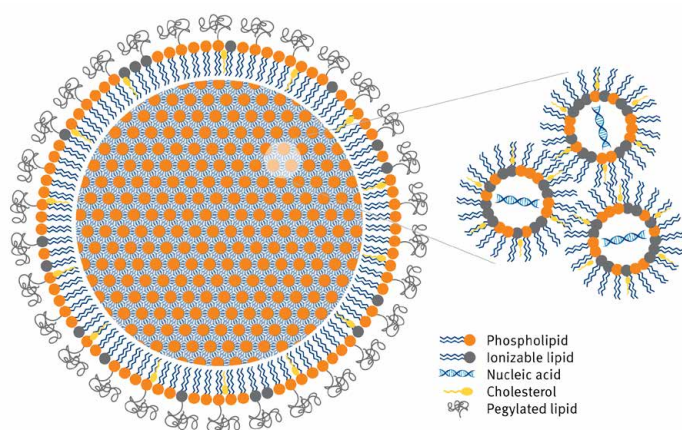


# Collaborating with Croda to help supply lipids for the global response to COVID-19 and mRNA vaccine development

## Customer Case



## Introduction

Moving from a traditional lab based synthetic process to more commercially orientated and efficient processes with a limited timeline is often a challenge. In 2020 Croda approached Biotage with just such a challenge relating to the growing and unprecedented humanitarian health crisis that was unfolding relating to the spread of the COVID-19 virus. At the time, large scale production of mRNA vaccines was in its infancy, and there had never been a such a global demand for raw materials used for the therapeutic application on this scale.

In a collaborative project, the Biotage team contributed their expertise in scaling up purification chromatography. With the help of the large scale Biotage® Flash 400 purification platform, Croda successfully scaled up their processes from development to production in just four months. This not only resulted in a stable, commercial grade manufacturing process, it also saved Croda valuable time and reduced their solvent consumption compared to existing, traditional methods.

### Smart science to improve lives™

Croda is the name behind the high performance ingredients and technologies in some of the biggest, most successful brands in the world: creating, making and selling specialty chemicals that are relied on by industries and consumers everywhere.

<https://www.croda.com/en-gb>

**CRODA**  
Health Care

## Biotage and Croda collaborate

For a number of years, Biotage and Croda have enjoyed a positive working relationship. In 2020 Croda approached Biotage in connection with a new and priority project relating to the emerging fight against COVID-19. Croda needed fast reliable access to pure lipids for LNPs used in mRNA vaccines.

As part of a rapid response, a technical team from both companies met routinely to discuss the challenge and scale up. Initially, the use of Biotage automated lab scale systems to develop efficient purification methods, which were then transferred to the larger Biotage® Flash 400 skid purification platform resulted in significant time saving potential compared to traditional process development. The application of a new high performance silica enabled a significant increase in sample loading on the column, resulting in both a higher concentration of final product, and even less solvent usage. The stationary phases used in purification cartridges at lab scale was the same as that used in the larger 40Kg cartridges, so there were no technical or process surprises and everything proceeded as expected.

“ A great example of how two teams of people came together and used smart science to improve lives”

Rebecca Murray, Croda

During this process, the team at Croda were also able to engineer out the use of more toxic solvents, as used in the original synthetic lab procedures, and replace them with fewer, and less toxic solvents optimized for this type of purification. The adoption of more efficient purification protocols also allowed the synthetic route to be further simplified and the total number of steps reduced.

Purification of lipids is a technical challenge but with the Biotage flash purification solution, skilled PR+D chemists at Croda were able to scale-up the purification for the required production output scales in an unprecedented manner in a record 4 months. Reviewing the chemistry, sharing ideas and experiences, the teams made some significant headway into this difficult area. The team at Croda were also able to engineer in some significant process improvements, reducing the use of solvents while also improving outputs and yields.



Jennifer Smith, Process Development Scientist, Croda.

“ It’s been a pleasure to work with the team at Croda in the UK and witness firsthand the efforts that the team have gone to in order to scale up production in such a short time”

Tim Jones, EMEA Sales Manager Scale Up.

## Overall process Improvements

The outcome resulted in a greener, more efficient process which produced significantly less waste than the original methods transferred from lab scale as shown in the table below.

Status per batch	Existing Process (steel/glass column)	Improved CRODA Process using Biotage® Flash 400L cartridges
Volume of solvent used	-	91% reduction
Number of column runs	-	97% reduction
Number of class I/II solvents used	3	1
Number of class III solvents used	0	1
Solvent Mixes	Multiple mixes and combinations	2 optimized mobile phases

“ This is a success story that we are proud to share. Usually it takes 2-3 years to complete major projects such as this but in 6 months we got the technical solution in place. Using the Biotage Scale-Up platform saved enormous amounts of solvents. Croda designed and built a new factory in six months for this purpose. We are proud of the hard work our respective organizations have achieved and we feel proud of being part of solving a serious societal problem using Smart science to improve lives”

Steve Mellor,

Research & Technology Director – Health Care, Croda

“ Helping a client to save days of plant time, increase overall process safety profiles, reduce risk (both business and technical) while playing our small part in helping to make the world more sustainable, healthier, greener and cleaner has been very satisfying”

Dr. Sunil Rana, Global Scale Up Business Manager, Biotage

## Conclusions

The team at Croda needed enough pure material quickly and reliably for the overall project and also to support future vaccine program development with their partners, based on lipids for LNP delivery systems. Technical project discussions and the combined experience of the teams involved helped identify a number of areas to explore and develop. Close collaboration, coupled with the initial use of the Biotage purification solutions such as Biotage® Selekt to determine and optimize methods, and Biotage® Flash 400 in commercial production facilitated the overall rapid development and production of key lipids in the global fight against COVID-19.

### EUROPE

Main Office: +46 18 565900  
 Fax: +46 18 591922  
 Order Tel: +46 18 565710  
 Order Fax: +46 18 565705  
 order@biotage.com  
 Support Tel: +46 18 56 59 11  
 Support Fax: +46 18 56 57 11  
 eu-1-pointsupport@biotage.com

### NORTH & LATIN AMERICA

Main Office: +1 704 654 4900  
 Toll Free: +1 800 446 4752  
 Fax: +1 704 654 4917  
 Order Tel: +1 800 446 4752  
 Order Fax: +1 704 654 4917  
 ordermailbox@biotage.com  
 Support Tel: +1 800 446 4752  
 us-1-pointsupport@biotage.com

### JAPAN

Tel: +81 3 5627 3123  
 Fax: +81 3 5627 3121  
 jp\_order@biotage.com  
 jp-1-pointsupport@biotage.com

### CHINA

Tel: +86 21 68162810  
 Fax: +86 21 68162829  
 cn\_order@biotage.com  
 cn-1-pointsupport@biotage.com

### KOREA

Tel: +82 31 706 8500  
 Fax: +82 31 706 8510  
 korea\_info@biotage.com  
 kr-1-pointsupport@biotage.com

### INDIA

Tel: +91 11 45653772  
 india@biotage.com

Distributors in other regions are listed on [www.biotage.com](http://www.biotage.com)

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