

Acino Contract Manufacturing Overview

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Global Key Account Manager, Contract Manufacturing





## Technology we're proud of

We have the know-how, technology and infrastructure to support you achieving your needs.

Our in-house engineering team has the experience and know-how to be able to adapt or bring in technology solutions quickly.

We continue to invest in a range of technologies, capabilities and company structures to stay competitive.

We are ready for serialization; not only bringing it in before market deadlines, but ensuring we can easily scale to future products.

>50

Years experience in pharm. manuf.

10

multi-national pharma customers

>60

Countries being supplied with our products

27

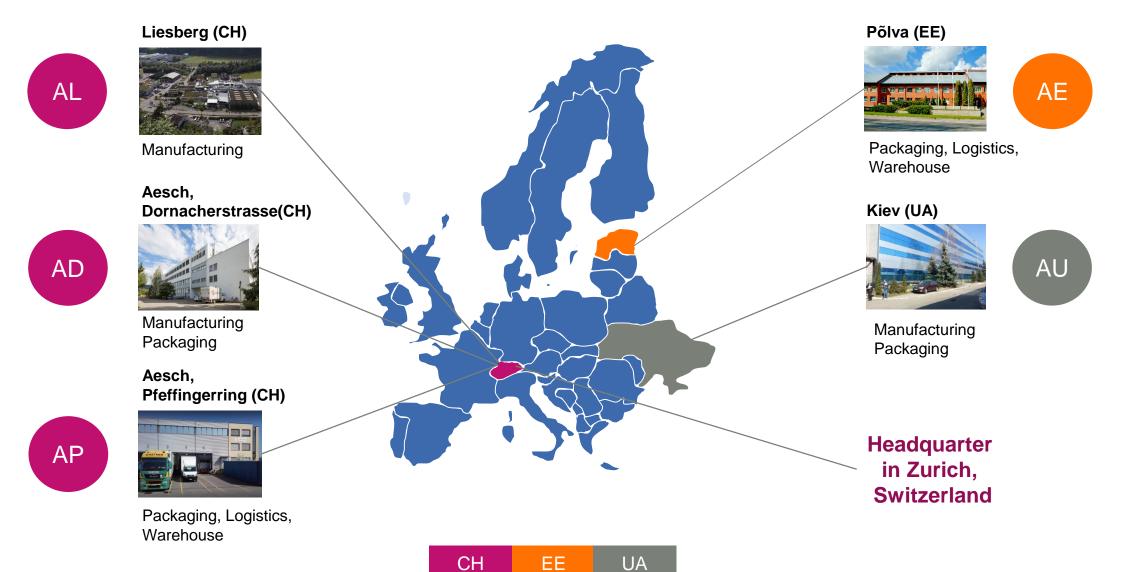
small-medium sized pharma customers





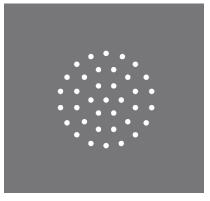
### Our global CMO presence

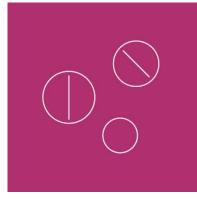


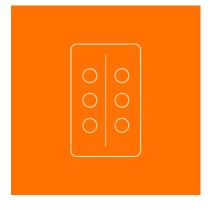


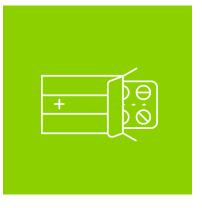
#### **Our Offering - Overview**











#### **Granulate/Pelletization**

- Granulation
- Extrusion
- Spheronization
- Direct pelletization in Fluid Bed Process
- Fluid bed granulation
- Aqueous & organic granulation
- Dry granulation

#### Oral Solid Dosage Bulk

- Modified-release Tablets (MUPS & Matrix Tablets)
- Film- or Dispersible-Tablets
- Printed Tablets
- Modified-release Capsules (MUPS)
- Capsules
- Micro-tablets in Capsules
- Narcotics & broadspectrum antibiotics

#### **Primary Packaging**

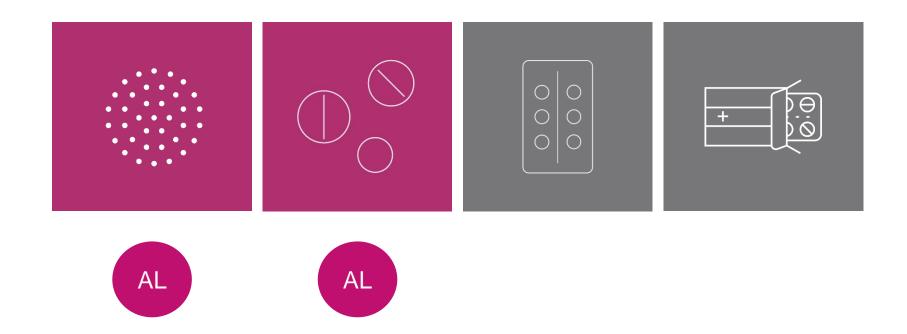
- PVC/PVDC
- Alu/PVC
- Alu/Alu
- Narcotics packaging (AP & AE)
- Highly actives packaging.
- Bottles (Glass, plastic, aluminum) with different caps (pushon, screw, snap safe, desiccant capsules)

#### **Secondary Packaging**

- Standard secondary packaging (for packs & bottles)
- PIL-packages
- Artwork management
- Serialization (starting from Q3 2018)
- Warehousing & logistics

### Our flexibility – your choice

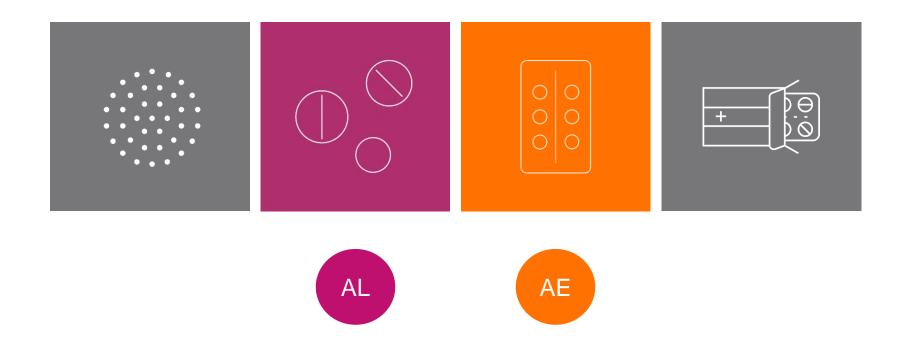




Due to our flexibility, our customer can choose the right set-up for their supply chain. Our team will assist our customers to choose the perfect solution.

### Our flexibility – your choice

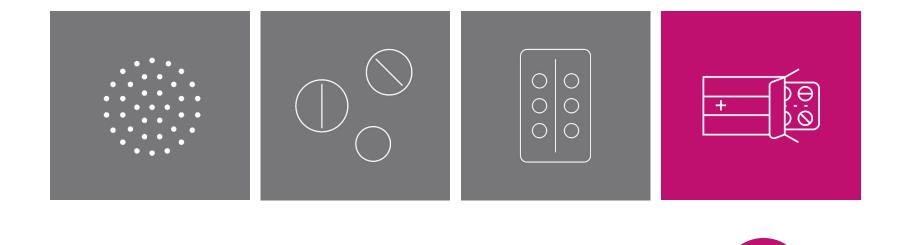




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### Our flexibility – your choice





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#### Granulation

- Pelletization:
  - Granulation / Extrusion / Spheronization
  - Direct pelletization in Fluid Bed Process
- Wet granulation:
  - Fluid Bed Granulation
  - Aqueous & organic granulation (Iscpropanol & Ethanol / with recovery of organic solvents)
- Dry granulation
- Our offerings:
  - Pellets
  - · Granulates.

<u> 10</u>

Fluidized Bed Granulator in CH 350 t

of pellets & granulate produced in 2016

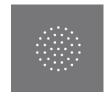


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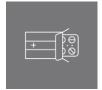












#### **Bulk Production**

- Focus on hard-to-make generics & niche-technologies
- Suspension layering & modified-release dosage forms
- Strong expertise in narcotics & broad-spectrum antibiotics production
- Our offerings:
  - Modified-release Tablets (MUPS & Matrix Tablets)
  - Film- or Dispersible- Tablets
  - **Printed Tablets**
  - Modified-release Capsules (MUPS)
  - Capsules
  - · Micro-tablets in Capsules.

3bn bulk units capacity

in CH

up to 900k

tablets/h















## Manufacturing at scale

- Small scale to large scale batch sizes (50'000 4'000'000 units)
- **Process Optimization**
- Support in late stage development & product launch
- Support in product transfer
- Our offerings:
  - · Granulation / Pelletizing
  - Encapsulation
  - Compression
  - · Coating.

floor space

300 m<sup>2</sup> 2-2'000 kg Batch size



available at



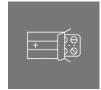












# **Primary Packaging**

- Price competitive:
  - High speed lines in AP for larger batch sizes
  - Low-cost packaging in AE for small batch sizes
- Transport to AE under GDP conditions and in full responsibility of Acino
- Our offerings:
  - PVC/PVDC
  - Alu/PVC
  - Alu/Alu
  - Narcotics packaging (AP & AE)
  - Highly actives packaging.
  - Bottles (Glass, plastic, aluminum) with different caps (push-on, screw, snap safe, desiccant capsules)

blisters packed in 2016

133 mio 5'250 km

of aluminium foil used in 2016



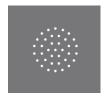
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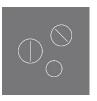


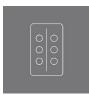














# **Secondary Packaging**

- Batch release according to customer wishes
  - · CH batch release in AP
  - EU batch release in AE
- Transport to AP under GDP conditions and in full responsibility of Acino
- Serialization/UI & tamper evidence implemented and running in AP. Acino wide implementation within Q3 2018
- Our offerings:
  - Standard secondary packaging (for packs & bottles)
  - PIL-packages
  - Artwork management
  - Serialization

40 mio

~ 1'000 km

packs shipped in 2016

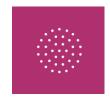
high tower of all packs shipped in 2016

















#### **Additional Services**

- Acino can be your **full service CMO**:
  - Worldwide API/raw material/FDF sourcing (incl. qualification of supplier)
  - Warehousing & distribution services
  - Regulatory assistance
  - Process optimization
  - Additional QC Services for customers

2'303

Own global registrations Qualified suppliers in 2017



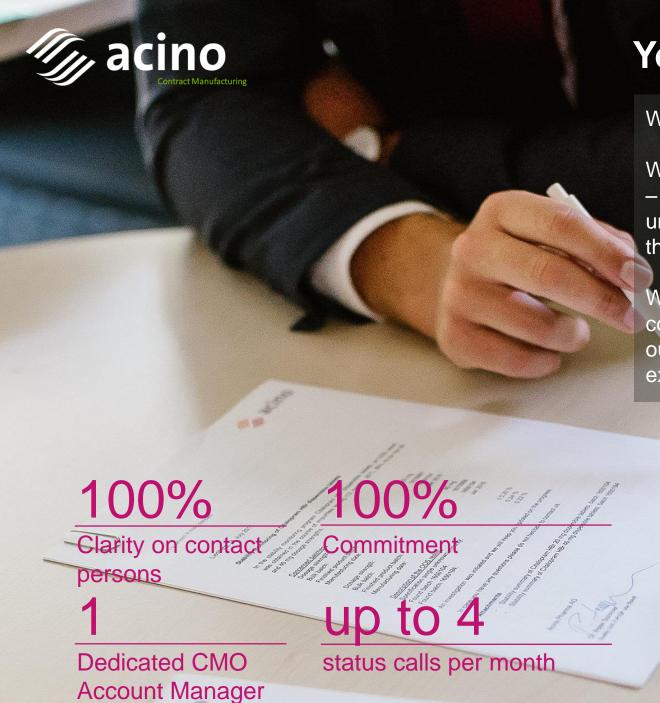
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# Your partner from wish to product

When you engage Acino, you are getting a true partner.

We think this starts with transparency and right expectations – before we go in to business together we make sure we understand your means in full. Our team will then propose the best options.

We know how situations can change within a minute, so we commit to highest flexibility in our offerings, services and in our every-day work to meet our customer's demands & expectations

# Project Management that goes beyond



Our project management goes beyond the technical realization of your project: By assuring fairness and transparency in our project proposal, we keep an eye on your budget and timelines.

The key to a successful project is a good planning – we strive for close collaborations and open communication with our customers directly from the start to make it work right from the beginning.

With our long-term experience in manufacturing of oral delivery forms, knowledge of your target markets & regulatory excellence, we can advise our customers in many aspects to make your project a success.



14

Transfer-projects in 2017

max. 1

month from RFQ to offer

 $\sim 6 - 8 \text{ m}$ 

duration of a packaging project

 $\sim 1 - 1.5Y$ 

duration of a bulk project (until final. of validation)

# **Acino Transfer Projects**



#### 9 - 15 months

Project Preparation Technical Feasibility Trials

Preparation Process Validation

Process validation

Stability Studies Document ation

Registration

Continuous Supply

Documentation exchange

Transfer Plai

Preparation Material No.

Ordering/ Delivery of API/Excipients

Ordering of Tooling

Small Scale Technical Trials

Testing of Analytical Methods

Analytical Method Validation Preparation Validation Plan

Signature round Documents

Ordering/ Delivery of API/Excipients Production of Validation Batches

Analytics of Validation Batches

Stabili Studie Validatior Report

Stability Report

Submission to relevant authorities

Approval of authorities









# Our Liesberg Team

#### Your contacts within Acino



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Thank you for your attention!

**Our Quality** Our Technology Our Flexibility YOUR BENEFIT YOUR CHOICE

