A Conversation with Tom Damratoski, Lead of Civica's Affordable Insulin Initiative

Tom Damratoski is Senior Vice President, Biopharmaceutical Products at Civica Rx. In this role, he leads Civica's Affordable Insulin Initiative and brings to life the commitment by the non-profit pharmaceutical company to produce three biosimilar insulins in vial and pen forms and make them available at one low, transparent price – regardless of health insurance – to people with diabetes who require insulin to live. Civica's insulins will be available in 2024.

Learn more about Tom, the unique experience he brings to his role and the future he anticipates for Civica's Affordable Insulin Initiative.

Talk about your role and responsibilities as head of the Insulin project at Civica.
Along with the Civica leadership team, I am leading the Affordable Insulin project, including development, approval, manufacture and supply of three biosimilar insulin products to patients who need them.

My responsibilities include building the infrastructure for biosimilars in a growing Civica organization. We're working with our technical partner, GeneSys Biologics, to co-develop and commercialize glargine, lispro and aspart (biologics interchangeable with, Lantus, Humalog and Novolog, respectively). These insulin analogs will be available in devices – pre-filled pens and vials – beginning with glargine, which we've committed to delivering as soon as 2024.

What brought Civica to your attention and what brought you to Civica?
I guess you could say I have been a Civica follower since the company's creation in 2018. I found myself observing Civica's progress, asking the big question: Can they do it? And cheering on their success and growth of their innovative not-for-profit supply model.

In our industry there are many large teams working on important medicines, including the innovative cell therapy products I supported with a great team at Bristol Myers Squibb. In contrast, there is much less effort focused on ensuring the robust, cost-effective supply of essential, everyday medicines, which impacts patients across the U.S. Insulin is one of these – discovered nearly 100 years ago and still too many patients can't afford it. With diabetes an epidemic in this country, the snowball effects of the high cost are serious, even life-threatening, health impacts. Civica's insulin project will ensure that patients have the capability to manage their insulin by making it available and affordable to all who need it.

The project resonated with me, as there are so many Americans impacted by high insulin cost. My grandfather lived with diabetes until he passed more than 20 years ago, and I feel since then access to insulin has not improved.

Another big influence on my decision was meeting and getting to know the leadership team and the people at Civica. They are a strong, experienced team working fast and unified with a high level of capabilities, to solve problems that need solutions. I wanted to come in and learn from them and be part of the culture they've built at Civica that starts with doing what is in the best interest of patients. Everything else derives from that.

Tell us about the skills and experience you bring to this role and your priorities for the project.
I've been fortunate to work on many critical biologics/cell therapy products, in manufacturing technology and operations for a large part of my career, in plant-based and global roles, at small and large companies. I have focused on tech transfer and launch of products in late stage development. I understand what systems, processes and people we need – and, as importantly, don't need – to be successful. I bring this experience to an ambitious program, and believe we have the plan and the people to be successful.

Our short-term priority is to build and execute a biosimilar development program to prove our insulins are safe and comparable to established products.

Long-term, we are building our organization for sustainability. A key is to get manufacturing capacity in place, which is crucial in building the foundation as well as the sustainability of a product. Capacity to launch is a critical short-term priority, but equally important is ensuring a supply chain that remains robust over time.

What excites you about the Insulin project?
In science and engineering, there's a point in your career where you ask: What's the biggest problem we can help solve to help others? For me in the last 10 years, that was by working with large teams to bring new oncology projects to the market. More recently, I have been looking for the next way I can take my skill set and apply it to best benefit others. I can do that here.

This is a huge step for Civica, which has exceeded expectations already. I am looking forward to the day we deliver on our commitment, and people with diabetes no longer worry about how to afford their insulin.

Civica just announced it has selected Profil for clinical trials. Tell us about that.
Yes, we recently shared the news that Profil will be our clinical trial partner to support the development of our affordable insulins. Human clinical trials are an important final step to demonstrate biosimilarity to branded insulins already in the marketplace.

Profil has extensive experience, conducting over 30 biosimilar insulin trials. Its team includes physicians with decades of research experience in every aspect of diabetes management, including prediabetes, drug development, clinical care, insulin pharmacology and diabetes technology.

What do you do for fun?
I like outdoor activities – hiking, skiing – and spending time with my wife and two teenage daughters as they participate in sports and music. My family has a bit of a homesteader drive, with home-grown vegetables, several chickens and fresh eggs, and two dogs and a cat. So, there are always projects at home to keep me busy. I am also an award-winning home brewer! It's a hobby I've enjoyed since I started five years ago, though I find it increasingly challenging to find time to brew.