistry, I was fortunate to work for a local start-up biotechnology company which combined scientific and engineering expertise to develop robotic platforms for high throughput protein expression and structure-guided drug design. The entrepreneurial spirit and 'can-do' atmosphere at work was rewarding and enriching. As the company grew, so did my interest and insight into the many different types of skills, information and technologies required for the development of new drugs.

In January 2004, I founded Custom Biologics™ with a business model centered on providing protein expression, characterization and analytical

services. I began simply by offering proteomic and mass spectrometry services to academic, industrial and government institutions. The high quality of our work was recognized early on in the prestigious journal, Science .

Since its inception, the company has rapidly grown and is now comprised of three divisions - bioanalytical, bioassay and quality assurance.

The bioanalytical division is engaged in the development and validation of bioanalytical methods to identify, quantify and characterize small molecules, new chemical entities and biologics from many different matrices. Mass spectrometry methods reliably characterize batches of protein biologics throughout the stages of discovery, production and lot release.

The bioassay division provides custom assay development and validation for biological macromolecules utilizing ligand binding assays, cell culture based assays, flow cytometry and mass spectrometry. Immunoassays and anti-drug antibody/neutralizing assays are developed and validated for the analysis of samples obtained in phase 1 and phase 2 trials. Flow cytometry is routinely employed to define the binding properties and cell specificities of novel bio-therapeutics as well as for lot release testing of biologics destined for the clinic.

Our quality assurance division operates independently to ensure that all projects and day to day activities are



compliant with the FDA Code of Federal Regulations, 21 Part 58, for Good Laboratory Practice (GLP). Our quality assurance group is mandated to apply and implement the latest regulatory guidelines for bioanalytical and biological assay validation.

Custom Biologics™ remains committed to the use of the most advanced scientific methods and assays to provide our clients with data that meet the highest regulatory standards. I attribute the success of Custom Biologics™ to the devoted efforts of our excellent scientific and regulatory staff and to the close working relationships we establish with our clients.

1. Science. 2006. 314,1308-11.

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