The pursuit of excipient excellence
Our roots are in dairy producing companies in both the Netherlands and New Zealand. Companies that have a history of more than 100 years. Companies that gradually transformed into modern producers of lactose excipients and that have joined to become the world’s leading excipient manufacturer.
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1900</td>
<td>Hollandsche Melk Suikerfabriek (Dutch Milk Sugar Factory) founded</td>
</tr>
<tr>
<td>1913</td>
<td>The New Zealand Sugar of Milk and Casein Company Ltd founded – later to become The Lactose Company of New Zealand (LNZ)</td>
</tr>
<tr>
<td>1926</td>
<td>Six Dutch dairy producers form a cooperative: De Meijerij Veghel (DMV)</td>
</tr>
<tr>
<td>1960</td>
<td>DOMO-pharma starts producing pharmaceutical grade lactose</td>
</tr>
<tr>
<td>1965</td>
<td>First production of direct compression lactose by DMV in Veghel</td>
</tr>
<tr>
<td>1985</td>
<td>Start of inhalation grade lactose by DOMO-pharma in Borculo</td>
</tr>
<tr>
<td>2003</td>
<td>Superdisintegrants business and factory acquired from Avebe</td>
</tr>
<tr>
<td>2006</td>
<td>DMV-Fonterra Excipients created from DMV International and LNZ’s pharmaceutical lactose business groups</td>
</tr>
<tr>
<td>2006</td>
<td>DMV-Fonterra Excipients created from DMV International and LNZ’s pharmaceutical lactose business groups</td>
</tr>
<tr>
<td>2010</td>
<td>DOMO-pharma integrated into the DMV-Fonterra Excipients organisation</td>
</tr>
<tr>
<td>2011</td>
<td>DFE Pharma brand established, combining the businesses of DMV-Fonterra Excipients and DOMO-pharma</td>
</tr>
</tbody>
</table>
We are DFE Pharma

We are the global leader in excipient solutions. We develop, produce and market excipients for oral solid dose and dry powder inhalation formulations. Our customers are pharmaceutical companies, operating globally, regionally and locally.

We are a joint venture between two leading global dairy cooperatives: Royal FrieslandCampina (the Netherlands) and Fonterra (New Zealand). We are headquartered in Germany (Goch) and have production facilities in Germany (Nörten-Hardenberg), New Zealand (Kapuni) and the Netherlands (Borculo, Foxhol, Veghel). We operate in more than 100 countries and have sales offices in Germany, the United States, Singapore and Japan. We work with a global network of over 100 well-trained agents and distributors.
The pursuit of excipient excellence

Excipient excellence is a pursuit that will never be fully achieved. What is excellent today will be outdated tomorrow. That's why to us the pursuit of excipient excellence is a way of life. A source of inspiration. Excipient excellence is what guides us on our way to developing and producing the best possible excipient solutions for our customers. Today, tomorrow, always.

We are DFE Pharma. We invite you to join us in our pursuit of excipient excellence.

Pursuit ‘the act of striving towards an ideal with strong determination.’
Excellence means we are leading in developing excipient solutions.

Excellence means we create excipient solutions that result in better performance of your pharmaceutical products, enabling you to contribute to the health of people around the world.

Excellence means we base our solutions on state-of-the-art expertise and over 100 years of know-how.

Excellence means we are committed to working together with you to develop the best possible new products and applications.

Excellence means we strive to be 100% reliable in our supply.
Leading in expertise

We are here to help you create formulations that set the new standard. When you are developing a new pharmaceutical product, you need a partner with proven expertise. A partner that shares its expertise and co-operates with your formulators. A partner whose excipient solutions result in consistent performance of your formulations.

We are that partner.

“Excellence means we base our solutions on expertise and over 100 years of know-how.”

Services

We have over 100 years of experience in developing and co-developing excipients for the pharmaceutical industry.
- We share our expertise with you through our online Knowledge Database that provides access to application suggestions and background data.
- We offer web seminars and regional customer seminars.
- We specialise in developing customised inhalation products.
- We offer a complete package of regulatory and quality support.
Leading in supply

We are here to ensure you can always produce your products. No matter what happens.
People’s lives depend on your products. So you can’t run the risk of not receiving your excipients. That’s why we offer complete reliability; a guarantee that our products will reach your factories. All over the world. In time.

Always.

“Excellence means we strive towards 100% reliability in our supply.”
Services

The geographical spread of our plants enables us to guarantee security of supply.

• We offer **Dual Sourcing**, which means you can always rely on the delivery of our products from one of our sites.
• We operate in more than 100 countries and own sales offices in Germany, the United States, Singapore and Japan. In addition, we work with over 100 agents and distributors all over the world.
• We offer you the option of **Guarantee of Supply**, a service to guarantee product availability.
Leading in time to market

We are here to help you grow by minimizing the time to market.
When you launch a new product, there is no time to waste. The sooner you get it on the market, the stronger your position. We support you in achieving that priceless competitive edge.

“Excellence means we help you to grow by offering the shortest possible time to market when you launch a new product.”
In our online Knowledge Database, your formulators can find exactly the right excipients for their formulation.

Our ‘Match Your Spec’ application allows you to immediately find a lactose product matching your requirements.

We have an online Q&A service which answers more than 95% of your questions, 24 hours per day.

Our technical and regulatory support ensures quick and successful registration.

To facilitate your registration process, Drug Master Files for the majority of our products are available at the FDA.
“Excellence means working together with a team of people devoted to delivering superior performance.”
Statement of excellence

We are committed to excellence.
As the leading manufacturer of excipients in the world, we need to make sure you can rely on us. That's why we only work with highly skilled people to manufacture the right quality products. Resulting in excellent excipient performance.

Excellent people
We know how a company culture defines its performance. Therefore we invest in a culture of excellence. A culture that puts customers first, is process oriented and cultivates reliability. A culture that inspires and challenges our team of 150 highly motivated people. People that come from all over the world and have a profound knowledge of formulation technology and the pharmaceutical market. People that have experience in a wide area of fields. People who deeply understand your needs.

Excellent quality
- We supply from manufacturing sites all over the world.
- Our facilities are dedicated to the manufacture of pharmaceutical excipients only.
- We have implemented a single, uniform quality system based on ISO 9001:2008 and IPEC® PQG** cGMP and – where applicable – ICH Q7***, at all manufacturing sites, including the parent companies.
- A program to monitor the effectiveness of the quality system is in place and ensures continuous improvement.
- Our customers are welcome to audit our manufacturing facilities in order to verify our quality status.

* IPEC: International Pharmaceutical Excipients Council
** PQG: Pharmaceutical Quality Group
*** ICH Q7: applicable for inhalation grade lactose
### Starch
DFE Pharma offers three reliable pharmaceutical-grade starch products:
- Solani Amylum: native potato starch
- Prejel PAS PH: fully pregelatinised potato starch
- SuperStarch® 200: partly pregelatinised maize starch

### Lactose
DFE Pharma supplies more than 30 pharmaceutical lactose grades off the shelf from multiple production sites. In addition, we develop customised products to meet your specific requirements. To simplify the selection of your lactose grade, we have created three product ranges:
- **Key range**: a selection of highly consistent lactose products suitable for most of your Oral Solid Dose Form (OSDF) applications. These grades are part of a formulator’s first choice during the start of a new OSDF project. This range includes milled, sieved and direct compression products (spray-dried, granulated and anhydrous lactose grades).
- **Speciality range**: a unique, broad range of milled and sieved lactose products with specific particle size distributions, accompanied by direct compression lactose products that provide unique functional properties helping you in your application.
- **Customised range**: a fully customised lactose product to meet your specific needs mutually developed in the shortest possible time.

### Inhalation
DFE Pharma is the world’s leading supplier of inhalation grade lactose. Used in all the leading Dry Powder Inhalation devices that are currently available worldwide, these products are produced to the high standards required for inhalation applications in their own dedicated production plants. DFE Pharma offers the following inhalation grade lactose brands:
- Lactohale® (sieved, milled and micronised grades)
- Respitose® (sieved and milled grades)

### Superdisintegrants
DFE Pharma is the world’s largest manufacturer and supplier of superdisintegrants. DFE Pharma offers the following superdisintegrants:
- Primojel®: sodium starch glycolate
- Primellose®: croscarmellose sodium
### Applications

<table>
<thead>
<tr>
<th>Product type</th>
<th>Product brand name</th>
<th>Tablets</th>
<th>Other solid dosage forms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Wet Granulation</td>
<td>Dry Granulation</td>
</tr>
<tr>
<td>Native potato starch</td>
<td>Solani Amylum</td>
<td>+++</td>
<td>++</td>
</tr>
<tr>
<td>Fully pregelatinised potato starch</td>
<td>Prejel PAS PH</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Partly pregelatinised maize starch</td>
<td>SuperStarch® 200</td>
<td>++</td>
<td>++</td>
</tr>
<tr>
<td>Milled lactose</td>
<td>Lactochem®, Pharmatose®</td>
<td>+++</td>
<td>+</td>
</tr>
<tr>
<td>Sieved lactose</td>
<td>Lactochem®, Pharmatose®</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Spray dried lactose</td>
<td>Lactopress®, SuperTab®</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Granulated lactose</td>
<td>Lactopress®, SuperTab®</td>
<td>+</td>
<td>0</td>
</tr>
<tr>
<td>Anhydrous lactose</td>
<td>Lactopress®, SuperTab®</td>
<td>+</td>
<td>+++</td>
</tr>
<tr>
<td>Inhalation grade lactose</td>
<td>Lactohale®, Respitol®</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sodium starch glycolate</td>
<td>Primojel®</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Crosscarmellose sodium</td>
<td>Primellose®</td>
<td>+++</td>
<td>+++</td>
</tr>
</tbody>
</table>

Dry granulation in this overview includes roller compaction and slugging.
Spheres in this overview are made by extrusion spheronisation.

+++ Highly recommended  
++ Recommended  
+ Possible but not first choice  
o Not advised