



Siegfried

expect more

Siegfried Drug Product



CPHI 2017
Vladimir Hornak



Our Vision

To be a world-class **integrated service partner** to the global pharmaceutical industry in the development and manufacture of drug substances and drug products that improve life.

Siegfried's Growth Builds on Three Distinct Businesses Tailor-Made for Four Target Business Segments

	Exclusive products	Portfolio products
Drug Substances	Contract Development & Manufacturing Intermediates and API – single client	Portfolio of APIs – multi-clients
Drug Products	Contract Development & Manufacturing finished dosage forms – single client	Portfolio of final drug products – multi clients

Underlying business models:

- Contract development and Contract manufacturing
- Co-development
- (In-house development)

Siegfried – Who we are

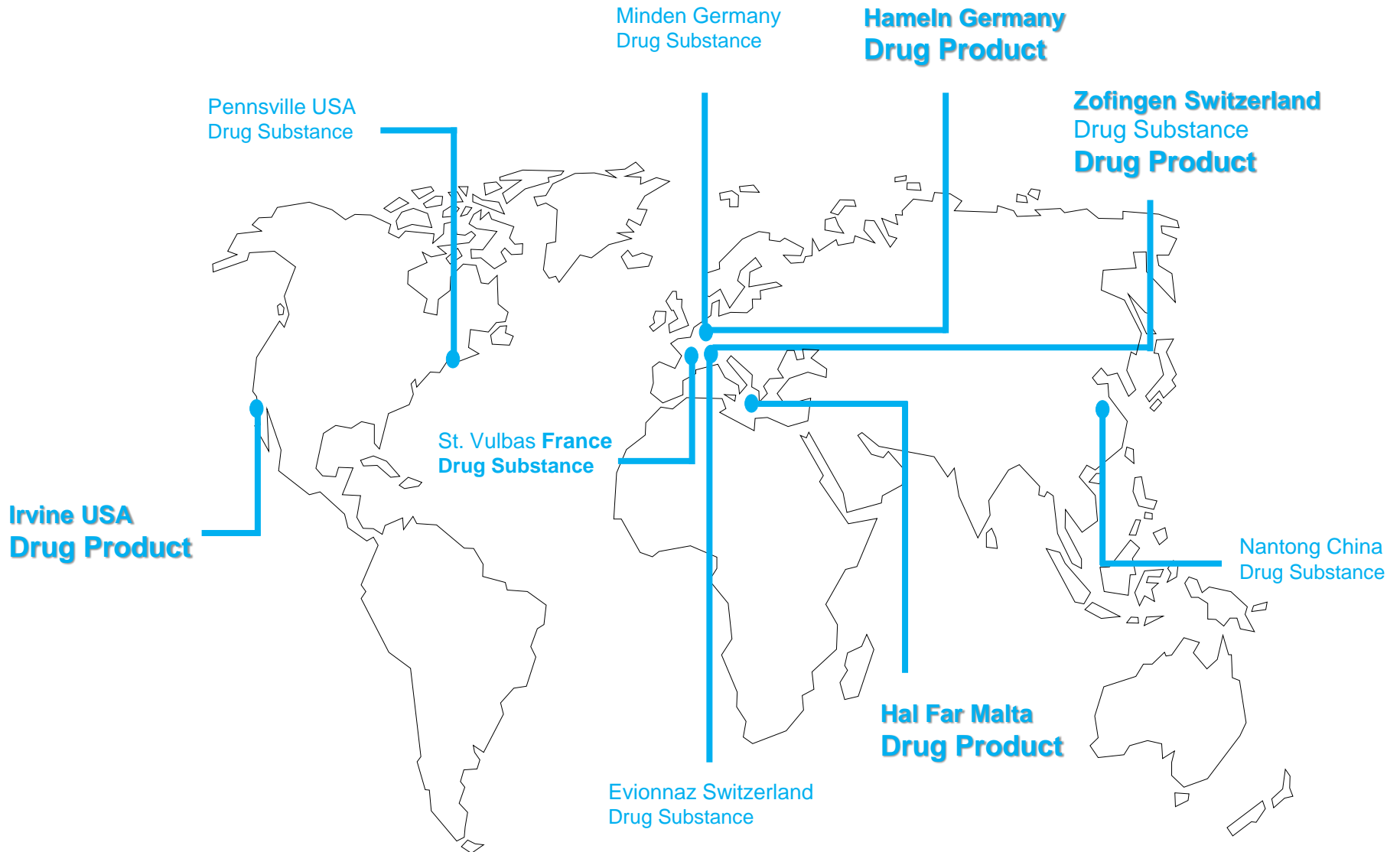


- Independent Swiss company, HQ in Zofingen (Aargau)
- Listed on the Swiss Stock Exchange SIX (Symbol SFZN)
- Total turnover (2016): 717 Mio CHF
- Total number of employees = ~2300



Siegfried is one of the very few custom manufacturing companies in the world that can provide an integrated supply for both APIs and FDFs

Locations



Manufacturing at Malta, Hameln and Irvine are the choices for drug product



Hameln, D

The site covers an area of approx. 40'000 m² with a roofed area of ca. 16'000 m²
Solutions, Suspensions in Vials and ampoules



Zofingen, CH

5 Pilot rooms with different equipment for cGMP Pharma production (lab and pilot scale), ExpoKat 1 – 2b (>10µg/m³) and 3 (1-10µg/m³)



Irvine, US

Total area: 5000 m² (+ 5000)
Aseptic fill/finish
Solutions, Emulsions, Suspensions, in vials, bottles, cartridges and PFS



HalFar, Malta

Built: 2004
Total Area: 9 600 (+8 000)
Tablets, Film-coated, Capsules, blister packaging
ExpoKat 1 – 2b (>10µg/m³) and 3 (1-10µg/m³)

Manufacturing at Malta, Hameln and Irvine are the choices for drug product



SOLID DOSAGE FORMS

TABLETS AND HARD CAPSULES



Zofingen, CH



Malta, EU

INJECTABLES

VIALS, AMPOULES



California, US



Germany, EU

OPHTHALMOLOGY

BOTTLE TIP CAPS, SQUEEZE TUBES



California, US

SPECIAL CAPABILITIES

CARTRIDGES, PFS
COMBINATION DEVICE ASSEMBLY



California, US

Siegfried Group: Locations

Irvine, CA, USA



Drug Product

Manufacturing and Packaging
(Aseptic fill & finish, sterile dosage forms)

Technical expertise and respective support capabilities provide comprehensive solutions for our customers from early stage clinical manufacturing through commercially marketed products

Site Irvine Overview



- Founded in 2002, located in Irvine, California; a Siegfried company since June 2012
- Specialized in difficult to manufacture formulations for the pharmaceutical and biotechnology industries
- Extensive experience supporting scale-up, process development, analytical testing, method transfer and product manufacturing

Site Irvine

Product Categories



- Injectables
 - Small Molecules
 - Biologics
 - Proteins
 - Antibodies
 - Oligonucleotides
- NCEs
- Ophthalmics
- Combination Devices

- Fill types
 - Solutions
 - Emulsions
 - Suspension

Site Irvine

Pharmaceutical Dosage Forms



- Liquid vials 2 - 50 ml
 - Dropper tip bottles 5 - 30 ml
 - Cartridges 0.5 – 3 ml
 - Squeeze tubes 1 – 50 g
 - PFS 0.1- 20mL
 - Assembly of combination devices
- Closures:
 - Screw Cap
 - Drop Tip
 - Septa / Stopper
 - Flip Cap
 - Crimp Cap
 - Luer Lock

Site Irvine

Regulatory Approvals and Certifications



FDA

- Drug Product
 - FDA registered drug establishment device
 - FDA registered device establishment
 - CA state food and drug branch licensed device manufacturing



EMA

- MHRA cGMP Certificate of Compliance
- European Clinical Trials Manufacturing



ISO

- 9001
- 13485



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