

An altogether different kind of CDMO



Ascoli
Oral Solids



Welcome

Welcome to our Pfizer pharmaceutical manufacturing site in Ascoli, Italy. We are a Pfizer CentreOne partner site dedicated to the production of oral solids. Located on the Adriatic Coast in Central Italy, the site delivers high-quality medicines to patients in more than 100 countries around the world.

- Our vision 01
- 02 Our mission
- 03 Your trusted CDMO partner of choice
- 04 A compelling approach to complexity management
- 05 Manufacturing capabilities
- Our commitment to quality 06
- Our commitment to innovation 07
- Frontline innovation 08
- Packaging capabilities 09
- 10 Our commitment to sustainability
- 11 Our commitment to people
- **12** Our commitment to patients

Click here

Discover how our Ascoli site is altogether different



Our vision

We aspire to be at the forefront of compelling science and manufacturing innovation by investing into resources, people, and partnerships. We have made meaningful contributions to improving patients' health for nearly 50 years and will continue to do so for years to come.



ASCOLI 2072 is our forward-looking vision and commitment to our site's future that guides our approach each day. Day-to-day, it reminds us that everything we do and the decisions that we make must serve to create a lasting future for our facility, leave a legacy and ensure that there is someone in our place in 2072.

We know that we will face competition on our journey in the years ahead, in ways that may be very different from what we know today. But we know that whatever the future brings, it's essential to stay true to our roots: Quality, Safety, Compliance and Supply Reliability.





Our mission

We are passionate about delivering the highest quality medicines while ensuring flexibility, cost competitiveness, speed, and safety.

Our impact on global health

Across our five decades of history, we have built expertise in a wide variety of therapeutic indications including Parkinson's disease, senile dementia, anxiety and sleep disorders, inflammation, mycobacterial infection, antifungals, migraine, oncology, smoking cessation and contraceptives. Our medicines reach patients all over the world, including Europe, the Americas, Asia-Pacific, Middle East, and Africa.







Your trusted CDMO partner of choice

As a Pfizer CentreOne partner site, we offer high quality pharmaceutical manufacturing in oral solids with specialization in highly potent medicines and high complexity management.

For over 35 years, we have expertly guided our partners' compounds from development to commercial manufacture. We offer end-to-end services from product and process development for lab and pilot scale to full manufacturing scale. Our team has experience in launching innovative products as well as producing established medicines.

We treat our CentreOne Partner's medicines with the same level of care as our own, using Pfizer's Global Quality System. With our culture of confidentiality and IP protection processes, your secret's safe with us.

Our dedicated stateof-the-art equipment and packaging lines, customer service and planning resources form a "site within a site" experience for our customers.

Site facts:

1972 130M 40+

Site established packs per year products

+088

Over **2,270**

3.7B

colleagues

SKUs

dosages per year Discover how we're altogether different

A compelling approach to complexity management

Experts in high potency medicines

Approximately 80% of our products are OEB 4–5 produced in our multipurpose area and more than 30% of products are controlled substances. Our entire facility is designed to ensure access and quality control across all phases, from the management of API to the finished goods phase.

Experts in managing complex supply chains

Operating in over 100 markets and supplying over 40 therapeutic products, we excel in complex supply chain management.

No matter what the requirements of your product may be, we help manage batch size ranges from five packs up to more than 400,000 packs.





Manufacturing capabilities

In 2019 Ascoli packaged 4.7B single dose units, of which 75% were manufactured on site.

We have experience in over 40 product families in OEB 1–5 and are licensed for cytotoxic manufacturing and controlled substances. We have expertise in containment and segregation, and offer five segregated

areas for manufacturing and packaging of high potency medicines. We are approved for clinical supply manufacturing and primary packaging.



We produce:

- Highly active compounds
- **Hormones**
- Cytotoxics
- **Controlled medicines**
- Steroid and non-steroid anti-inflammatories
- **Antimicrobial medicines**
- Cardiovascular medicine



As a global manufacturer, our medicines are destined for locations across the world, with more than 100 markets served.

The global nature of our operations and the high complexity of our medicines means we focus on delivering value through flexibility, innovation and continuous improvement.



Specific multi-product manufacturing capabilities include:

- Electronic batch records
- Isolated dispensing/weighing
- Automated dispensing
- Dry granulation
 - Roller compaction
- Wet granulation
 - Aqueous
 - Isopropyl alcohol
 - · Ethyl alcohol
- Tablet compression/ Capsule filling
- Coating
 - Film organic or aqueous solvent
 - Sugar
- Printing tablet





Our commitment to quality

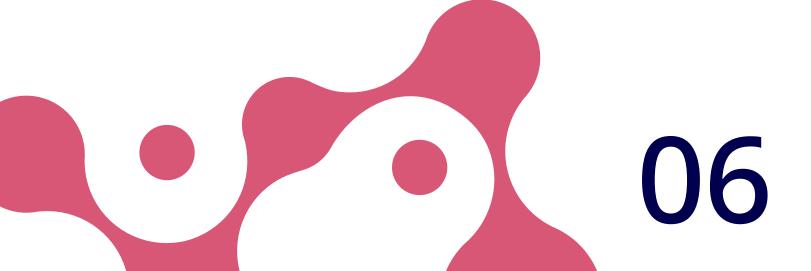
At Ascoli, high quality and safety standards are in our DNA. Our on-site Quality team consists of 150 colleagues focused on assuring that we always meet our rigorous standards.

We've walked in your shoes and understand the unique challenges facing your drug product. That's why our Quality Control laboratories conduct thousands of analysis to work toward continued Manufacturing Excellence and total product integrity.

Around 7,550 samples are submitted to process control analysis each year, with close to 3,200 release samples and 3,000 stability samples.

Our commitment to quality is evident in our solid regulatory compliance record, with zero critical observations throughout the history of the site.

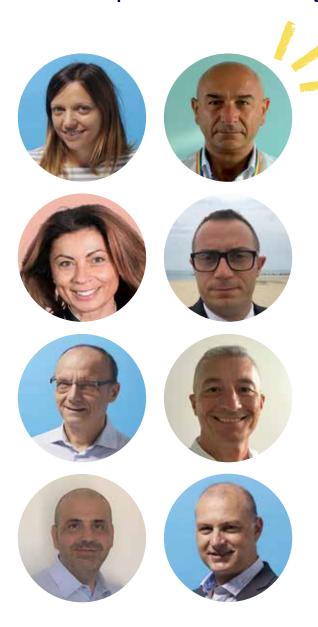
We receive regulatory inspections from major regulatory bodies such as FDA (USA), ANVISA (Brazil), AIFA (Italy), Turkey, Russia, and MFDS Korea.





Our commitment to innovation

Ascoli is home to an innovation team whose goal is to improve efficiency, safety and our environmental footprint through technology. They look for ideas inside and outside pharma manufacturing to generate process improvements.



Our team has pioneered the use of augmented reality and 3D printing for equipment maintenance. Experts can now inspect equipment remotely and spare parts can be printed efficiently on site.

We have also brought in robots from the automotive industry to facilitate the palletization of products.

Frontline innovation

80

In August 2020, we installed and validated new hightech machinery across one of our packaging lines.

Created by our engineering and manufacturing departments in collaboration with a local supplier, the robotic machine reaches new heights of performance assuring high quality and safety standards.



Packing capabilities

With nearly 50 years of packaging experience, we provide a wide range of options to meet your projects' needs. We offer 26 blister and bottle packaging lines, including high speed, high complexity, and high active equipment.



- Cold-forming and thermoforming capability
- Containment control (packaging of cytotoxics & hormones)
- Humidity-controlled packaging
- Primary packaging under isolator/ Pressure Air Barrier
- Multi-folded booklets for multi-region packs
- Tamper-evident glue-closure cartons and labelling

- Customization opportunities include Dosepack, Hospital-unit-dose packaging, Combo product blister, Calendar pack, Color Differentiation, UV printing and Late Stage Customization on **Bottle Packs**
- Online printing for foils on 100% of blister lines
- Multipurpose Packaging -EU Serialization and T&T (USA, China, Korea, MEA)

Color Differentiation



Our online printing capabilities allow for a high level of customization. The **Hospital Unit Dose** packaging on blister products can display the GTIN or the batch number and expiration date, preventing mix-ups and increasing efficiency when each tablet is distributed internally at the hospital. Our color differentiation options can also provide a clearer way to distinguish between medications and dosages.



Our commitment to sustainability

Located in a small town in the Italian countryside, the Ascoli site is the largest of its kind in the surrounding area. We believe it is our responsibility to have a positive impact on the local community and the environment.

Through the use of solar power and cogeneration, Ascoli has reduced CO2 emissions by 52% and water usage by 20% in the last ten years.

In the last eight years we have reduced our total waste by 1/4. We have installed energy efficient water pump systems, cooling tower fans and chillers. Nearly 2/3 of our electric consumption comes from renewable sources. We promote and sustain the application of Forrest Stewardship Council Program for our clients.

The site has a strong connection to the local community. We provide tours to high school and university students and host various projects to give students real-world experience. We participate in local Earth Day volunteer activities, provide relief for natural disaster victims, and support local hospitals and nursing homes.





Our commitment to people

We believe that the quality of our team is essential for our success, and we do everything possible to recruit and nurture the best talent. We have hosted more than 55 internships in the past three years, with the highest performing students joining our ranks. Nearly one third of our colleagues have a graduate degree. The average length of service is 17 years. We offer coaching, job rotation, training, and certification which ensure the top quality of our teams.







Our commitment to patients

Patients are at the forefront of everything we do. Every year we make 3.7B dosages for patients in need. The medicines produced at our site have helped those with cancer, rare disease, infections, pain, diabetes, cardio-vascular disease, smoking and many other conditions.

Through intelligent collaboration with our partners, we bring medicines to patients well beyond Ascoli. With every tablet and capsule we manufacture, we enable you to deliver breakthroughs that change patients' lives.

Discover how we're altogether different

For more information on Ascoli CDMO services, please contact:

pfizercentreone@pfizer.com



For more information, visit **pfizercentreone.com**