Biotherapeutics development requires accurate and robust analytical testing methodologies with dependable separations. Agilent is committed to the biopharmaceutical market, and has a company-wide initiative to leverage the entire product portfolio, application-specific total workflow solutions, and global presence to deliver the support customers rely on to make trusted decisions. In this interview with *BioPharm International* and *LCGC*, Padraig McDonnell, executive vice president and general manager for the Chemistries and Supplies Division at Agilent Technologies, explains how Agilent’s products address customer pain points including poor reproducibility and difficulties with their instrumentation and methods.

**BioPharm International and LCGC:** Can you tell us a bit about your customers in the biopharmaceutical market and some of their specific challenges?

**McDonnell:** The future of biopharmaceuticals looks promising with life-changing treatments, and the field keeps growing, powered by innovative ground-breaking therapies to treat cancer and autoimmune diseases. Advancing these novel biotherapeutics safely in the clinic requires reliable manufacturing and quality control processes.

The complex heterogeneous nature of biotherapeutics requires accurate and robust analytical testing methodologies with dependable chromatographic separations. Identifying critical quality attributes (i.e., impurities that could impact the product safety and efficacy) is the most difficult step in the implementation of a Quality by Design approach for biopharmaceutical development and production.

Defining each product attribute is extremely challenging. Therefore, consistency of product quality becomes even more important. Some of the key challenges are accuracy, robustness, and reproducibility of the data. It all comes down to speed and efficiency of the workflow.

**BioPharm International and LCGC:** You mentioned speed and efficiency workflow as being of major importance. What can Agilent bring to those customers to help them solve some of those challenges and meet those demands?

**McDonnell:** We, at Agilent, design and manufacture our own AdvanceBio LC columns and consumables to match our customers’ needs. It is important to recognize that several analytical techniques are used as part of our workflow solution. This includes sample preparation, separation detection, and data analysis. Each part of the workflow must work seamlessly with the other components to ensure trusted answers.

At the 2017 American Society of Mass Spectrometry (ASMS) conference in Indianapolis, we launched an end-to-end AdvanceBio solution for biologics characterization, focused on intact protein and peptide mapping, which are critical quality attributes. Reproducible chromatographic separation is key to these workflows.
Our AdvanceBio Peptide Plus columns and PLRP-S columns are designed for reproducible performance. There is quality at every step of the columns manufacturing from the receipt of raw materials to the finished column. We know that quality is an important step to be productive and gain efficiencies in the overall process.

**BioPharm International and LCGC:** Can you provide examples of innovative solutions that your organization has brought to the industry in the context of biologics characterization workflows?

**McDonnell:** Let me pick one example among many, where Agilent has redesigned a product to address our customers’ needs. During the biotherapeutic manufacturing process, there are many things that can cause a protein to aggregate into dimers, trimers, and higher order aggregates. This can be caused by many things: changes in temperature, concentration, pH, and so on.

Size-exclusion chromatography (SEC) is the preferred technique for quantifying these aggregates. Agilent developed an entirely new LC column for this purpose, and then demonstrated superior performance in terms of data reliability and quality. Not only did we address the issue of the column lifetime that presented challenges to customers analyzing aggregation, we also ensured the AdvanceBio SEC product would work with more complex molecules such as antibody-drug conjugates or ADCs.

**BioPharm International and LCGC:** Many companies are focused on biopharma, but what puts Agilent in a strong position to serve these customers also in the mid-to-long term?

**McDonnell:** We differentiate our commitment to biopharma in three major ways. First, about three and a half years ago, Agilent launched a strategic initiative to help solve our biopharma customers’ challenges by offering complete end-to-end solutions. Since then, we’ve been bringing several innovative and easy-to-use solutions to the market. I talked about a recent solution launched at the ASMS 2017 that shows our continued commitment.

Second, Agilent is in a unique position, compared to any other vendor in the market, to leverage the entire product portfolio. Automated sample prep using the AssayMAP Bravo Platform, InfinityLab Bio-inert HPLC systems, AdvanceBio columns, AdvanceBio Standards, application-specific total workforce solutions, a global presence through Agilent CrossLab services and throughout Agilent, collaborating to deliver support to our customers that rely on making trusted decisions.

Regular customer contact and integrating the voice of customer is really critical to us. It gives us exceptional insight into the scientific challenges our customers face. These insights enable Agilent to put an intentional focus on biopharma, as we continue to develop new products and services that help our customers. Collaboration and cross-functional teamwork have enabled us to deliver new products and workflow solutions that better address customer analytical needs.

Third, we continue to invest in the biopharma business. On June 28, 2018, we announced that we entered into a definitive agreement to acquire privately held ProZyme, Incorporated, a leading provider of glycan analysis kits and standards. The acquisition will expand Agilent’s portfolio of biopharma consumables in the fast-growing glycans space. We have a strong base of customers and expanding our consumables portfolio is key to our strategy. This fits our strategy to provide a complete workflow solution that will help biopharmaceutical companies reduce the cost and time required to bring new therapeutics to market. We stand by our customers on this journey, to help them develop safer and more effective biotherapeutics more quickly.

**LCGC:** Anything new on the horizon that we should look out for?

**McDonnell:** I would like to also tell you about the latest product that Agilent is launching, the AdvanceBio HIC column. Hydrophobic Interaction Chromatography is a powerful tool that can be used to separate out impurities that can prove too difficult to analyze by any other analytical approach.

The biotherapeutic industry has struggled with the products that were already on the market. Our customers explained the challenges they faced and we listened. Things like poor reproducibility, as well as difficulties with their instrumentation and methods, due to mobile phase conditions that are used (HIC often requires a high concentration of salt) were recurring themes that we heard from our customers.

Agilent has once again listened closely and used our R&D resources to address the pain points customers experience right now. As a result, we have developed a new product, the AdvanceBio HIC column, that has designed-in features to overcome many of these problems.