

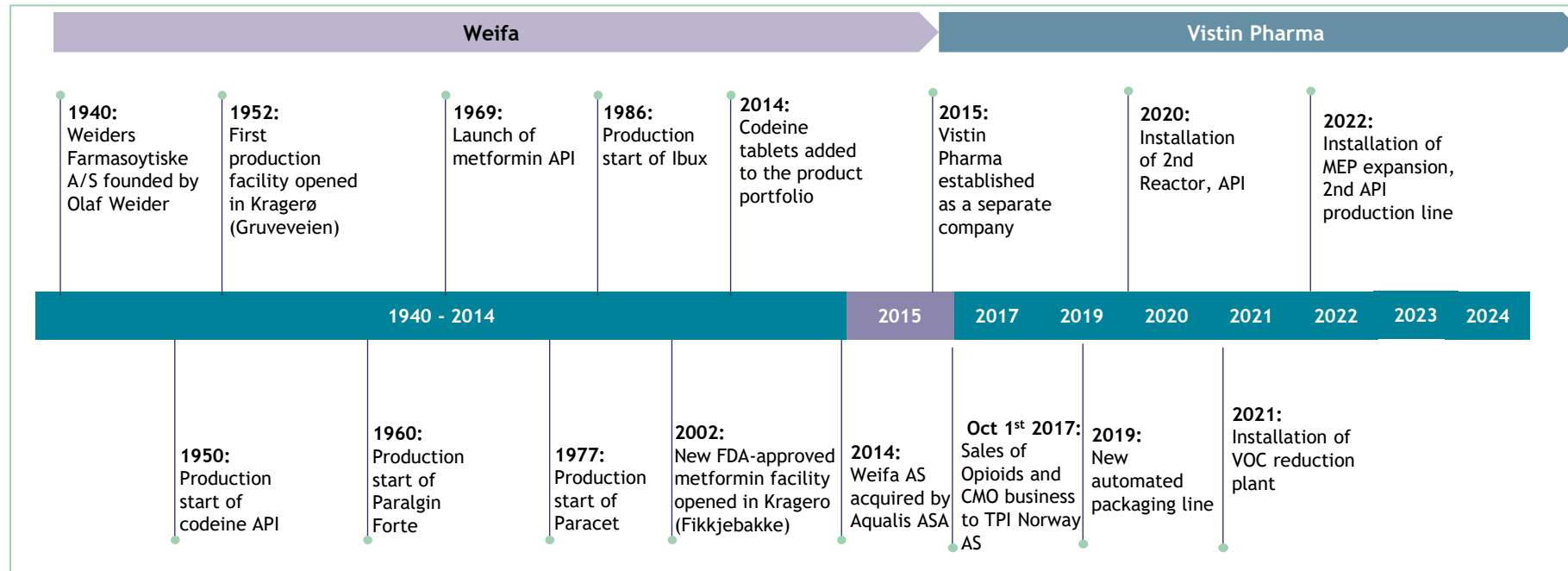


## Vistin Pharma AS

Global API producer of Metformin HCl, supplying 10% of the worlds demand for the treatment of Type II Diabetes. European High Quality producer with fully automated manufacturing plant in Norway.



# Vistin Pharma history



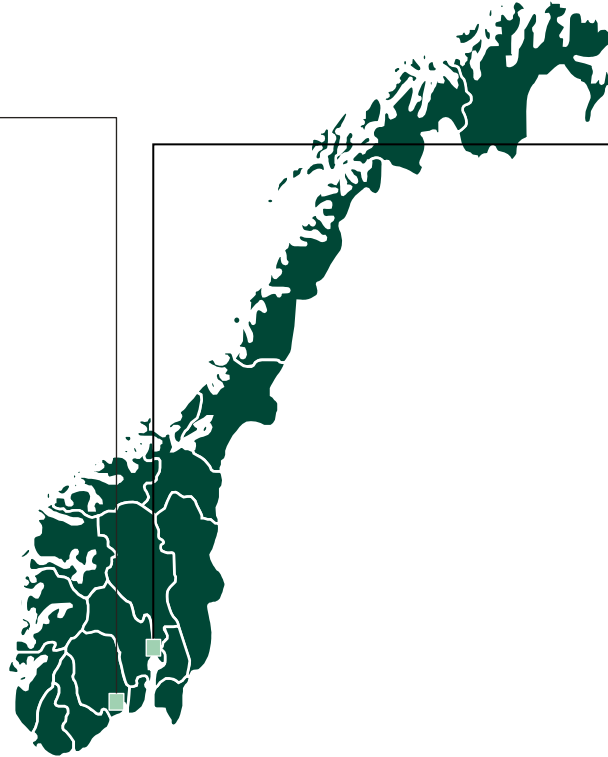
# Vistin Pharma site location



Site Fikkjebakke  
Stuttlidalen 4, Kragerø  
~75 employees

## Dedicated Metformin manufacturing site

- Opened 2002
- Manufacturing of Metformin HCl and DC
- QC laboratory and release center
- Procurement and logistics
- EHS
- Warehouse (raw materials and finished products)



Oslo Headquarter  
Østensjøveien 27, Oslo  
8 employees

- Administration
- HR
- Finance
- Regulatory Affairs
- Sales



# We are pure play metformin company with a bright outlook



- Market demand for Metformin is expected to grow 5-6% annually
- Vistin global market share will be approx. 15% with the new capacity



# A leading global dedicated supplier of Metformin



- **High Quality Premium manufacturer with ~10% global market share**
  - Dedicated & fully automated manufacturing site in Norway with 5500 MT Metformin API capacity
  - Ongoing expansion project increasing capacity to 7000MT during 2023
  - >60 years' experience in Metformin manufacturing
  - Long term collaboration and sales to global multinational pharmaceutical companies
  - Certified by all significant international regulatory bodies
- **Products offered**
  - Metformin HCl (bulk API)
  - Metformin DC (directly compressible granules)
  - Metformin HCl with specific particle size distribution (PSD)
  - Metformin HCl with lubricants (Premix)
- **Unique offering**
  - High delivery performance (>98%), on time in full
  - Flexible customer solutions and excellent customer service
  - Competitive pricing due to economy of scale
  - Strong focus on Environment, Social and Health (ESG)
  - Customized Particle Size Distribution
  - All shipments according to GDP (Good Distribution Practice)
  - API with no detectable content of nitrosamine
  - Low levels of residual DMA, impurity f
  - Best free-flowing API on the market





# Product Range, Capacities & Compliance

Product	Pack & batch size	Annual capacity	Regulatory compliance
<b>Metformin HCl</b> Active Pharmaceutical Ingredient	Pack size: 25 kg carton  Batch size: ~3100 kg	~5500 MT  Additional capacity from 2024 +1500 MT	Ph.Eur. (CEP), USP, JP and BP US DMF - LoA to US DMF available on request
<b>Metformin DC</b> Direct Compressible lubricated granules, 92,6%	Pack size: 25 kg carton (Big-bag available on request)  Batch size: ~800 kg	~800 MT Additional capacity from 2023 +800 MT	US DMF - LoA to US DMF available on request

## Regulatory Compliance

### Regulatory Status

- GMP Certificate for covering manufacturing of Metformin HCl (API) and Metformin DC (drug product intermediate)
- Certificate of Suitability to the European Pharmacopoeia (CEP)
- API in compliance with current Ph.Eur., USP and JP monographs
- US DMF filed for Metformin HCl and DC
- Other DMFs filed in Japan, Korea, Brazil, China and more
- Letter of Authorization to DMF available on request

### Latest authority inspections at Vistin Pharma

- Norwegian Medicines Agency (NoMA), March 2022
- US Food and Drug Administration (FDA), 2019. 2 Form 483 observations. (Audit closed)
- PMDA “paper audit”, 2019 (Approved)
- Korean Food and Drug Administration (KFDA), 2012
- Brazilian Health Authorities (ANVISA), 2011



# Business update Vistin Pharma

## 2019-2021

- Successful installation of new fully automatic packaging line in 2019.
- High demand for Vistin's volume, sold out in 2019, 2020 and 2021

## 2022

- In April 2020 our board approved a 10MEUR investment to double our manufacturing capacity
- Finalization of installation of expansion project in Q2 2022 to double capacity to ~7000 MT

## Nitrosamines

- Based on risk assessment and current available data (approx. 230 batches tested in-house, and more than 700 batches tested by customers):
- No detectable content of NDMA present in our Metformin HCl
- No routine testing is required for controlling levels of Nitrosamines in Vistin Pharma API
- Vistin's Metformin HCl has low levels of residual DMA (impurity F) which is relevant factor for limiting NDMA formation in formulated drug products.

## Covid-19

- No interruption in production due to raw material supply
- 98% delivery performance on time-in full to all customers during 2020 and 2021!
- Vistin is experiencing increased demand for European based supply of quality Metformin HCl



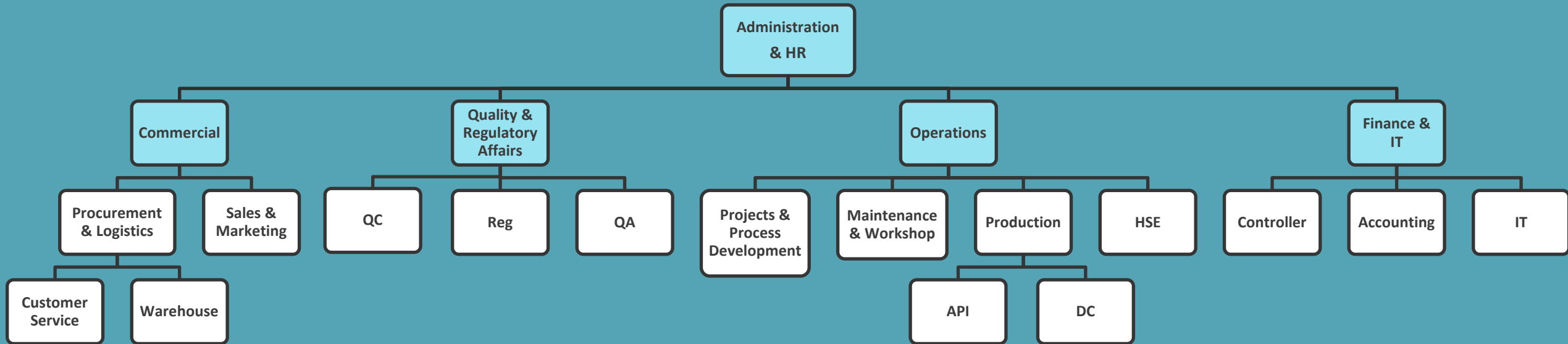











Vistin Pharma

## Organisation structure per March 2023



# Experienced management team

Name	Role	Experience
 <p><b>Kjell-Erik Nordby</b></p>	<p>Chief Executive Officer</p>	<ul style="list-style-type: none"> <li>■ Previous experience includes several years in top management positions at Alpharma, a leading international generic pharmaceutical company</li> <li>■ Holds a Master's degree in Pharmacy and Master's degree in Business Administration</li> </ul>
 <p><b>Alexander Karlsen</b></p>	<p>Chief Financial Officer</p>	<ul style="list-style-type: none"> <li>■ 10 years at GE Healthcare in various financial management roles, latest role as Country Finance Manger (CFO) for GE Healthcare in Norway</li> <li>■ Holds a Master's degree in Finance from Norwegian School of Management (BI)</li> </ul>
 <p><b>Vegard Heggem</b></p>	<p>VP Operations</p>	<ul style="list-style-type: none"> <li>■ Extensive experience from different managerial positions within operations, engineering and investment projects</li> <li>■ Holds a Master's degree in Chemical Engineering from The Norwegian University of Science and Technology (NTNU)</li> </ul>
 <p><b>Magnus Tolleshaug</b></p>	<p>Chief Commercial Officer</p>	<ul style="list-style-type: none"> <li>■ 20 years' experience from International Pharmaceutical industry, covering various managerial positions in Global Manufacturing Operations and R&amp;D</li> <li>■ Holds a MSc in Chemistry and Chemical Technology from The Norwegian University of Science and Technology (NTNU)</li> </ul>
 <p><b>Hilde Merete Hagen</b></p>	<p>VP QA</p>	<ul style="list-style-type: none"> <li>■ Previously spent 20 years at Pronova BioPharma, where she held several management positions within Quality Assurance and Quality Control</li> <li>■ Holds a Master of Science in Chemistry the University of Oslo (UiO) and a Master of Management from Norwegian School of Management (BI)</li> </ul>



# Vistin Sales Team



Vistin is now “ exploring “ Animal Health Diabetes for the champion market, and actively looking to advance in collaboration with J Lyons Marketing (US) for Animal Health Market



# Our strategic intent: Become the leading premium global supplier of metformin

- Decided in April '20 to invest MNOK 100 to build a 7000 MT metformin business through world class operations and strategic customer partnerships
- Make our manufacturing plant in Norway the most technology advanced and environmental sustainable state of the art metformin plant in the world
  - Increase the current production capacity from 5500MT to 7000MT through ongoing process development projects and operational efficiency
  - Become a front runner on sustainability by continuous focus and innovations on reduction of emissions and waste production
- Maintain superior supply delivery performance, high quality and competitive pricing







# ESG - Our vision is zero harm

**Vistin is a «green» and environmentally friendly pharmaceutical company with a “no harm” vision and “front runner” ambition**

**Vistin’s long term vision is to have zero impact on environment, people and local community by our presence**

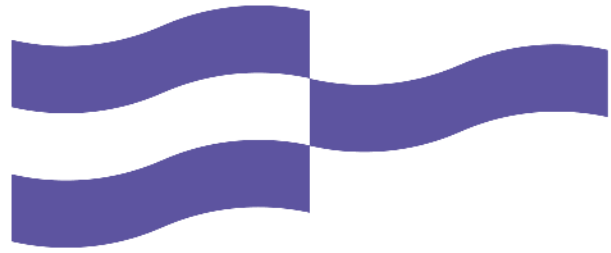
**Our goal is to double our manufacturing capacity without increasing environmental impact on water, air and soil**





# ESG achievements and Initiatives

- **Shifted from oil-based energy to hydro powered energy** to reduce carbon footprint
- **Recover and reuse > 95% of solvents** used in the manufacture of metformin
- **Ongoing project to reduce water consumption in the plant by 85% through recycling by 2023**
- **Reduced emission of Volatile Organic Compounds (VOC) to air by 90% during 2022**
- **Invested in a 2nd barrier (discharge tank) for wastewater in the plant to avoid any accidents or uncontrolled discharge.** Result: no discharge to the local community sewer above the strict permits set by the Norwegian Environmental Authorities during the last 5 years
- **Actively taking part in the circular economy; waste sent to approved incineration plant where the energy is reused as heat media for local communities and industry**
- **Since 2017, been part of a national program for surveillance of industrial impact on fjords and effluents.** Surveillance program and ecotoxicology test confirm that Vistin do not impact the effluent negatively
- **“Double capacity – Double care” No increase in discharge to air, sea or soil from doubled production capacity**



**Vistin Pharma**