



FACILITY TOUR

# Making a Promise to Empower Biologics Delivery

*Croda Pharma's Innovation, Expertise, and Collaboration Enables the Next Generation of Drug Delivery Systems*

## CRODA

The biopharmaceutical industry has seen remarkable changes in recent years. From cancer treatments, to cell and gene therapy, to the COVID-19 vaccines and other vaccines – there is no doubt the innovations seen from biopharmaceutical developers and manufacturers have made a significant impact on worldwide healthcare. The path to bring a new biopharmaceutical product to market is typically a long and costly process, with no guarantee of success. Innovator companies developing these products need a partner with the innovation pace and application expertise needed to get products to market faster than ever. Croda Pharma is a leading partner for the development of excipients and the supply of high purity materials for pharmaceutical formulations. Along with the announcement of a new strategy and promise of 'Empowering biologics delivery', the company has strength in the breadth of portfolio it offers including high purity excipients, vaccine adjuvant solutions, and lipids for delivery systems.

Over the past 20 years the pharmaceutical industry has increasingly seen the need and the benefits to partnering with companies that can offer solutions to formulation problems.

Croda Pharma offers the tools and technologies to drive formulation success. The company offers the industry a broad range of excipient and formulation options to unlock more therapies and bring therapies to market quicker, more efficiently and with the highest quality.

### Company Background

Croda is a global company with a commitment to becoming the most sustainable supplier of innovative ingredients, serving both Life Sciences and Consumer Care markets through its Smart science to improve lives™ purpose. Croda Pharma focuses on empowering biologics delivery, having grown out of the leading Health Care business of topical and liquid OTC applications, with a real specialty in working with difficult to formulate actives. As the biologics space developed over the years, the need for high purity excipients for sensitive APIs grew with it. That's where Croda's Super Refined™

product line played a key role, delivering the consistent, low impurity profile that formulators need to help de-risk development efforts.

Croda's high purity excipients paved the way for its success within the pharmaceutical industry. Continuing its growth, Croda Pharma further expanded into vaccine adjuvants with the acquisition of Biosector and the Alhydrogel™ product line in 2019. Further, in 2020, Croda completed the acquisition of Avanti Polar Lipids, a market leader in developing novel lipids, reinforcing Croda Pharma's position as a leading excipients expert.

Today the company is focused on empowering biologics drug delivery, through its Small Molecule, Protein, Nucleic Acid Delivery and Adjuvant Systems platforms.

"We provide solutions from start to finish," says Suresh Swaminathan, North America Business Head, Croda Pharma. "Ranging from formulation expertise all the way through the manufacturing and purification of our products. We have the custom capabilities to drive a formulation to success and bring the necessary support throughout the life-cycle of the drug bringing it to market."

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## Manufacturing Milestones: First Excipient Supplier to Achieve Global EXCiPACT Accreditation Across Facilities

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Croda Pharma's manufacturing sites embody pride in manufacturing and range from FDA registered, inspected, to EXCiPACT GMP certified. Recently, Croda and the United States government entered into a cooperative agreement investing millions of dollars to expand the manufacturing capacity of ingredients for lipid systems used in novel therapeutic drugs, such as mRNA vaccines. This investment will allow Croda Pharma to establish a new lipid facility in Lamar Pennsylvania, strategically located near our existing Mill Hall, PA manufacturing site. This site will supplement the company's lipid portfolio range centered in Alabaster, Alabama and provide ingredients and solutions to highly complex biologic formulations including vaccines and Nucleic Acid Delivery.

"The materials that we provide to our customers empower drug delivery, particularly those formulating with APIs that are difficult to formulate with or are very sensitive to impurities," says Suresh Swaminathan. "Quality is at the heart of everything we do, from our commitment to our customers to the purity and consistency of the ingredients we bring to the market."

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## A Closer Look at the Princeton, NJ Facility

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In 1950, Croda Inc. established its first North American office in New York City. As it grew, that corporate office moved to Edison, NJ and recently, the company established its innovative facility in Princeton, NJ.

Croda has multiple manufacturing sites scattered through the country ranging from Delaware and Pennsylvania to California and Alabama.

The Princeton, NJ site was designed with the experience gained from working with pharmaceutical partners over the last 20 years. Emphasis was placed on enabling collaboration and offering the best formulation technology and expertise available.

Croda's Princeton, NJ facility is the site of the company's Cell and Tissue Culture Lab. This facility positions the company to help develop next generation vaccines and other therapies, for example, gene therapy and mRNA technology. A broad range of expertise is offered which can support applications from nanoformulations in both small molecule and nucleic acid delivery, protein delivery, and adjuvants.

"We understand how important it is to choose the correct excipient when developing successful formulations," Sreejit Menon, PhD., Research and Development Manager, Croda Pharma. The scientists at Croda support in advancing technologies and further expanding their broad data portfolio through validating the performance of the excipients they produce. Used as solubilizers, drug delivery aids, bioprocessing aids and adjuvants "we support our customers by generating high quality data allowing our customers to fully understand how our products will improve a customer's new drug substance, formulation and stability."

The Cell and Tissue Culture facility is designed and equipped as a Biosafety Level 2 laboratory and has enabled Croda's work with cell and tissue cultures and blood, to better understand a range of biological applications for their products which are of interest to pharma and biotechnology customers.

The facility can handle, maintain, and cryopreserve a variety of cells and tissues. Croda generates data to validate performance of its high purity excipients, lipids and adjuvants in customer relevant applications, including bioprocessing, immunogenicity and small molecule, nucleic acid and protein delivery.

Sreejit Menon adds "We developed this lab to recognize and address our customer's needs. Applications data is needed to understand how a product is performing. This lab is designed to support just that." In addition to the Cell and Tissue Lab at the Princeton, NJ facility, Croda also offers Customer Experience Labs which are designed to support and inspire collaborative work which goes beyond the company's internal scientific expertise.

"At our facility, we have designed a specific lab for the purpose of holding customer collaborative and training events," says Russ Niksic, Senior Vice President, Croda. "We take pride in having and building strong interpersonal relationships with our customers and this lab supports going beyond research. It allows us to share information, build experience, advise, and support our customers."

Croda's facility also includes The New Product Development Lab which supports custom high purity excipient design and synthesis to provide unique solutions for customers and to support GMP manufacture and monograph testing.

## Worldwide Collaboration: From Lab to Customer - Partnerships that Span the Globe

Valuing the importance of direct customer conversation, Croda Pharma has a global network in all the major regions of the world in which its scientists routinely interact with a variety of universities, research institutes and customer companies.

“When we collaborate,” says Stephen Rumbelow, PhD., Life Sciences Research Fellow, Croda, “it is not just about funding research. It’s also about sharing information, building experience, and advising.”

Within individual regions, Croda offers well-known experts in particular subject areas. The company’s strong interpersonal relationships with several leading academics show that they value Croda for their product portfolio that covers the whole spectrum of the pharmaceutical industry.

On a global scale, Croda offers the experience and knowledge to help companies develop and formulate products whether it be adjuvants, a surfactant or polysorbate, or for a company looking to develop an emulsion.

Rumbelow elaborates, “We have a global network of people who work together and collaborate. For example, if a certain region wants to gain access to a particular expert, there are no barriers within the company. We openly encourage people between regions to participate and support projects in other regions. We can leverage our resources very effectively and at the same time, enable the people within the team to develop.”

“Our ability to cover a broad range of formulation needs found throughout the pharmaceutical industry, as well as call on our specialists that can deep dive into complex technical issues, is what makes Croda Pharma stand out.”

“We are not just passively supplying materials, we’re about active engagement,” adds Rumbelow.

## The Evolving Pharmaceutical Excipients Business

As the pharmaceuticals industry advances to develop more complex therapies requiring nucleic acid delivery, protein delivery and biologics, there is a clear lack of novel excipients for large molecule drug substances, thus new and innovative formulation components and excipients are needed. Concerns such as drug stabilization, surface adsorptions, agglomeration, and purity are found throughout the drug development process, especially within biopharma. Unlocking new therapies relies on empowering excipient development.

The COVID-19 pandemic proved that developing a successful vaccine outweighed any reluctance or concerns related to using novel excipients. In addition, the FDA’s Novel Excipient Review Pilot Program will help reduce some of the barriers to novel excipient introduction. This

program will serve to accelerate the analysis of, and importantly, the purity of excipients.

“We recognize the importance and lack of novel excipients and have positioned ourselves to support the industry interest in developing new and innovative ingredients,” says Iain Moore, PhD., Head of Global Quality Assurance, Croda.

As the acceleration of examining the purity in excipients heightens, it is important to take all considerations of an excipient into account in its selection to ensure it not only does the job it’s supposed to but does it at the highest possible level. Thus, high purity versions of existing excipients can help bridge the gap caused by the lack of novel excipients.

Croda’s proprietary purification processes which are used to develop its range of Super Refined™ excipients align with the expanding regulations and investments in innovation seen throughout the industry. Developed to support the most sensitive of formulations, its growing range of Super Refined™ excipients will continue to support customers and the growing need to formulate with the purest excipients available, both today and in the future.

## Looking Ahead

Croda’s Princeton, NJ site is the company’s center of commercial innovation in North America.

Strategically located along the east coast, this facility supports the wealth of innovation at pharmaceutical companies within the region. Having this in mind, Croda Pharma will further develop and expand its R&D capabilities in this location.

The Princeton location allows numerous business functions and sectors to work under one roof allowing teams to collaborate effectively; work together, solve problems, refine ideas, and ultimately support customers to create technical solutions to problems that improve patients’ lives. Located halfway between New York City and Philadelphia, Croda recognizes not only the ability to strategically collaborate, but also the potential to attract and attain talent within the industry, growing and investing in complex science.

The facility also boasts a commitment to sustainability. The inclusion of electric vehicle charging stations, and using electrical service derived from renewable resources helps to lower their carbon footprint.

Russ Niksic adds “Croda has for decades been the sustainability leader in the consumer care and crop industry, catalyzing our customers’ own sustainability journeys’ and now we are looking to do the same in the pharmaceutical industry.”

Future goals for this location include efforts to provide even better customer support, create solutions for customer problems, continue to foster an innovative culture, attract and develop talent, collaborate, and further develop sustainability initiatives.

“We want to be the supplier of choice within the pharmaceutical and biopharmaceutical industries; not only for our highly purified excipients but for the support and services we provide alongside our products,” concludes, Russ Niksic.