

AQVIDA



2015



AQVIDA

AqVida – Partners for the pharmaceutical industry

AqVida is a German pharmaceutical company based in Hamburg, Germany.

We are active in the fields of:

- Development of Generics, mainly Oncology Sector
- Registration procedures
- Supply of Finished Dosage Forms (FDFs) and APIs
- Compilation of registration dossiers for less regulated markets
- Technology-Transfer for local production
- Distribution, mainly business-to-business out-licensing



AqVida – BRIDGING THE GAP

Our credo is „Bridging the Gap“:

We bridge the differences in:

- Quality standards
- Regulatory
- Cultures
- Needs in the various markets



AqVida – Development of the company

2005

- Founding year of the company
- Main business: API sourcing
- Sales to unregulated and semi-regulated markets

2008

- First FDF registration in semi regulated market
- G-CSF was second biosimilar registration in Russia

2010

- Further FDF registrations in EU
- API sales to regulated markets

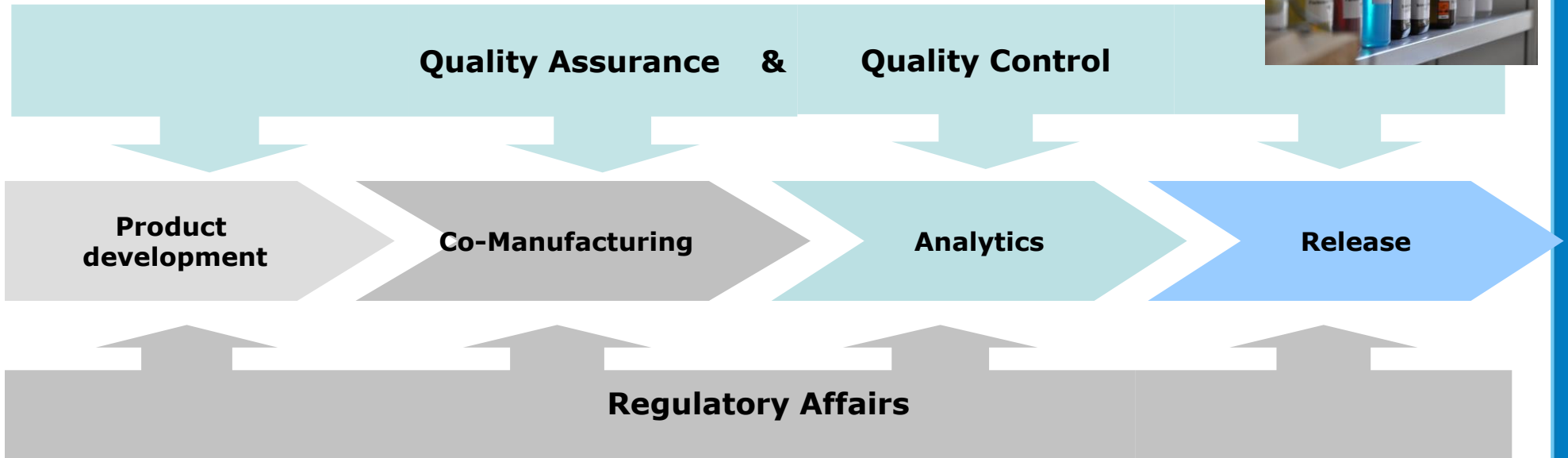
2015

- Today we have 7 FDF registrations in EU
- We hold a EU GMP

AqVida - Quality Assurance

No matter where: Quality is Key. Our vision is to make high quality oncology products available to every patient suffering from cancer.

- EU Quality is ensured by an uncompromising SOP system.
- Quality Assurance accompanies the complete product cycle.
- Regulatory Affairs team is involved from the scratch for best registration strategies

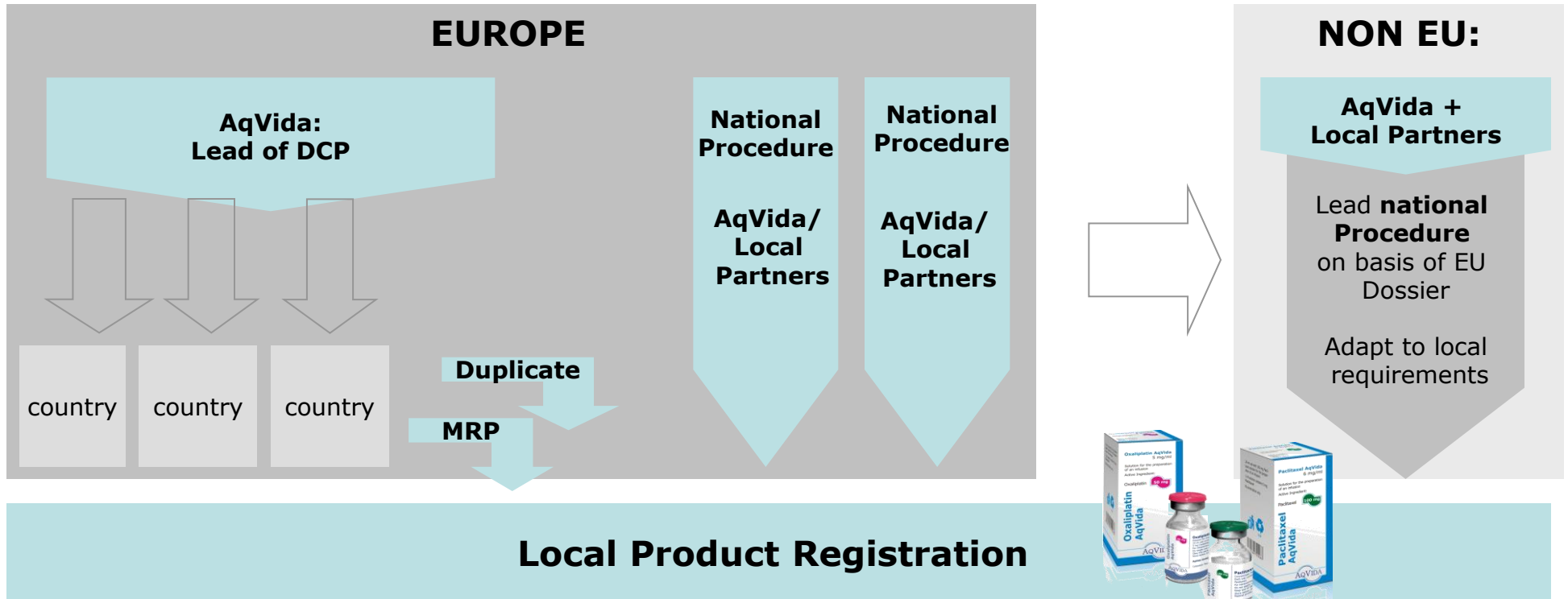


AqVida - Registration strategies



AqVida Regulatory team supports with best registration strategies

- Decentralized procedure, Centralized procedure, MRP, national procedure or duplicate have to be decided based on your individual situation
- AqVida Regulatory Team optimizes time and cost for you.
- Product registrations outside EU we carry-out together with our local partners.



Manufacturing

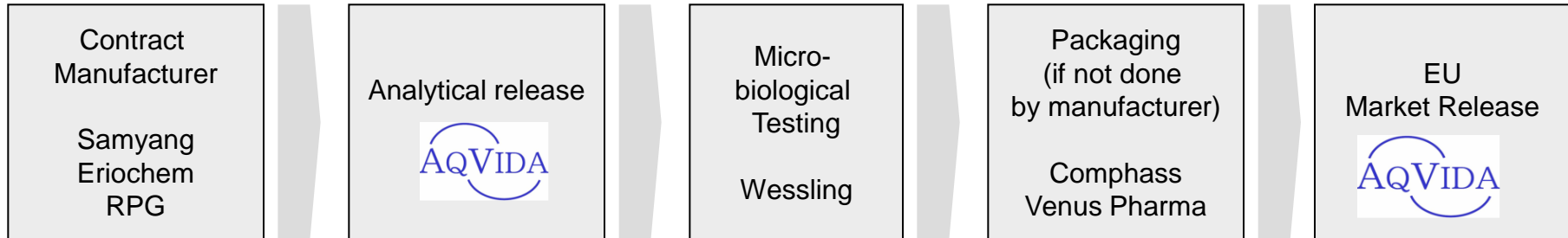
AqVida works in close relationship with contract manufacturers.

- All manufacturers are EU GMP certified
- They are regularly inspected by German Health Authorities

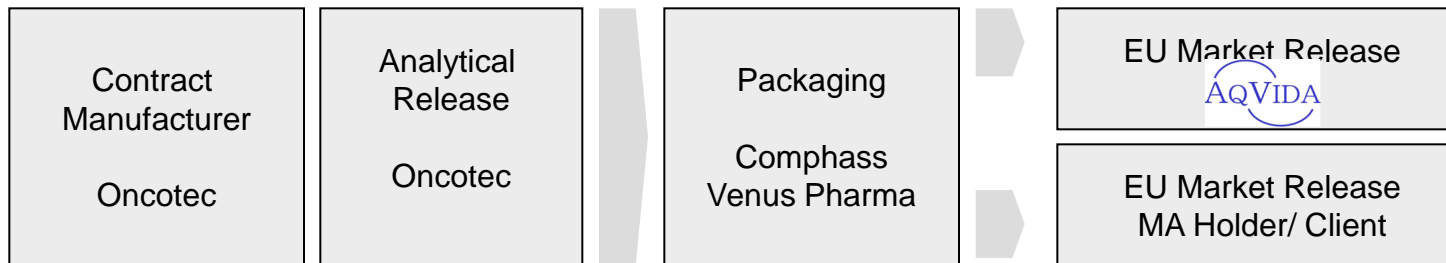


The actual process of Manufacturing and Release

1.) Non EU Manufacturing Generics



2.) EU Manufacturing Generics



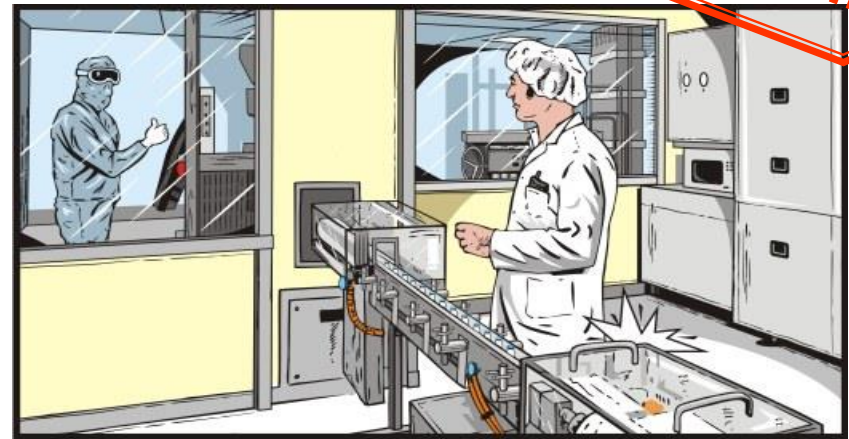
3.) Manufacturing Biosimilars



Future: AqVida Manufacturing Site

- AqVida is building its own site to produce oncology injectables
- Site will be located in the greater Hamburg area
- EU and German GMP compliance
- Commercial production expected to commence end 2016
- Full integration from development to manufacturing down to maintenance of dossiers and marketing authorisations

- All products 100% made in Germany



AqVida Product Portfolio

Injectables

Registered in EU

- Oxaliplatin, lyophilisate
- Oxaliplatin, solution for infusion
- Docetaxel, solution for infusion
- Epirubicine, solution for infusion
- Gemcitabine, lyophilisate
- Paclitaxel, solution for infusion
- Irinotecan, solution for infusion



Registered in non-EU

- Filgrastim, solution for injection

Under development

- Melphalan, lyophilisate

Orals

Registered in EU

- Azathioprine, film-tablets



Under registration

- Imatinib, capsule

Under development

- Sunitinib, capsule
- Erlotinib, tablet

Business Models Finished Dosage Forms

Depending on market structure and product we offer different business models

- Distribution of AqVida brand products
- License for sales under partners' brands
- Technology transfer for local production

AqVida branded Products



We deliver finished product ready to sell

Under Partners' Brands



We deliver finished product in partners' layouted package or we offer local production

AqVida Marketing Support

AqVida is regularly offering marketing support to its international sales partners, including e.g.:

- **Knowledge exchange:** Opinion leaders are invited to Germany to exchange know-how and get guided tours to German oncology day-clinics
- **Scientific studies:** AqVida is carrying out studies for optimizing treatment regimens
- **Supportive care:** We provide you with devices which add value to doctors and patients, e.g. needle free device for more safety in handling and catheter dressing patches to decrease the risk of infection



What we offer

- Development, manufacturing and supply on a **business to business** level without going into direct competition with our partners
- **Flexibility:** We are looking for the best solution for each market
- An **attractive product portfolio** for the oncology sector
- Support in **registration** procedures and regulatory affairs
- **High quality** products with EU GMP
- **EU release** analysis and market release
- **Know-how exchange** on expert level (e.g. oncologists)
- **Cost advantages** in procedures
- **Cost competitiveness**

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AqVida GmbH is compensating its CO₂ emissions by supporting reforestation programmes.