

Uncertainty and Challenges Brew Rewards

Ronald Bowsher has faced times of uncertainty and many challenges in his career, but his perseverance and dedication have reaped rewards for himself and the pharmaceutical sciences.

By Joy Metcalf

It's a dynamic and interesting time for the pharmaceutical biotechnology industry, Ronald Bowsher, Ph.D., recently stated. There is globalization in drug development with multiple countries involved; the first wave of approved biotech compounds are coming off patent; and there is now a shortage of people on the development side, among other factors.

But this isn't the first time that Bowsher has seen a time of changes and growth in the biotech industry throughout his established career. In fact, it was "the emergence of biotechnology as a major source of new, innovative drugs" that helped shape a large part of his career.

Bowsher, now chief scientist for EMD Millipore's BioPharma Services and adjunct assistant professor for Indiana University's School of Medicine's Department of Biochemistry, began his career at the Lilly Research Labs, where he was hired to develop ligand binding assays for conventional small molecule drugs.

"However, Lilly was the first company to employ rDNA methods to create a new commercial biotherapeutic, biosynthetic human insulin. I was fortunate to participate in the early years in biotechnology," Bowsher stated. He supported Lilly's biotherapeutic pipeline by providing bioanalytical and ADME support on the development side of research and development. He "gained early first-hand experiences with respect to the challenges in this new field of rDNA biotherapeutics." And it was this appreciation of the challenges, he said, that motivated him to network with others to overcome them.

However at that time "there was not an extensive network of individuals who were involved in the new field of



Binding Assays Bioanalytical focus group (LBABFG).

The group started late in the year 2000 with about 50 members and has grown to more than 460 members. "Because of strong leadership and the dedicated efforts of many, much progress has been made

pharmaceutical biotechnology." So Bowsher turned to the American Association of Pharmaceutical Scientists (AAPS).

In early 2000, he participated in the AAPS cosponsored Crystal City Workshop on Bioanalytical Methods Validation for Macromolecules. This workshop brought together individuals from pharma, biotech, academia, and regulatory agencies to share information about bioanalytical methods validation to support regulated bioanalysis of macromolecules.

"Prior to this event," Bowsher said, "there were few interactions among scientists who conducted support for biopharmaceutical drug development, and the validation practices for macromolecules lacked harmonization. But AAPS provided a professional society and forum for interactions by pharma/biotech/CROs and reps from regulatory agencies."

And this meeting inspired Bowsher to do more.

"Because the allotted time did not allow us to address all the key issues for a number of important topics, I recognized the need for ongoing discussions to build on the momentum from this meeting." Bowsher went on, "There was no standardization prior to 2000. This meeting just scratched the surface at building a network." Joining with some friends and aligning with the AAPS Biotechnology section, Bowsher founded the Ligand

in standardizing bioanalytical assays for pharmacokinetic assessments, assays to detect and characterize anti-drug antibodies (immunogenicity testing), and bioanalytical methods for novel biomarkers."

Bowsher chaired the LBABFG from 2000–02. He worked subsequently with other members in the LBABFG to create two training courses, one for the application of ligand binding assays to support biotherapeutic pharmacokinetics and one for immunogenicity testing of antidrug antibodies. For his work on these training courses, Bowsher was awarded a Presidential Citation in 2008. He was also elected an AAPS Fellow in 2004.

"The impact of this focus group has been extraordinary during the past decade," Bowsher commented.

"I had no idea that the focus group and the Biotech section would accomplish as much as they have. I am most proud of how this group has demonstrated inclusiveness. They have welcomed participation by all who are interested in these topics, which has fostered even more collaboration for advancing our science."

He continued, "AAPS and the membership should be proud; individuals have collaborated to create standardized processes to reflect best practices—everyone wins."

When asked if he is where he thought he would be in his career when he began,

Bowsher quickly retorted, "Goodness no! I joined Lilly in 1973 and did not think I would retire until age 65. However, the world is a very different place today."

As such, Bowsher retired early from Lilly Research Labs—after 30 years of leading research groups that were responsible for ADME and bioanalysis therapeutic proteins, novel biomarkers and anti-drug antibodies—and embarked on new endeavors. He served as vice president and chief science officer at LINCO Diagnostics for several years before joining EMD Millipore. He also started his own consulting firm, B2S Consulting, in 2003, of which he remains partner and president.

A SPORTS METAPHOR

"During my nearly 40-year career...I have had the pleasure to work with some exceptional people who just happened to be outstanding scientists too. Some common attributes in these exceptional people are that they were focused outwardly, committed to excellence, and dedicated to the success of others," Bowsher stated.

We're in a period of significant change in the pharmaceutical industry, according to Bowsher. And this is the time when leadership is extremely important, Bowsher noted. He pointed out four qualities that, in his experience, make a person a good leader: "having vision, being a good listener and analytical thinker, and being dedicated to the success of others."

"The truly great leaders make the people (the players) around them (play) better." This sports metaphor is the philosophy on which Bowsher has tried to model his leadership. He went on, "A great leader (coach) surrounds him/herself with outstanding people (team), empowers them and then holds them accountable."

Bowsher has led many to play better, and he has surrounded himself with outstanding players. And he plans to continue doing so.

"I would like to contribute to creating professional career opportunities for the next generation of pharma/biotech



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scientists," he stated. "Pharma/biotech is definitely a rewarding profession."

However, Bowsher notes that the younger generation needs to be prepared to embrace changes and seize opportunities that may come their way, much like he has done throughout his career. "They are about to embark on an exciting endeavor, but one that has an uncertain course. With change comes uncertainty, challenges, but yet rewards."

Although Bowsher has encountered periods of uncertainty and many challenges along his career path, he has also seen the rewards that can come from perseverance. LBABFG is one prime example of this. Bowsher surmised, "It took a lot of work, but it paid off."

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