

Ensuring regulatory compliance with Brenntag Specialities

With regulations tightening and supply chains shifting, we asked a Brenntag expert with more than 40 years' experience in the industry how Brenntag and Novo Nordisk Pharmatech can support the US pharma market – now and in the future.

Brenntag is the global market leader in chemical and ingredients distribution. Brenntag Specialities is dedicated to high value pharmaceutical APIs, pharma excipients, personal care, nutritional and material science products, with exclusive relationships with the manufacturers it represents, including Novo Nordisk Pharmatech.

Joseph Giaimo is Senior Director of Sales for Life Sciences and Marketing Manager for the Novo Nordisk Pharmatech line of pharmaceutical Quats, including Benzalkonium Chloride. "The most important application area for us is ophthalmics," he says. "Novo Nordisk Pharmatech's Benzalkonium Chloride is a potent antimicrobial used in most ophthalmic solutions. It's used in very small quantities, but it's critical to maintaining the integrity."

The only company manufacturing under cGMP and ICH Q7

"One of the biggest challenges for our customers is to be able to purchase very high quality multi-compendial Benzalkonium Chloride made under both full pharma cGMP and ICH Q7 regulations to be used as a pharma excipient and as a full API," explains Joseph Giaimo. "Novo Nordisk Pharmatech is the only manufacturer in the world who produces pharma grade Quats under cGMP and ICH Q7 regulations. They produce the highest quality Quats in the world and have extreme consistency lot to lot, and year to year."

"We deal with multi-national companies that manufacture in the US and export throughout the world, so they need multi-compendial products," he adds. "Novo Nordisk Pharmatech's Quats meet the European, US, British and Japanese pharmacopoeias, which is a great asset for our marketing."

Meeting rapidly changing regulatory requirements

“Regulatory compliance is perhaps the biggest challenge in the pharma market today. The regulations covering pharma products here in the US and globally are under constant change and need constant monitoring to remain in compliance,” says Joseph Giaimo. “Full transparency between Brenntag Specialties and Novo Nordisk Pharmatech regulatory departments allows for immediate Change Control Notification and document updates. Novo Nordisk Pharmatech has a dedicated portal on its website that instantly and automatically sends any changes in documentation to our regulatory team and myself.”

A partnership prepared for future market trends

Looking ahead, Joseph Giaimo predicts that products used in the US pharma and personal care markets will be under increasing scrutiny for safety and effectiveness: “Manufacturers will need to tighten up Standard Operating Procedures and step up their regulatory compliance in general. Companies that cannot meet these challenges will fall by the wayside.”

“We also believe there will be significant ‘re-shoring’, moving pharma production back to the US, as recent disruptions in the global supply chain due to COVID-19 have demonstrated,” Joseph Giaimo shares. “We expect to see less dependency on manufacturers from China and India, and a higher concentration of high quality US and EU producers – including of course Novo Nordisk Pharmatech. Brenntag stocks Novo Nordisk Pharmatech products locally in a certified GMP distribution centre in Philadelphia for immediate dispatch throughout the US.”

For more information regarding Novo Nordisk Pharmatech’s cGMP manufactured Quats products, please contact International Sales Manager Phil Stafford at ppsf@novonordisk.com