



**An altogether
different kind
of CDMO**



**Newbridge
Oral Solids**



Welcome

Welcome to our Pfizer pharmaceutical manufacturing site in Newbridge, Ireland. We are a partner site for Pfizer CentreOne and offer access to leading oral solid capabilities, innovative manufacturing technologies and collaborative problem-solving.

We're dedicated to being your dependable manufacturing partner, at the scale you need.

- 01 Who we are
- 02 Our expertise
- 03 Your trusted CDMO partner of choice
- 04 Technical capabilities
- 05 What makes Newbridge unique
- 06 Packaging capabilities
- 07 Our commitment to sustainability
- 08 Our commitment to people
- 09 Certifications

[Click here](#)

Discover how our Newbridge site is **altogether different**



Who we are

We are Newbridge, 800-colleague strong with more than 10,000 years of manufacturing experience.

We've walked in your shoes and understand many of the drug development challenges you face. That's why we're a trusted CDMO partner of choice for so many of our customers.

We are driven. We show up and aim for our best every day because millions of patients around the world rely on our medicines.

We are global in reach, yet hands-on and local in our approach. We are a good neighbor with a goal to positively impact our surroundings. We believe that by doing good, we are investing into the future.

We don't stop at the impossible. If solutions don't exist, we seek to invent them. Our open and collaborative approach means we strive to offer you what you need, when you need it. We are experts in complex oral solids.



***We are Newbridge.
Discover our story.***

01



The patient is at the center of everything we do here in Newbridge. There's nothing like the pride you feel when a product makes a difference in someone's life. Working in Newbridge, we get that feeling every day.

Tony Walsh, Site Lead



Our expertise

We enable breakthroughs that change patients' lives through manufacturing high-quality oral solid medicines for our partners.

We manufacture over 10 billion oral solid SKUs annually, covering 100+ markets across five continents, specializing in multiple compounds: immunosuppressants, sensitizers, controlled substances, osmotic, multi-product, highly active, and hormones.

We offer dosage form flexibility from low dose, single and dual dosage forms, to combination products, and immediate/extended release.

Our capabilities range from pilot to commercial scale and our manufacturing expertise includes OEB 1-5, segregated areas for hormones and primary and secondary packaging.

We have an excellent compliance record, with zero critical observations in our history.

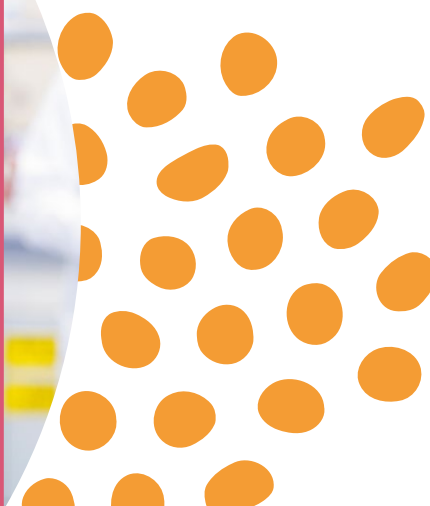
Site facts:

Over
10 billion

Oral solid SKUs per year

Across
5

Continents



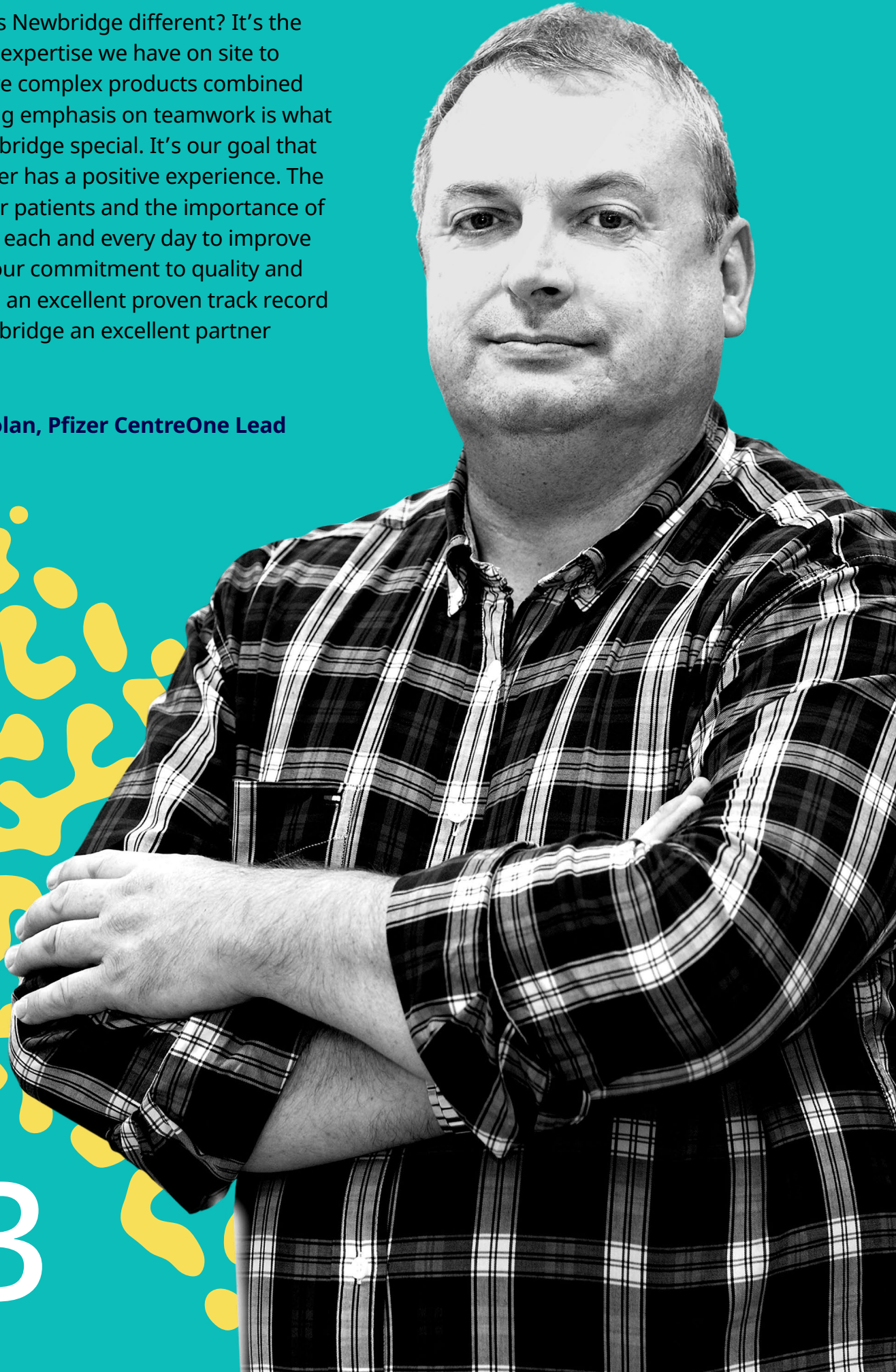
02





What makes Newbridge different? It's the people, the expertise we have on site to manufacture complex products combined with a strong emphasis on teamwork is what makes Newbridge special. It's our goal that our customer has a positive experience. The focus on our patients and the importance of what we do each and every day to improve their lives, our commitment to quality and service with an excellent proven track record makes Newbridge an excellent partner of choice.

Michael Nolan, Pfizer CentreOne Lead



03



Your trusted CDMO partner of choice

Our Pfizer CentreOne dedicated team treats your compound with the high standards reserved for Pfizer products.

We take the time to understand exactly what you need and give you honest advice. We're dedicated to delivering on what we promise. Which is surprisingly refreshing.

Our contract manufacturing experience spans more than 25 years.

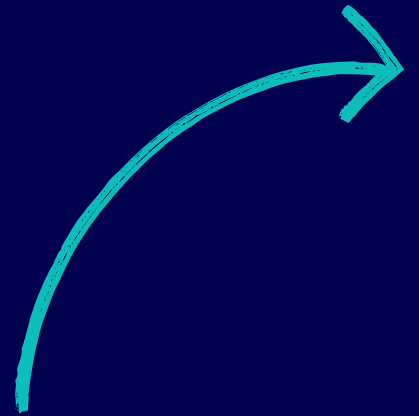
Our customers entrust us with some of their toughest manufacturing challenges.

We have a strong record of meeting and accelerating our partners' timelines. You can rest assured that we are dedicated to you and your success.

Your partner of choice
– click [here](#) to see our
video presentation



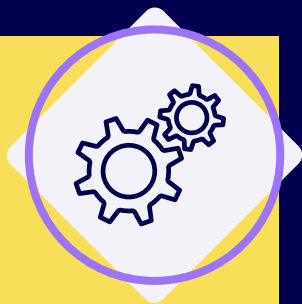
Technical capabilities



Our technical expertise is rooted in decades of experimentation, learning, and optimization. Our diverse solutions allow you to deliver medicines into the hands of patients with speed and efficiency.



Newbridge capabilities:



- Experts in complex tablet coating, including active coating
- 25+ years of experience in technical transfer
- 5KG – 1,000KG scale
- 20+ years of multi-particulates, pellet manufacture & encapsulation expertise
- Process robustness and optimization
- Speed to commercialization
- In 2021 osmotic drug product technology including:
 - Solvent membrane coating
 - Laser drilling
 - Aqueous film coating
 - Printing
 - Bead solvent coating
 - Active (Hormonal & Non Hormonal) coating
 - Sugar & Film coating
 - Encapsulation



What makes

Newbridge unique?

Technology Innovation Centre

Through partnerships built around intelligent collaboration and mutual understanding, we help solve your oral solids challenges and **guide your products to market.**

Newbridge key facts:



- Centre of Rapid Experimentation – CORE
- Understanding critical parameters and quality attributes
- Process development and manufacture for clinical supply
- Capability to handle potent compounds including hormonal production
- Licence to supply clinical trial material
- Scale up in complex processes
- Transfer 1 – 70KG scale capability
- Lean Six Sigma methodologies



05



In Newbridge we are passionate about science and how we can best use it to solve problems. We are lucky to be able to have small scale capability that replicates our commercial scale equipment. This means that we can really understand the science behind a process which results in fast transfers, improved processes and robust, repeatable commercial supply.

Kieran Coffey, Technical Services Lead



Click [here](#) to watch Kieran's webinar on coating

Packing capabilities

Newbridge offers more than 20 years of packaging experience.



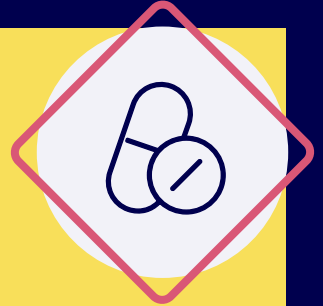
06

- Cold-forming and thermoforming capability
- Humidity-controlled packaging
- 2D data matrix applications
- Blister laser printing of variable data
- Online blister foil artwork and variable data printing
- Hospital-unit-dose (HUD) packaging
- Blister and carton harmonization programs
- Multi-folded booklets (MFB) support multi-region packs
- Tamper-evident glue-closure cartons

- Tamper-evident labelling
- Multiple labelling applications including reimbursement and security
- Serialization

We have segregated areas to pack:

- Oral contraceptives
- Central nervous system drugs
- Hormones
- Immunosuppressants



Our commitment to sustainability

We believe in building a good legacy and giving back to our community, and our goal is to be at the forefront of environmental protection.



07



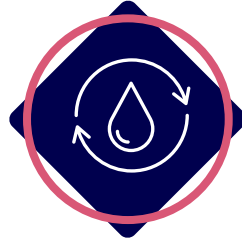
Zero waste to landfill



100% of electricity from renewable sources



Wastewater achieve drinking water quality standards following onsite treatment



On-site wastewater treatment plant recycles ~30,000+ m3 of wastewater per year for use in cooling towers



Hundreds of trees planted to offset carbon footprint



Our commitment to people

People are our most valuable asset. Newbridge colleagues are driven to deliver breakthroughs that change patients' lives.

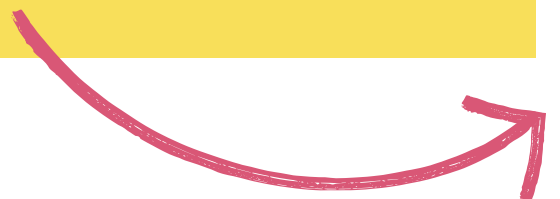


Our people:



- Highly engaged professional workforce committed to your patients' needs
- High performing process centric teams
- ~800 colleagues with combined expertise of 10,000+ years in OSD manufacture
- Average tenure of 14+ years
- Pfizer Newbridge leadership development programme
- Engineering apprentices
- Graduate programme
- Partnerships with Learning Institutes

08





I love introducing change and new ways of working. I enjoy coaching people through change and celebrating the successes with the team along the way. At Pfizer Newbridge I am constantly learning and developing new skills, which allows me to grow and develop every day.

Aisling Ahearne, Quality Control

Certifications

Certified by Health Products Regulatory Authority.

- Manufacturing Authorisation and GMP Certificate for non-sterile solid dosage forms – bulk tablets and capsules, and packaging
- Investigational Medicinal Products
- API Manufacture
- Controlled Substances – possess, produce and supply schedule 3 & 4 drugs
- Real Time Release

Inspections

- Zero critical observations from regulatory inspections
- 25 Regulatory Inspections in the last 10 years

- Ireland (HPRA)
- US FDA
- Argentina
- Brazil
- Libya
- Saudi Arabia
- Kenya
- Korea
- Turkey
- Russia

Other Regulatory Approvals via Inspections

- FDA (US)
- ANMAT (Argentina)



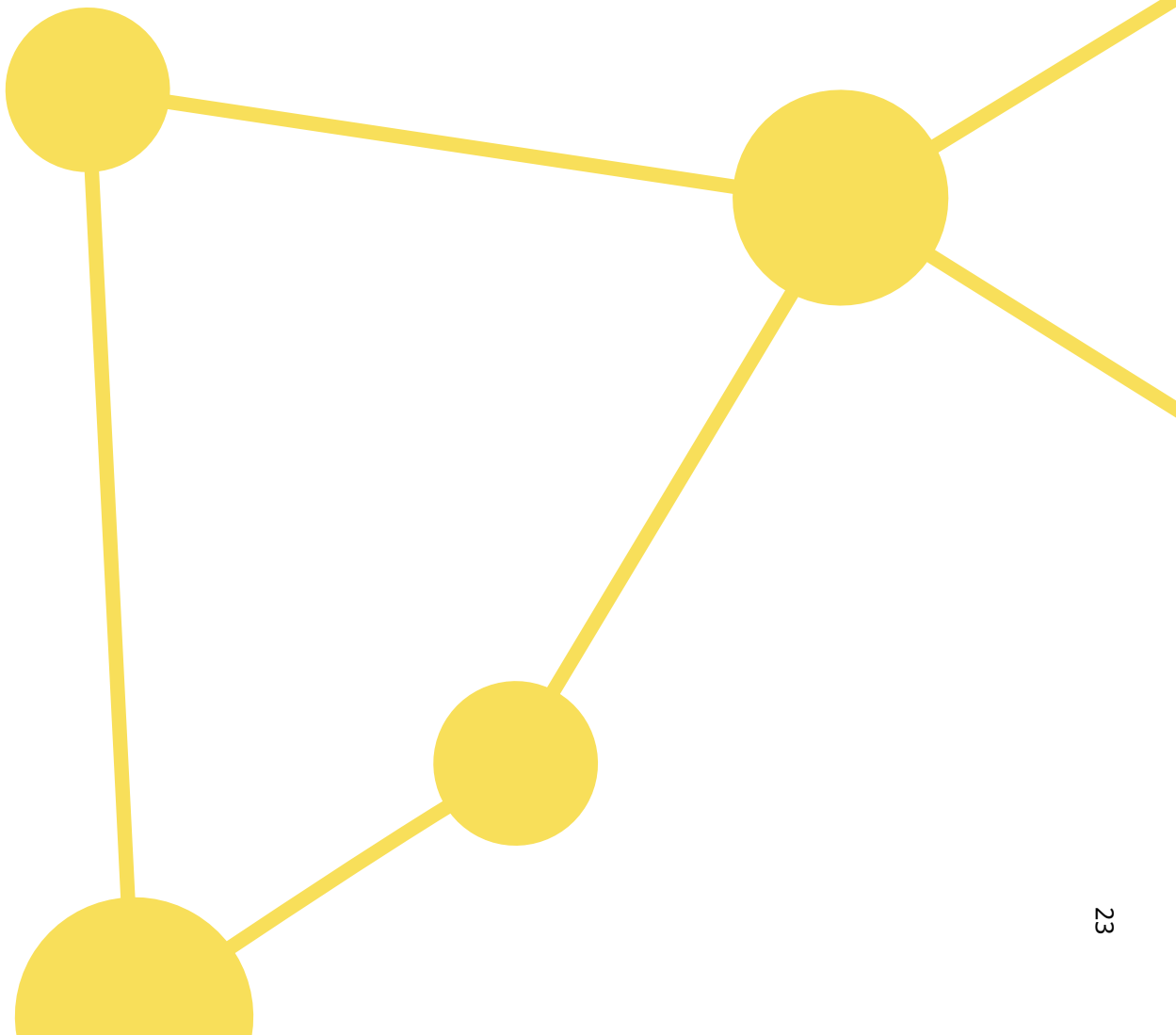
09





Discover how we're altogether different

For more information on Newbridge
CDMO services, please contact:
pfizercentreone@pfizer.com





For more information, visit
[pfizercentreone.com](https://www.pfizercentreone.com)