Cathereine Soo Abstract

Biotherapeutics are the fastest-growing sector in the biotechnology industry with new developments in immunotherapies, gene and cell therapies, and antibody drug conjugates all contributing to the growth of biologic products being brought to market.

Biologic drugs are generally administered by the parenteral route such as intravenous (IV), subcutaneous (SC) or intramuscular (IM). Recently there has been an increasing trend in the development of biologic drugs to be delivered by the SC route, which is a cheaper and more convenient method of drug administration. The inherent biophysical and variable characteristics of biologic drugs introduce challenges in their manufacturing and delivery by the SC route. However, with the development of novel excipients by the biotherapeutic industry to overcome such challenges, it is anticipated that more SC formulations will be become available for clinical use in the future.

As the race to develop new dosage forms continues, the biotherapeutic industry should be reminded that they need to meet the Canadian regulatory requirements in demonstrating that the new formulations are of high quality, safe, effective and do not pose additional risks to Canadians.