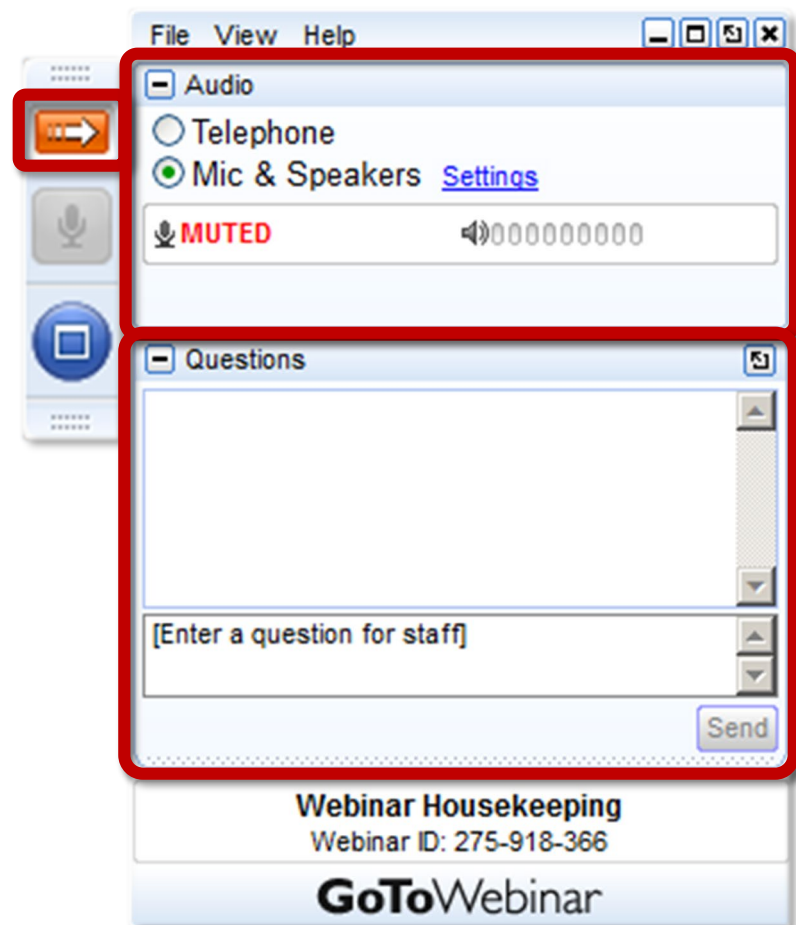
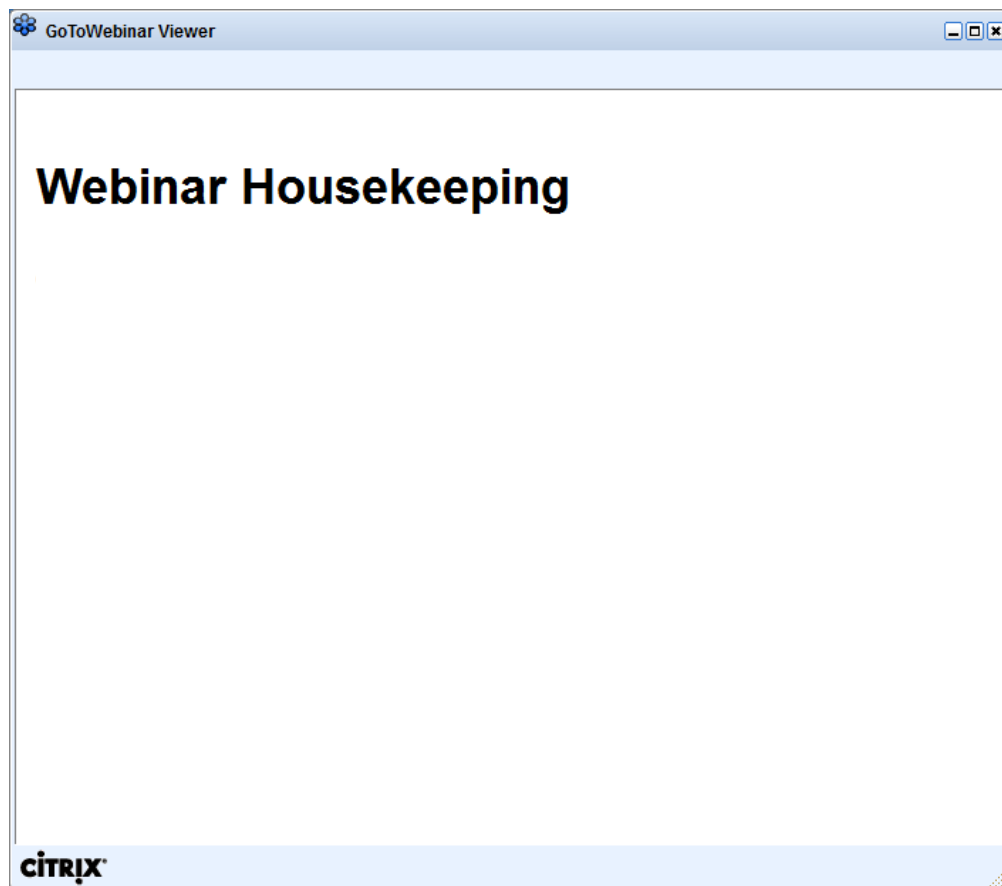


Going global in Biopharma: How to navigate the regulatory maze

GZA Webinar – May 29, 2019



Today's speakers



Dr. Maria Heimgartner

CEO of regulanet® Switzerland GmbH

maria.heimgartner@regulanet.ch

Since 2012, she has practiced as a principal consultant at Target BioScience. Previously, she served 8 years as General Manager for Genzyme Switzerland and 8 years as Business Unit Manager at Schering Plough.

Maria brings over 15 years of experience in the pharmaceutical industry and holds a PhD in Biology from the University of Munich and Bachelor of Science from the University of Houston, Texas.

Today's speakers



Douglas Karl Ebert

Senior Advisor Americas
for Greater Zurich Area Ltd (GZA)

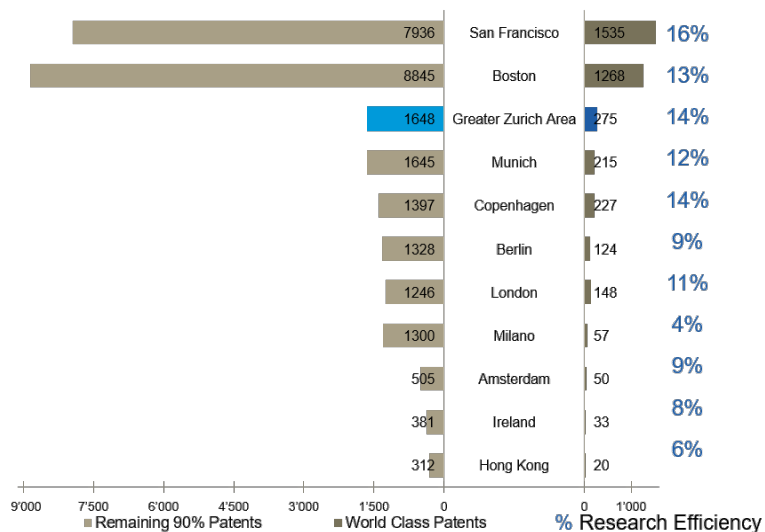
douglas.ebert@greaterzuricharea.com

He has over 25 years of experience in the field of international economic development and foreign direct investment, including engagements with a number of cantonal and regional development agencies in Switzerland as well as state governments.

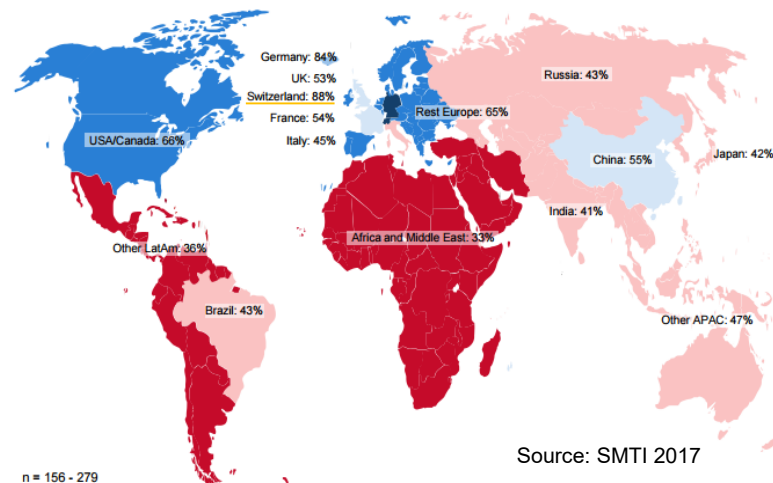
Prior to his work in economic development, Douglas Ebert specialized in work-force development as Vice President of Consulting and Client Services for an international outplacement firm.

Greater Zurich: Europe's Life Science Power House

World leading for life science innovation and talent



Highest growth prospects for bio- & medtech companies

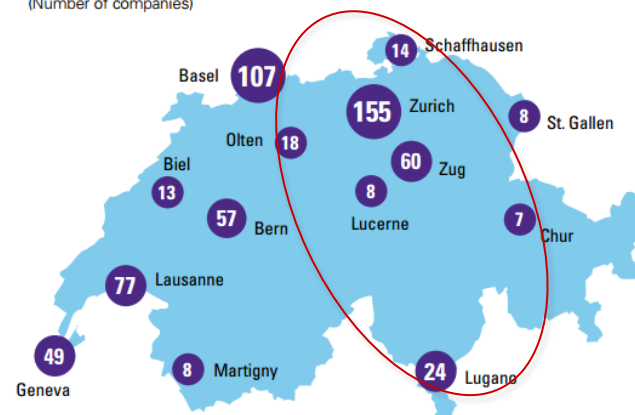


Source: SMTI 2017

Highest Density of Life Science Companies in Switzerland:

Largest number of regional HQs of non-domestic life sciences companies compared to other European countries such as Germany, France, Ireland, Netherlands and UK

LS clusters in Switzerland
(Number of companies)



AMGEN

ALEXION



Biogen

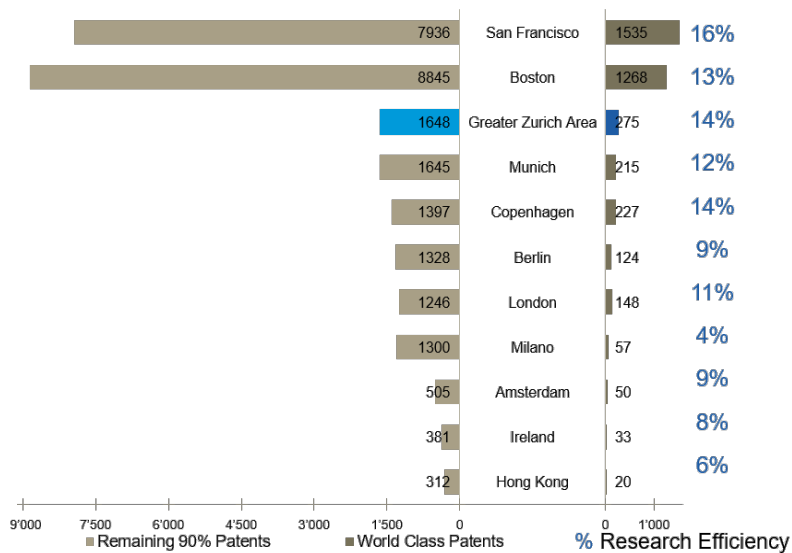
Pfizer

Takeda
LUPIN

Greater Zurich: Europe's Life Science Power House

World leading for life science innovation and talent...

...driven by world renowned academic institutes

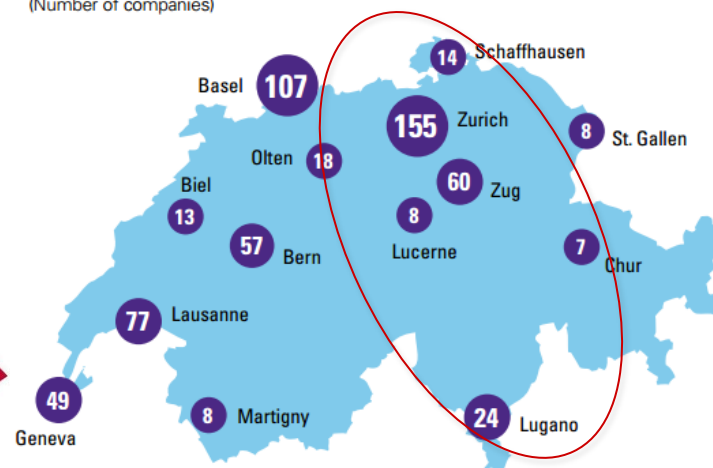


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Greater Zurich Area is the Preferred European Headquarters Location for Bio-Pharma Companies



and many more...



Greater Zurich Area
Expanding business horizons



Life Science Education & Innovation in the Greater Zurich Area

Life Sciences Education-, Innovation Centers, Business Incubators and Technology Parks in the GZA

- **School of Life Sciences FHNW:** www.fhnw.ch/lifesciences

Specialization in Pharma, Environmental and Medical technology, Biomedical IT, Chemistry and Molecular Bioanalysis.

Contact: Prof. Dr. Falko Schlottig, Director, falko.schlottig@fhnw.ch



FHNW School of Life Sciences

- **University of Zurich / ETH Zurich:** www.lifescience-graduateschool.uzh.ch

The Life Science Zurich Graduate School consists of sixteen highly competitive Ph.D. programs, run jointly by the ETH Zurich and the University of Zurich.

Contact: Prof. Raimund Dutzler, dutzler@bioc.uzh.ch, +41 44 635 6550



University of Zurich

ETH zürich

- **University of Zurich / ETH Zurich, Neuro Science Center:** www.neuroscience.uzh.ch

The ZNZ is a joint competence center of ETH Zurich and the University of Zurich creating synergies between its 1000 neuroscientists in research and education as well as with leading Hospitals.

Contact: Prof. Jean-Marc Fritschy, Director ZNZ, fritschy@pharma.uzh.ch

- **BIO-TECHNOPARK® Schlieren, Zurich:** www.bio-technopark.ch

Innovation Hub and top location for technology transfer in Switzerland. Bringing people together from the fields of science, technology and economy.

Contact: Mario Jenni, Managing Director, mario.jenni@bio-technopark.ch,



- **Balgrist Campus:** www.balgristcampus.ch

Research, Development and Teaching Centre, where research groups from various disciplines work on their own projects and exchange their experiences with developers and industry.

Contact: Thomas Huggler, General Manager, thomas.huggler@balgristcampus.ch

balgristcampus

Life Sciences Education-, Innovation Centers, Business Incubators and Technology Parks in the GZA

- **ETH Innovation and Entrepreneurship Lab (ieLab):** www.ow.ly/J3mua

The ieLabs are accelerators and melting pots of innovation, exploration and translation. It empowers young talents on their pathway to innovation and entrepreneurship.
Contact: Dr. Tomas Brenner, Head ieLab, tomas.brenner@sl.ethz.ch



- **Wyss Translational Center:** www.wysszurich.uzh.ch

A multidisciplinary research development center of the ETH and University of Zurich to foster efficient translation of discoveries into new medical therapies and innovative products.
Contact: Michael Stucky, COO, michael.stucky@WyssZurich.ch



- **Unitecra:** www.unitecra.ch

Unitecra is the technology transfer organization of the Universities of Basel, Bern and Zurich. With its services, it supports scientists in their collaborations with private industry and other public or private research institutions.
Contact: Herbert Reutimann, Managing Director, reutimann@unitecra.ch



- **Health Tech Cluster Switzerland:** en.healthtech.ch

The cluster of manufacturers, suppliers, research and training institutions, and investors unites companies from the various life science industries in a mutually profitable way, thus increasing their added value.
Contact: Patrick Dümmler, Clustermanagement, patrick.duemmler@healthtech.ch



Life Sciences Education-, Innovation Centers, Business Incubators and Technology Parks in the GZA

- **Grow Wädenswil:** www.grow-waedenswil.ch

Grow fosters innovative business ideas in the field of life sciences, facility management and IT and provides best infrastructure and high-tech facilities.

Contact: Prof. Dr. Dolf van Loon, CEO, dolf.van.loon@grow-waedenswil.ch



- **Toolpoint:** www.toolpoint.ch

Toolpoint for Lab Science is a vertical integrated cluster, which combines the knowhow and ability of the lab automation industry in Europe.

Contact: Hans Noser, Clusterpreneur, hans.noser@toolpoint.ch



- **TECHNOPARK® Zurich and Winterthur:** www.technopark.ch, <http://tpw.ch>

Bringing people together from the fields of science, technology and economy it is the top location for technology transfer in Switzerland and a key point of contact for innovative start-ups looking to transform knowledge into marketable products and services.

Contact: Michael A. Meyer, COO, michael.meyer@technopark.ch



- **Switzerland Innovation Park Zurich:** www.innovationspark.zh.ch

Offering laboratories, offices, pilot plants, test sites, jointly used technology platforms for companies of all sizes, it intensifies the level of cooperation between various players, allowing Swiss innovations to register market success in less time.

Contact: René Kalt, Geschäftsführer Innovationspark, rene.kalt@switzerland-innovation.com



Life Sciences Education-, Innovation Centers, Business Incubators and Technology Parks in the GZA

- **Inartis Network:** www.inartis-network.ch

Inartis, as one of the eight national thematic networks, aims to create value and jobs across the Swiss life sciences economy by fostering transdisciplinary R&D and connecting academia and business.

Contact: Dr. Joseph Maisano, joseph.maisano@inartis-network.ch



- **Start Smart Schlieren:** www.start-smart-schlieren.ch

Start Smart Schlieren is an innovation and business center that provides innovative start-ups and micro-enterprises with the infrastructure necessary for a successful business start.

Contact: Barbara Angelsberger, barbara.angelsberger@start-smart-schlieren.ch



- **Swiss Center for Electronics and Microtechnology (CSEM):** www.csem.ch

The CSEM is a private research and technology organization, with 30 years of expertise. It focuses on managing and fostering innovation to convert groundbreaking basic research into advanced processes and products in the fields of micro processing, medical technologies, scientific instrumentation and more.

Contacts: Stéphane Follonier, Vice President, stephane.follonier@csem.ch, (GR)

Matthias Krieger, Marketing Manager, matthias.krieger@csem.ch, (ZH)



Life Sciences Education-, Innovation Centers, Business Incubators and Technology Parks in the GZA

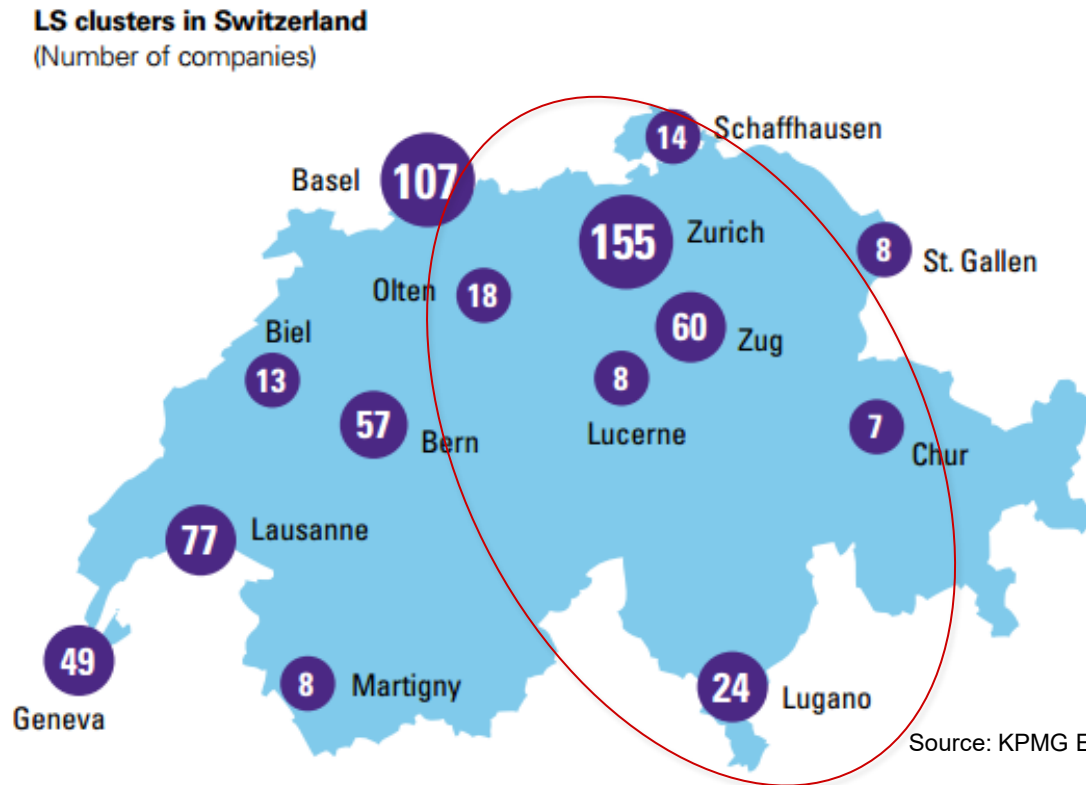
- **Swissbiolabs:** www.swissbiolabs.ch

Swissbiolabs's objective is to achieve a complete Diagnostic Incubator, which means different specializations and complementary technologies and offers a home for LS-start-ups and R&D organisations.

Contact: Urs Blaser, +41 62 296 88 08, urs.blaser@blaserpartner.ch

SWISS*biolabs*
WHERE SCIENCE MEETS BUSINESS

Highest Density of Life Science Companies



Largest number of regional HQs of non-domestic life sciences companies compared to other European countries such as Germany, France, Ireland, Netherlands and UK

1st rank in "Ease of attracting foreign skilled workforce", IMD World Competitiveness Yearbook 2015

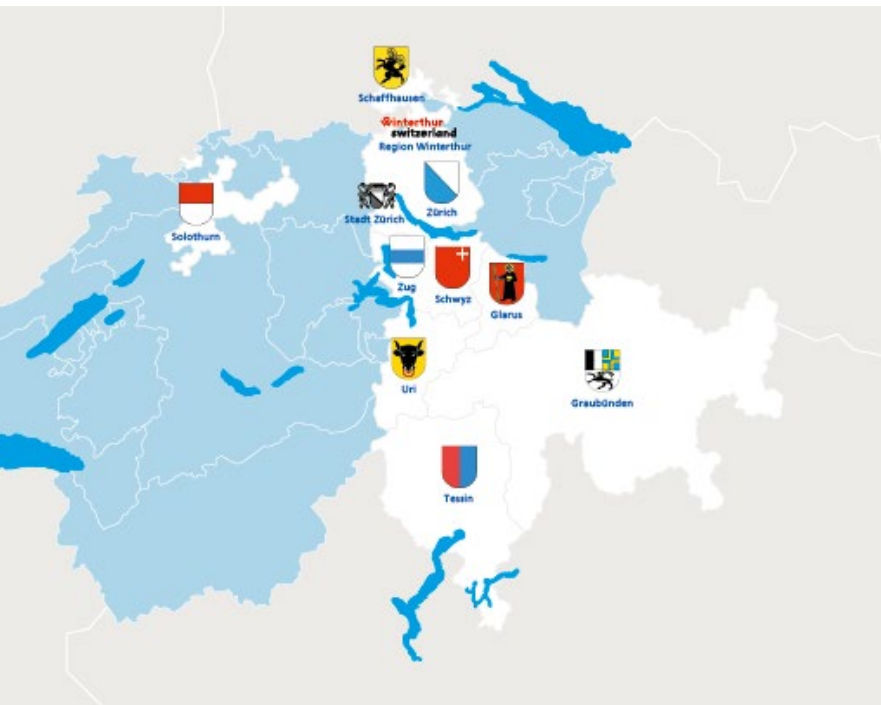
Third highest number of late stage products in development, with a strong focus on oncology

Greater Zurich Area Ltd.

A successful Public-Private-Partnership

Public members

Cantons of Glarus, Grisons, Schaffhausen, Schwyz, Solothurn, Ticino, Uri, Zurich, Zug as well as the city of Zurich and the region of Winterthur



Private members



...and from the science sector





GOING GLOBAL IN BIOPHARMA

How to navigate the regulatory maze

OVERVIEW

Required authorizations to market your medicinal product in the EU

Required Authorizations

- One Authorization to market your medicinal product in all 28 Member States: MA

- One Authorization for a subsidiary which imports and sells your product in EU: MIA
- Authorizations for any other local subsidiary in which you will sell product locally: WDL

- Local Authorizations for the price of your product to get reimbursed locally.

Health Authority to issue Authorizations

- European Medicines Agency: EMA

- Local Health Authorities

- Local Health Authorities

Subsidiaries in Member States to receive the Authorization

- EU subsidiary of your choice. MA holder will be hold responsible for safety of your product in all EU Member States.

- EU subsidiary designated to import your medicinal product
- Any EU subsidiary in which you want to sell and market your product locally

- Any local subsidiaries where you want to have your price reimbursed

US Headqaters Responsibilities

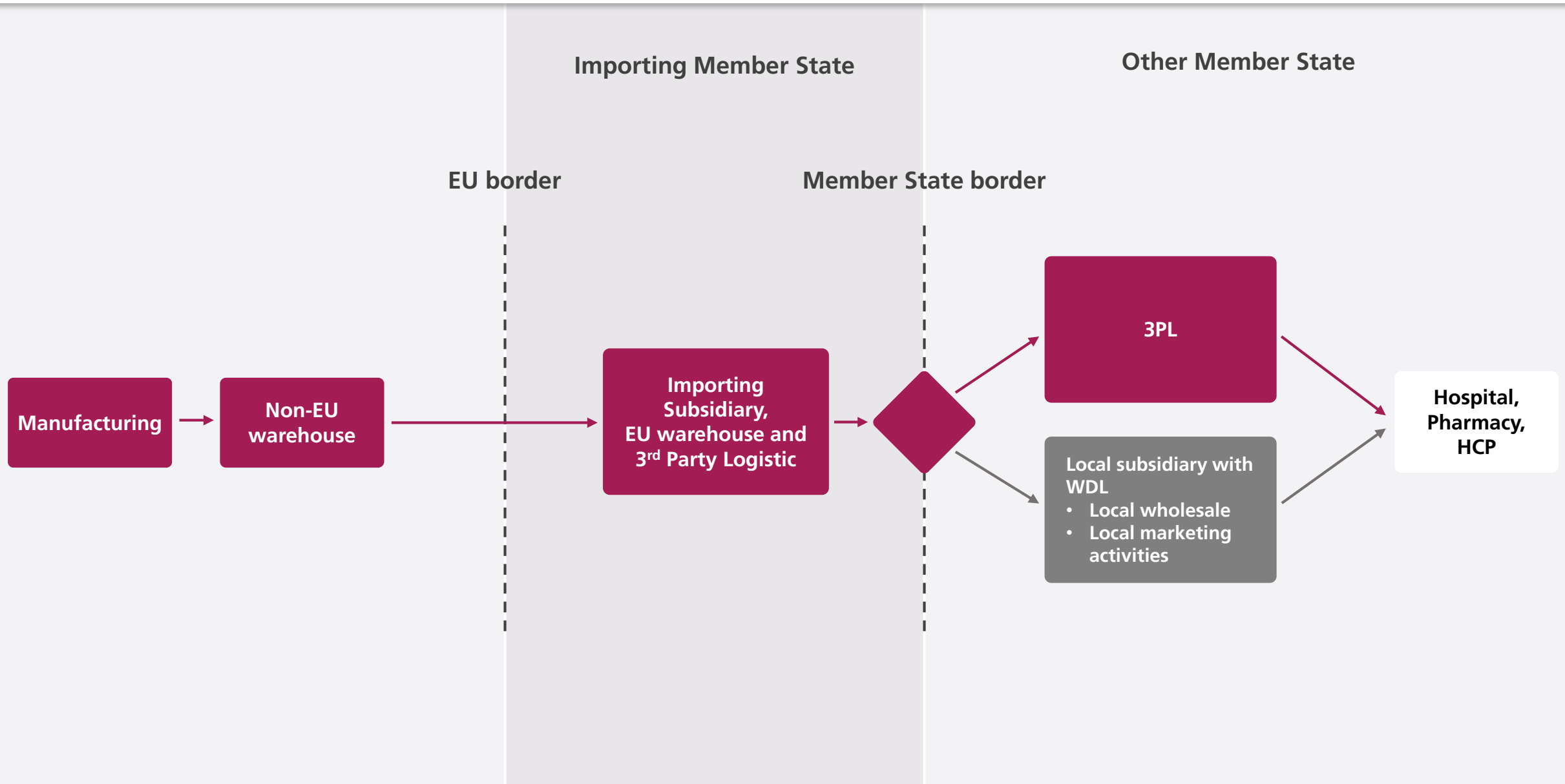
- Regulatory Department

- Product Supply
- Quality

- Access Department

OVERVIEW

Central vs. Local Product Supply



EU DIRECTIVES & GUIDELINES

relevant for the authorizations of your EU subsidiary to market your medicinal product

EU Commission issues EU Directives which are of relevance to all EU Member states.

Good Manufacturing Practice

Good manufacturing practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes.

The European Medicines Agency (EMA) coordinates inspections to verify compliance with these standards and plays a key role in harmonizing GMP activities at European Union level.

Good Vigilance Practice

Good vigilance practice (GVP) are a set of measures drawn up to facilitate the performance of pharmacovigilance in the European Union.

GVP applies to marketing authorization holders and health authorities in EU member states. They cover medicines authorized centrally via the EMA as well as medicines authorized at national level.

Good Distribution Practice













Good distribution practice (GDP) describes the minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain.

GDP applies to all persons involved in procuring, selling or providing medicinal product. Each person involved in the above has to hold Wholesale Distribution Authorization.

Each member state has its own local health authority responsible for implementing the directives.

The implementation process varies between member states.

The European Union consists of 28 member states

Austria	Belgium	Denmark	France	Germany	Ireland	Italy	Netherlands	Portugal	Spain	Sweden	UK
											
AGES	FAMHP	Lægemiddelstyrelsen	ANSM	BfArM	HPRA	TBA	IGJ	Infarmed	AEMPS	Läkemedelsverket	MHRA

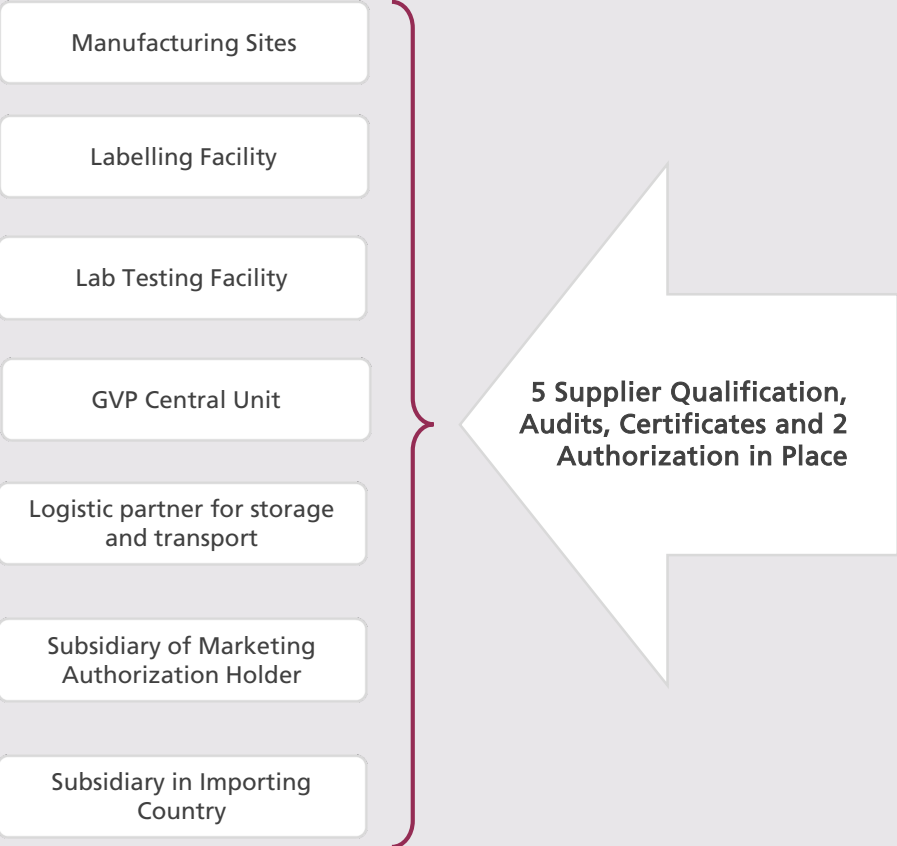
WORKSTREAMS AND ELEMENTS

required for your launch readiness

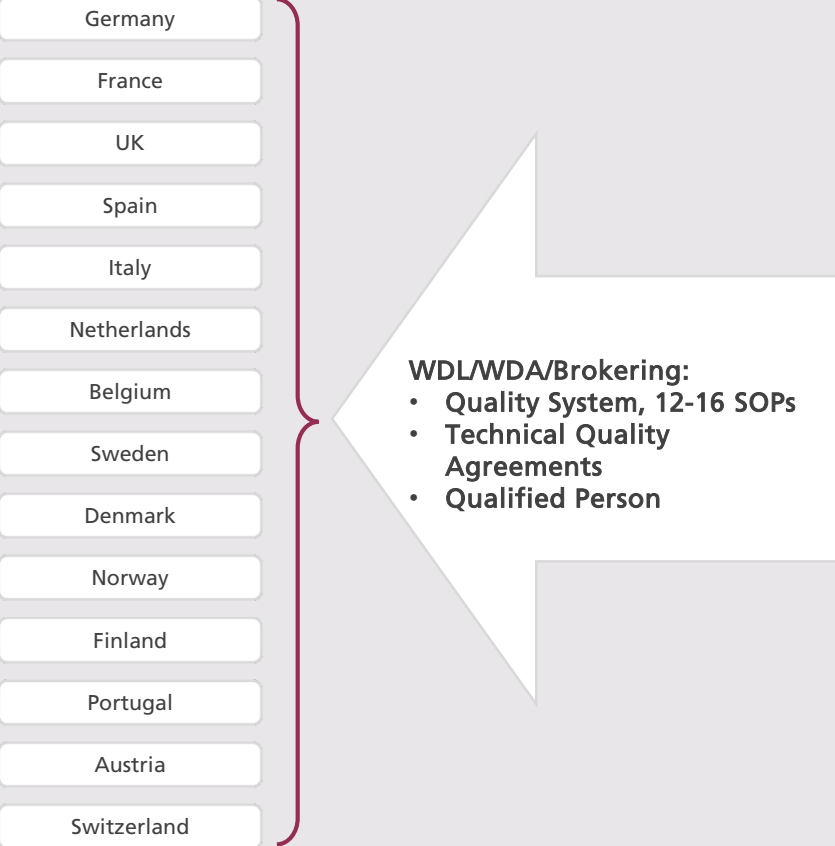
Marketing Authorization Workstream



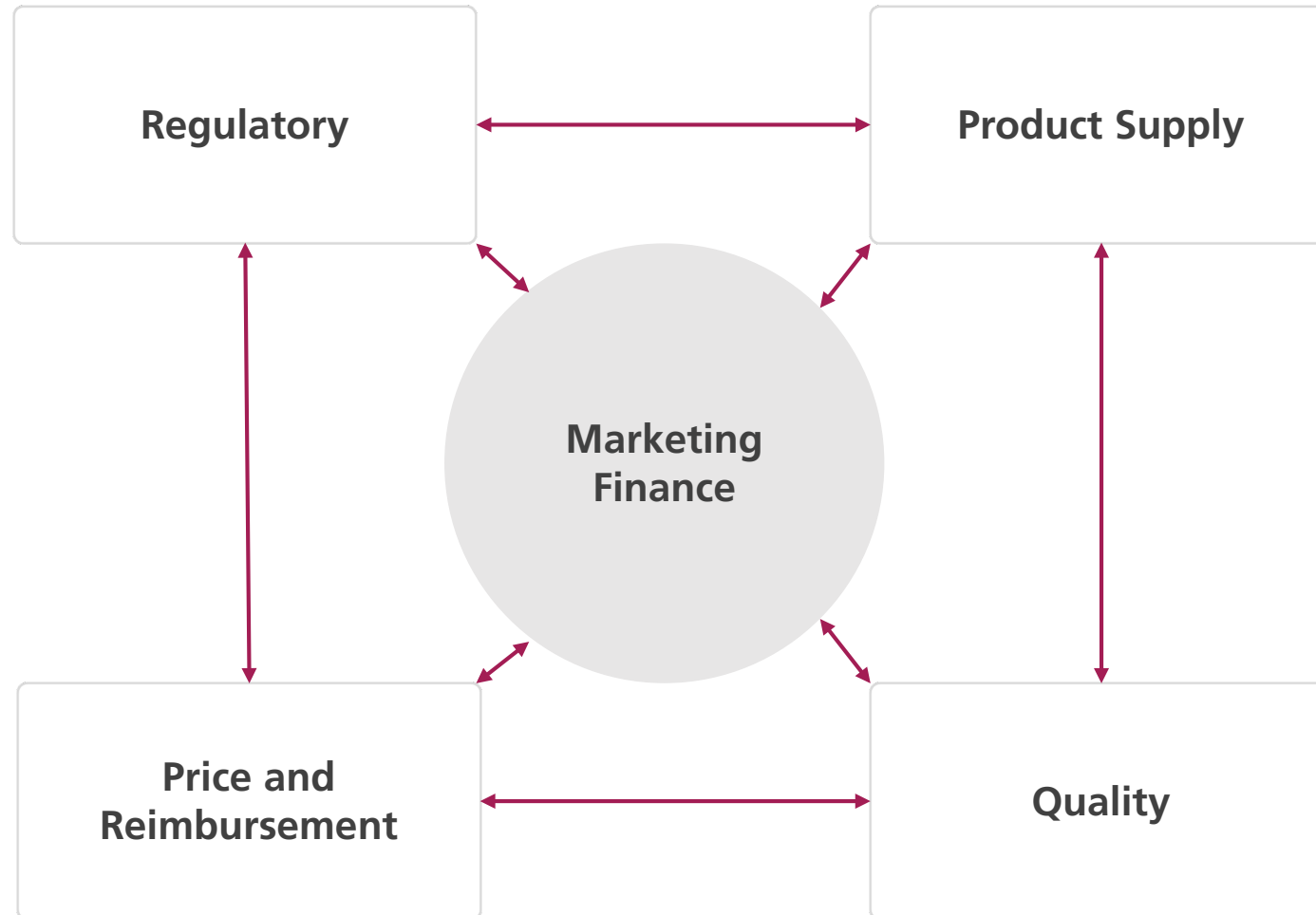
Product Supply / Quality Workstream



Launch Sequence Workstream

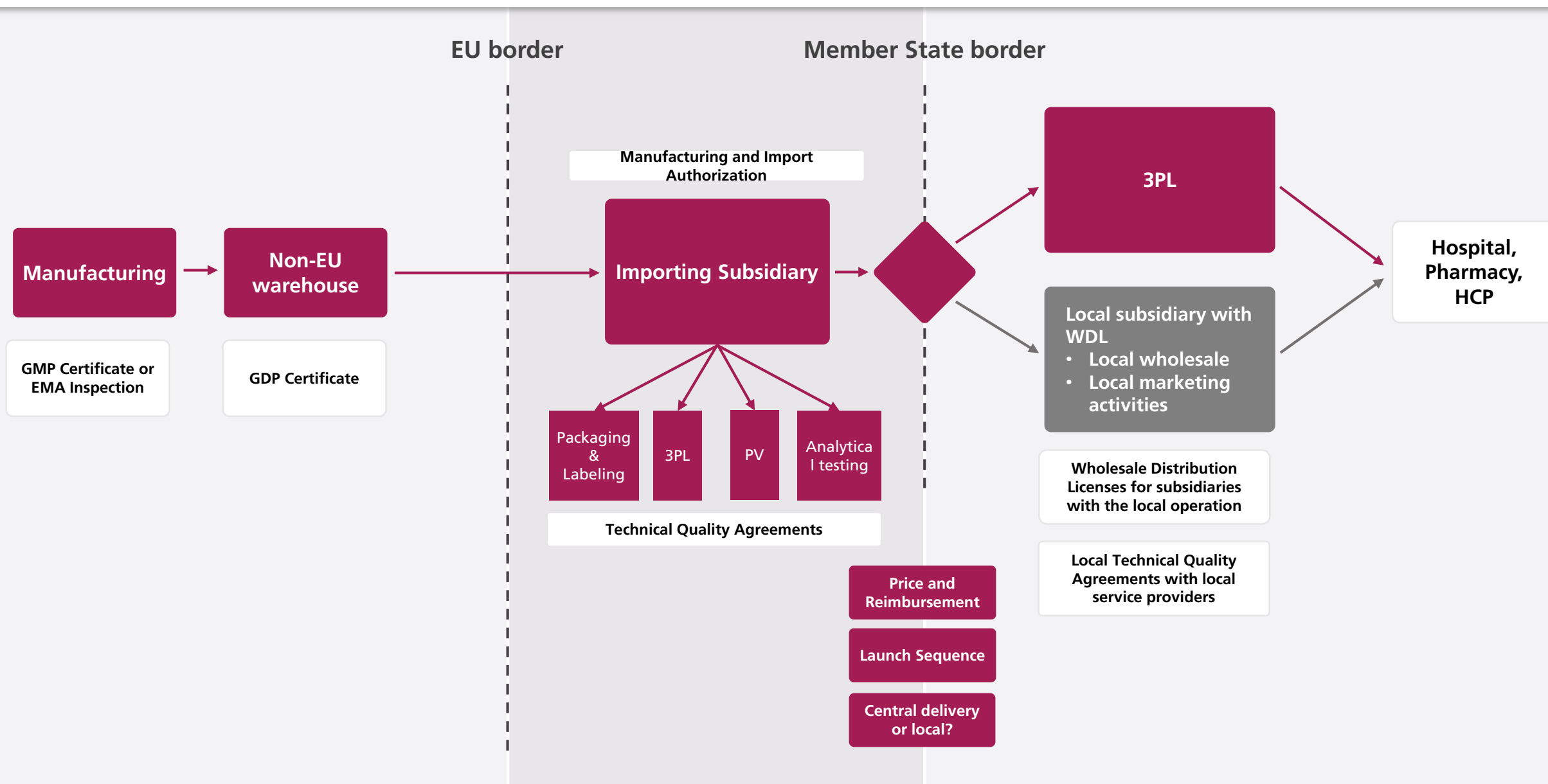


COLLABORATION BETWEEN YOUR DEPARTMENTS



LAUNCH READINESS

To be developed for each Member State



CONCLUSION

The way out of the maze: secure support of local service provider

EU Directives/Guidelines

Good
Manufacturing
Practice

Good
Vigilance
Practice

Good
Distribution
Practice

Local Medicinal Products Agencies

Austria



AGES

Belgium



FAMHP

Denmark



Lægemiddelstyrelsen

France



ANSM

Germany



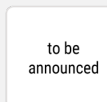
BfArM

Ireland



HPRA

Italy



TBA

Netherlands



IGJ

Portugal



Infarmed

Spain



AEMPS

Sweden



Läkemedelsverket

UK



MHRA

Local QS/Licenses Providers / Partners

Austria



ARAC

Belgium



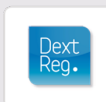
Archemin

Denmark



A-consult

France



DextReg.

Germany



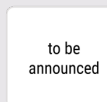
Dr. Regenold

Ireland



JensonR+

Italy



TBA

Netherlands



DADA Consultancy

Portugal



PTR Pharma Consulting

Spain



Qualitec Farma

Sweden



pharm assist

UK



JensonR+

IN-COUNTRY SERVICES



Austria
ARAC



Belgium
Archemin



Denmark
A-consult



France
DextReg.



Germany
Dr. Regenold



Ireland
JensonR+

to be
announced

Italy
TBA



Netherlands
DADA
Consultancy



Portugal
PTR Pharma
Consulting



Spain
Qualitec Farma



Sweden
pharm assist



UK
JensonR+

ONE-STOP-SHOP PACKAGE



In-depth understanding of client's situation, product & goals

- EU countries planned in the expansion
- Type of marketing authorization application
- Planned marketing activities



Briefings and contracting with local in-country teams

regulanet® Switzerland contacts relevant partners, requests offers, evaluation and consolidation of offers, communicates the offers to the client, finalizes the budget and contracts with the local partners.



Supervision and monitoring of work in progress

regulanet® Switzerland follows on the work in progress, identifies issues for clarification, confirms the milestones achieved, reports on the progress by country and confirms the offered costs and time frames if applicable.



Final control of deliverables and one invoicing

regulanet® Switzerland controls the licenses, registrations, authorizations and the overall practicability of the client's set-up and if approved issues one invoice, or, forwards multiple invoices in case this was agreed with the client.

CONTACT US

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> info@regulanet.ch

> www.regulanet.ch