

# Highly Potent APIs Experience Makes the Difference

## Our Experience for the Success of Your Project

**There is nothing as important as experience when it comes to handling highly potent active pharmaceutical ingredients (HPAPI) – from product development to commercial supply.** At Aenova we offer specialized, modern infrastructure and highly qualified experts for successful development and production of highest quality HPAPI products.

- HPAPI handling up to OEB 5
- Development and commercial supply for all solid dosage forms
- Oncology and immunosuppressants, hormones and low-dosed HPAPIs



## SITES

# Three Specialized Sites for HPAPI Handling in Germany and Switzerland

● **Münster**

### **Münster (Solid dosage forms)**

Hormone, hormone-like and low-dosed API drug products

### **Regensburg (Solid dosage forms)**

Oncology and immunosuppressant drug products

**Regensburg** ●

### **Kirchberg (Soft gelatin capsules)**

HPAPI drug products up to OEB 5

● **Kirchberg**

With our three centers of excellence, we are the one-stop shop for the entire product life cycle from development to commercial deployment.

Our most important assets are our experienced experts, our state-of-the-art facilities and highly competitive lean manufacturing concepts. Thanks to continuous investment in our site development, we can offer highly flexible technology solutions that are fully scalable from pilot to commercial scale.

## HIGHEST QUALITY STANDARDS – ENSURED EFFICIENCY

# An Outstanding Safety Concept



### **Dedicated plants**

Ensuring product separation



### **Closed containment technology**

For HPAPI handling



### **Isolator technology**

For dispensing of HPAPIs



### **Full protective garment**

With own monitored air supply offering high flexibility



### **Dedicated HVAC systems**

With 100% inlet / exhaust air



### **Continuously monitored**

Negative pressure cascade (clean floor principle)

## PRODUCTION

# Continuous Investment into Our HPAPI Sites

## REGENSBURG

### Investing in Scalable Growth

Advanced production capacity meets outstanding efficiency in our newest HPAPI building.

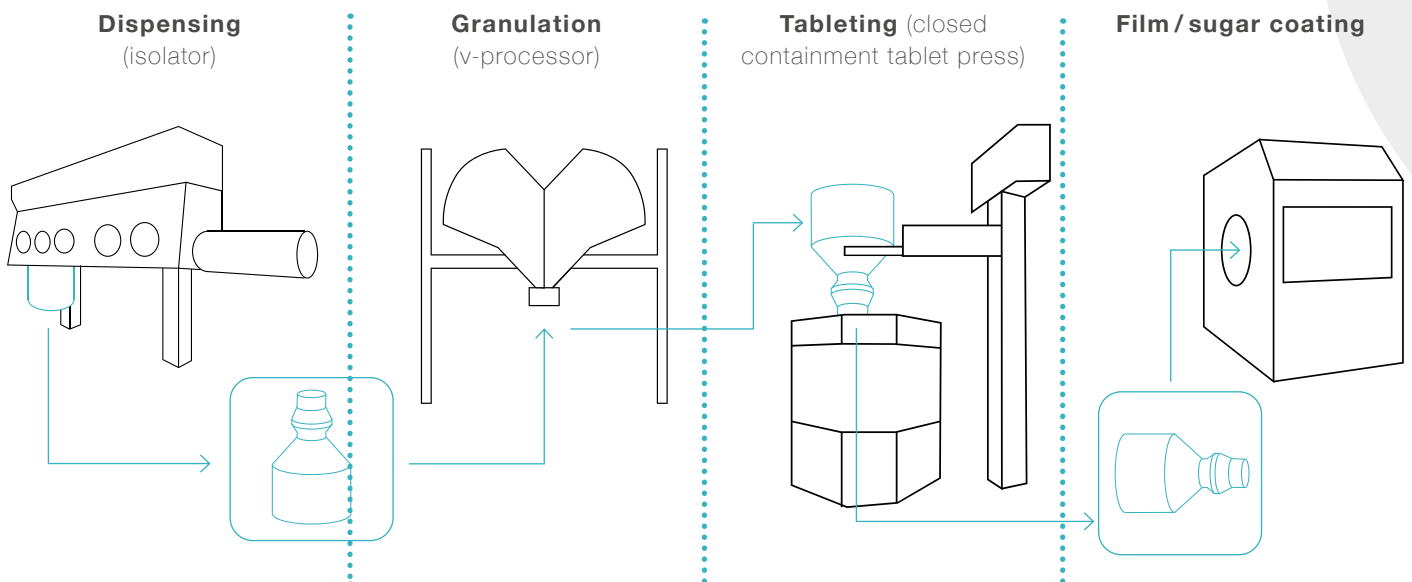
- 700 m<sup>2</sup> of new production and laboratory area to further extend HPAPI handling capabilities
- Offering customer-specific 'plant-in-plant' option
- Ensuring warehouse capacity for further growth



## MÜNSTER

### Closed Containment for Maximum Safety in HPAPI Handling

**We set standards for safety and process efficiency.** By using the end-to-end application of closed containment solutions for handling hormones and hormone-related APIs. This enables us to achieve outstanding performance in handling highly potent APIs and create maximum safety for products and personnel.



# Partnering Your Development to Accelerate Time to Market

## Development of oral solid dosage forms

- Offering utmost process flexibility for all types of solid dosage forms
- Scalable batch sizes from laboratory to commercial scale
- Full range of solid dosage forms, including low-dosed, micro-dosed, controlled release and fixed-dose combinations



Explore our whitepaper on HPAPI handling

> 100

Development projects ongoing

**Innovative medicines**

Phase I - III

**Generics development**



# We Cover a Broad Spectrum of Dosage Forms and Therapeutic Areas

Decades of experience, modern infrastructure and flexibility form the foundations of our service offering. This applies to various therapeutic areas such as oncology, immunosuppressive, hormone and hormone-like therapy. Thus, our offer covers all relevant solid dosage forms and a broad range of product designs (e.g. multi-blister, combination packaging and 'late-stage secondary packaging customization').

## Solid Dosage Forms



Tablets



Hard & soft capsules



Capsule dry powder inhalation



Specialty\*

## Solids Packaging



Blisters



Bottles



Secondary packaging



Clinical trial packaging

## CORE COMPETENCIES

# Therapeutic Areas & Products

### Hormone / hormone-like

- ✓ Oral contraceptives
- ✓ Hormone substitution
- ✓ Hormone oncology

### Immunosuppressive therapy

- ✓ Rheumatoid arthritis
- ✓ Psoriasis
- ✓ Organ transplants

### Oncology

- ✓ Cytotoxic
- ✓ Cytostatic
- ✓ Immuno-modulating

### TAKEAWAYS

- Expertise in all key therapeutic categories of HPAPIs
- Therapy-specific product design
- Track record for development, launch and tech transfer for innovative products and generics



## COMPLIANCE

# Our Commitment to Highest Quality Standards is Proven by Track Record

**Safety and product quality are our top priorities.** Our experience ensures compliance with key quality, regulatory and safety requirements, as shown by our impeccable track record of inspections by international health authorities and customers.

- ✓ **EU GMP**
- ✓ **US FDA**
- ✓ **ANVISA**
- ✓ **Russian MoH**
- ✓ **Turkey MoH**

- ✓ Many other certifications e.g.: **GCC, NMPA, PMDA, APAC**
- ✓ Specific knowledge for Japanese market supply

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