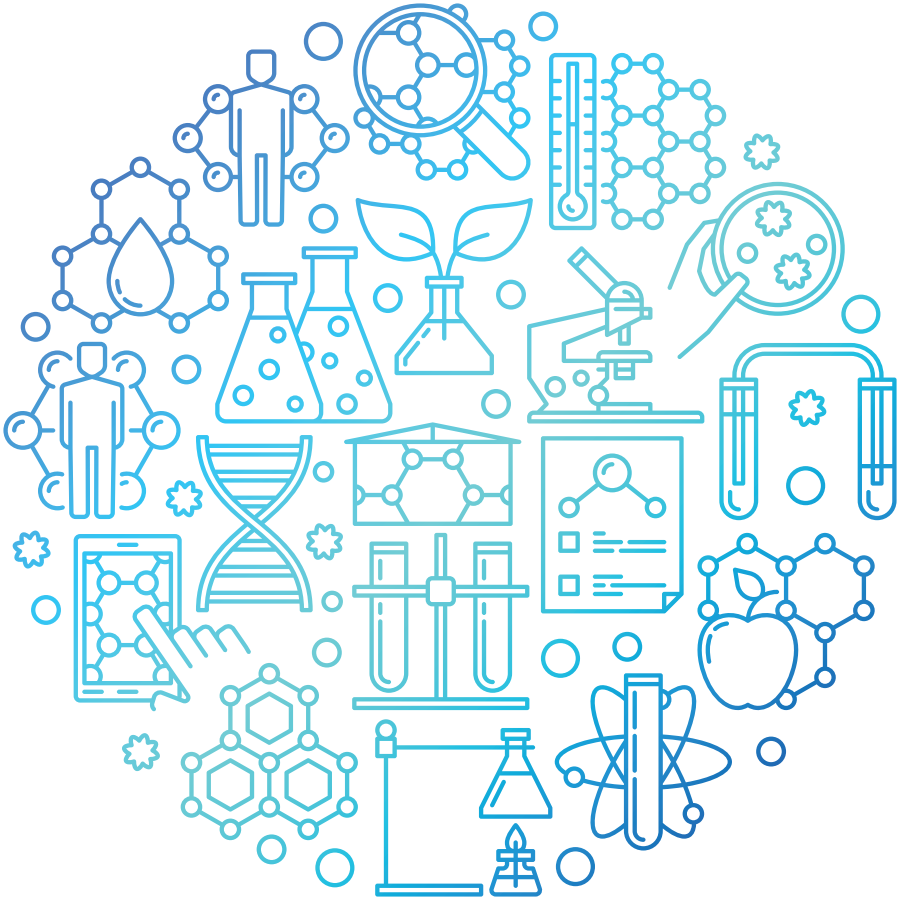
Deloitte.



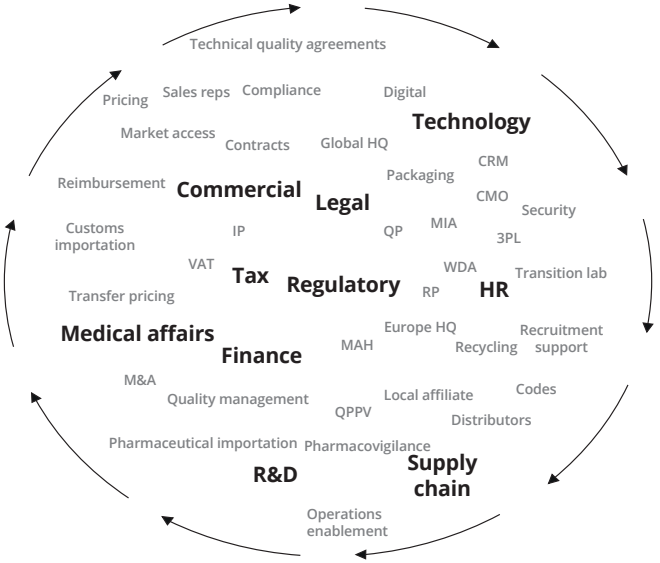
# Expanding to Europe

Your guide to Deloitte Switzerland's services

# 'One-stop shop' for Biotech companies expanding into Europe

By combining our Swiss, EMEA and global expertise across functional capabilities, we have tailored our proven solutions to Biotech companies settling in Europe

## Cross-functional capabilities that Deloitte Switzerland offers




**Typical project example:** US Biotech to set up its European operations from several perspectives: commercial (e.g. market access strategy and field organisation), tax (e.g. IP location), legal (e.g. legal entities set-up), regulatory (e.g. QP/RP) and HR (e.g. talent recruiting and retention).

## Leveraged by our comprehensive expertise

### Launch expertise

Expertise in supporting product launches across Europe (>100 overall launch-related projects over the past 12 months, with many still ongoing)

### Delivery expertise

Cross-functional/cross-cultural expertise from strategy to operational implementation, all housed under the same umbrella, Deloitte

### Global footprint

Global footprint (over 9,000 practitioners in life sciences and healthcare industry in over 90 countries) and extensive experience with leading companies across the life sciences industry

### Partnership expertise

Expertise in facilitating deals, partnerships and licensing agreements that deliver combined outcomes

*We work with our experts throughout Europe to ensure the highest quality of services*

# Switzerland: a hub for life sciences knowledge in the centre of Europe

## 5 competitive advantages of Switzerland for Biotech companies

**Innovation**

- Switzerland has ranked **number 1 in the Global Innovation Index** since 2010*. The focus in 2019 is on genomics and mobile health apps, and how these innovations can transform the healthcare system

**Talent**

- **Highly-skilled talents** in life sciences, easing the hiring process (i.e. finding and hiring gene therapy specialists)
- **Education at world-class universities** in multiple disciplines (i.e. ETH Zurich, EPF Lausanne, University of St Gallen)
- **Numerous partnerships** between investors & universities, leading to Biotech spin-offs & network effects (i.e. EPFL Innovation Park)

**Infrastructure/life sciences network**

- **Free trade agreements** with EU and 40 other countries (incl. China & Japan). Strong Swiss exports: CHF233bn in 2018 (45% in chemical and pharmaceutical products)
- Multiple **life sciences hubs** (e.g. Bio-Technopark Schlieren, incl. fully equipped labs, hosting 45 companies & academic institutions)
- Network of internationally-recognised **service providers and experts** dedicated to life sciences

**Tax**

- **Stable & predictable tax environment** with attractive corporate/individual tax rates (corporate income tax as low as 11.5% in some cantons)
- Introduction of a **patent box and R&D super deduction** from 1 January 2020 & possible **tax holidays** for new investments
- **Business-friendly** tax authorities & low level of reporting requirements. Numerous tax rulings provide certainty on tax matters

**Regulatory**

- Close **integration with EU regulations** on medicinal products and medical devices (through a Mutual Recognition Agreement)
- Swissmedic, the leading national authority, **supports foreign businesses** coming to Switzerland (e.g. communication in English)
- Biotech & genetic engineering **applications** require **approval from just one national authority** (reduction in bureaucracy)

*: An index assessing the extent to which innovation is stimulated among 126 countries

Sources: https://tradingeconomics.com/switzerland/exports; https://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2019.pdf

# We answer the key concerns of Biotech executives who want to settle in Europe

| | Key questions | Description | Early stage | Development | Launch | Scaling |
|---|---|---|---|---|---|---|
| 1 | What is the **size of the market**, and how to get **reimbursement**? | Product positioning & sizing the opportunity in Europe, and access and pricing strategy | | ——— | ——— | ——— |
| 2 | What should the **go-to-market** strategy look like? | Go-to-market options (i.e. alone or in partnership), customer engagement model and contracting | | ——— | ——— | ——— |
| 3 | What should the **launch strategy and plan** look like? | Sequence of steps: market entry, interdependencies of activities & responsibilities, progress monitoring | | ——— | ——— | ——— |
| 4 | Which regulatory and market **authorisations need to be considered**? | The authorisations required to market the drug | ——— | ——— | ——— | ——— |
| 5 | Where should the **intellectual property** (IP) be located? | Development of a tax-efficient IP strategy | ——— | ——— | ——— | ——— |
| 6 | How should the **financing** be organised? | The funding needs to get established in Europe | ——— | ——— | ——— | ——— |
| 7 | How should the **operations** be set up and where should the company be **based** (incl. legal entities set-up) in Europe? | Decision criteria for setting up European operations, incl. HQ location, supply chain, distributors, partners, sales affiliates, manufacturing | | | ——— | ——— |
| 8 | What **skills** are needed, and where? | Recruiting strategy and its implementation; talent retention and support | | | ——— | ——— |

# And provide matching services

## What Deloitte Switzerland offers

**1** What is the **size of the market,** and how to get **reimbursement?**

***Where are the patients?***

- **Product profile** and **positioning** along the treatment pathway
- **Landscape of European markets**, incl. market dynamics/competitive landscape/ market growth
- **Portfolio expansion:** Options to enlarge and/ or diversify the portfolio
- **Market sizing** and business case, incl. ROI

***How will the drug be paid for?***

- **Market access landscape** (regulatory & reimbursement pathways)
- **European market access and pricing strategy**, and deployment
- **Stakeholder mapping** (incl. key opinion leaders (KOLs))**:** Enabled by digital and social media
- **Early access programmes** strategy, and implementation

**2** What should the **go-to-market** strategy look like?

- **Go-to-market model:** Required capabilities and sizing of the organisation (both centrally and in the field), including competitive benchmarking
- **Go-to-market option evaluation:** Do-it-alone vs partnership
- **Segmentation and targeting** of healthcare professionals, KOLs, by country
- **Customer engagement model:** Channel mix strategy, balancing multiple types of customer experience innovations (i.e. digital vs tangible)
- **Commercial contracting & government pricing**, incl. value dossier
- **Commercial operations** implications and set-up
- **Technology enablement (e.g. CRM system):** Strategy design and implementation

**3** What should the **launch strategy and plan** look like?

- **Product launch plan** by function, across Europe and by country (i.e. prioritisation), key milestones, interdependencies, KPIs for success
- **Monitoring and tracking** tool
- **Roles & responsibilities**, and **ways of working**
- **Regulatory:** Support for local affiliates in becoming/being valid partners for National Competent Authorities, roles required for authorisations (i.e. QPPV, QP, RP), and liaison with HQ
- **Distribution:** Advise on finding right partners for distribution in countries, to cover the legal and regulatory requirements

# And provide matching services

## What Deloitte Switzerland offers

**4** Which regulatory and market **authorisations** need to be considered?

- **QMS strategy & business case:** Advise on the QMS strategy, the business case and implementation
- **Quality technical agreements** with CMOs and other service providers
- **Good manufacturing practice (GMP)/good distribution practice (GDP)** authorisations, **pharma codes, recycling**
- **Inspection support** and follow-up on potential findings
- **Direct communication (in local language)** with National Health Authorities and EMA
- **Evaluation of strategy, operational and 3rd party risk**
- **Quality team training**
- **Regulatory approvals, compliance and management** across the affiliates

**5** Where should the **IP** be located?

- Development of tax-efficient **IP strategy,** with particular focus on evaluating whether IP should be migrated to Europe
- Preparation of **relevant valuations** and obtaining possible tax incentives
- Drafting required **intercompany agreements**

**6** CHF How should the **financing** be organised?

- **Tax advice on financing:** Advise on tax-efficient financing and cash repatriation structure
- **M&A support:** Support on strategy, target screening, diligence, transactions, post-merger integration
- **Financial performance and impact analysis**
- **Asset target screening**
- **Capital efficiency**
- **Financial operations:** Advise on performance management solutions
- **Net operating loss (NOL) utilisation and limitations**

# And provide matching services

## What Deloitte Switzerland offers

**7** How should the **operations** be set up and where should the company **be based** (incl. legal entities set-up) in Europe?

- **Benefit analysis across European markets:** Benefits, pain points, time and cost requirements across European markets, with a cross-functional approach
- **Options validation:** Options validation process, through design principles and case study references
- **HQ and affiliates set-up:**
  - EU HQ location and distribution hub
  - Marketing authorisation legal title ownership location
  - Own entity with local distribution and selling authority
  - Regulatory compliance according to business operational model
  - Potential partnership agreements on co-selling/co-marketing etc.
  - Commercial and market access requirements by country
  - Supply chain set-up and application for necessary authorisations
- **VAT, customs & income tax review of supply chain:** Supply chain review from VAT, customs and income tax perspectives to minimise tax costs
- **Transfer pricing planning:** Planning of transfer pricing concept to determine the profit of each legal entity, depending on its profile
- **Intercompany agreements:** Preparation of intercompany agreements to document the flows of goods and services between European entities, incl. related technical quality agreements
- **Set up of companies:** Subsidiaries set-up in European countries from a legal perspective, leveraging the Deloitte network & providing seamless advice throughout Europe
- **High-level costing for European operations**
- **Security & cyber operations**
- **Core R&D operations enablement**

**8** What **skills** are needed, and where?

- **Organisation design, planning and outsourcing,** incl. **regulatory key roles:** RP, QP and QPPV
- **Recruiting and talent development**, incl. talent strategy, performance management scheme and on-boarding
- **Hiring process and international talents**, incl. education checks and criminal records, work permits
- **Vision definition/support the transition of team members,** i.e. conduct transitions labs
- **Social security, payroll tax:** Advise on payroll set-up in relevant European jurisdiction to be able to prepare social security and payroll tax returns
- **Legal employment contracts & background checks:** Preparation of master legal employment contract adapted to fulfil requirements of relevant European jurisdictions

# Our dedicated functional experts in Switzerland for the Biotech sector

As Deloitte Switzerland, we can also **mobilise** a **network** of experts **in all European countries** to bring the best local knowledge

### European life sciences lead

**Vicky Levy**

### Commercial/Market access/Medical affairs

**Barri Falk**

**Carlo Verri**

### M&A and corporate finance

**Michel Le Bars**

**Igor Heinzer**

### R&D

**Laveshni Reddy**

**Stephan Ohnmacht**

### Technology

**Silvano Perrotta**

### Legal

**Urs Sturzenegger**

### Tax

**Jacqueline Hess**

**Martin Krivinskas**

### Tax

**Jan Oberholzer**

### Supply chain

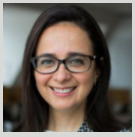
**Michael Graf**

### Regulatory

**Doug McKinnell**

**Martin Blanke**

### Human capital



**Veronica Melian**

**Sofia Stavri**

# Expanding into the European market

## Case study 1: Build a lean European business to support the launch

### Context

- The client, an American R&D company extends operations worldwide, aiming to build a **lean European business** to support its first European launch while transitioning into a commercialised Biotech
- Key objectives for the project included:
  - Setting up **legal entities & drafting legal agreements** to commercialise in Europe
  - Building **European distribution network**, incl. adaptation of QMS for inspections
  - Identifying the European **HQ location** and **European hub**
  - Establishing the physical **product flow** (considering supply chain and regulatory requirements) and **financial flow** (including tax and intracompany considerations)
  - **Defining roles:** establishing those insourced and outsourced

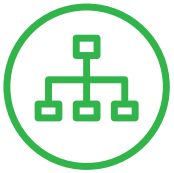
### Approach

- A **strategic collaboration** of legal, finance, tax, and regulatory capability led to defining scopes, identifying gaps, addressing open questions and making final decisions regarding the EU operating model, taking into consideration a global approach
- **Implemented the BMO "4R" methodology**, structured around 4 phases (feasibility, design, implementation, and maintenance & monitoring), to provide a rigorous framework for an integrated approach
- **Facilitated** organisation, support, and alignment among the client's functional and executive teams **through a PMO approach**, Deloitte's method for setting up and running intelligent, value adding programme management structures
- **Defined and constructed a global QMS** with regional and local requirements and definitions

### Results

- Reached **cross-capability alignment** through a steering committee and a country sounding board to support the project team
- **Analysed challenges** such as European HQ location, legal entity structure, physical product flow (including outsourcing and licensing requirements) and financial flow, and financial flow, taking into consideration tax, regulatory and supply chain issues
- **Analysed and built the QMS** to reflect the European operation model design and comply with laws and regulations and authorisations necessary for market launch
- **Obtained all necessary licenses**

### Deliverables



Distribution network mapped out by financial and product flows

Licensing and authorisation roadmap by country

# Expanding into the European market

## Case study 2: Launch of a rare disease therapy in Europe

### Context

- The biotech client aimed to **launch its rare disease therapy** first **in** the **US and** one year later **in the EU**, while being the first therapy to hit the market. The client had already decided on **6 countries** for the commercial launch in Europe and by when
- Key objectives for the project included:
  - **Collect plans** and **develop** consolidated preliminary **launch plan**
  - Conduct **gap analysis** and **launch assessment**
  - Finalise **global launch plan** and **roadmap**
  - Integrate **"launch central" tool** for launch plan management and execution

### Approach

- **Leveraged the biotech's input to draft EU operation model:** drafted EU operating model by collecting and consolidating input from the Biotech's global and EU leadership through interviews
- **Incorporated external expertise & local requirements:** compared organisational structure with external benchmarks and identified country-specific needs, such as profits locally
- **Identified gaps and key decisions:** provided suggestions to reconcile differences across the team and fill gaps. All being supplemented with external expertise
- **Alignment with EU operating model:** alignment on details of the recommended EU operating model, and ensuring understanding and commitment across the Biotech on financial and timing implications of resourcing needs

### Results

- Identified the initial **design gaps & inventory of open questions/decisions**, based on the Biotech's as-is evaluation
- Compiled key EU **operational considerations** and **'must have' requirements**
- **Accelerated critical choices** and **aligned leadership** with the EU operation model design
- **Built EU operating model**, showing how to implement the new EU blueprint

### Deliverables

As-is operations evaluation highlighting key open questions/ decisions

Global launch plan detailing cross-functional activities

Ready to implement EU operating model design

# Expanding into the European market

## Case study 3: EU distribution network design and portfolio on-boarding for a US Biotech

### Context

- The client, a Biotech firm focused on specialty pharmaceuticals, intended to strengthen its portfolio with an acquisition
- The acquisition encompassed the global rights to brands, which were sold globally – whereas the client had **previously only marketed products in the US**
- The transaction required a deep understanding of **portfolio onboarding activities** and their cross-functional interdependencies, to ensure seamless integration
- Deloitte was engaged to **support with day 1 Sales & Order To Cash (SOTC) switch preparation activities**, and advise on a strategy and roadmap for the set-up of the future European distribution network

### Approach

- Deloitte helped the client with the onboarding of the portfolio by:
  - Advising on **portfolio onboarding considerations** spanning supply chain, regulatory, quality, finance, and commercial issues (incl. the production of a set of templates for country plans and functional team charters, and initiating a cadence of meetings)
  - Supporting the design of the future national distribution network for Western European countries. This work entailed:
    - Documenting **key requirements** and market dynamics for Western European countries
    - Generating a **list of distributors** for the client to select and to negotiate with
    - Producing a **playbook** to support the negotiation process

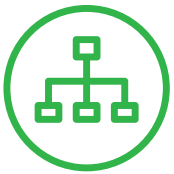
### Results

- The project is ongoing – the main differentiators highlighted were:
  - **Deep product transfer expertise** across functions, supporting the client project manager and executive team to take informed decisions for onboarding the portfolio plan
  - Acceleration and **enhancement of the collaboration** between client resources and communication with external parties (seller, CMOs, partners) through the use of a proven project structure and methodology (meeting cadence, templates, charters, etc)
  - Clear and compliant **distribution network set-up** strategy and negotiation playbook to engage with relevant distributors

### Deliverables

Onboarding portfolio plan for EU distribution

Negotiation playbook to engage distributors effectively



Future state design of the EU distribution network

# Expanding to the European market

## Case study 4: Supply chain strategy (incl. regulations) for US Biotech entering EU market

### Context

- The client, with an innovative medical product, aimed to build a **smart supply chain strategy for expanding into the European market**
- Key objectives for the project included:
  - Defining the organisational structure for supply of medicinal products to Europe, with **own entities and third party service providers**
  - Planning and executing set-up of organisational structure
    - Own entities with **necessary licenses**
    - **Commercial and quality agreements** with service providers
    - Adaptation of **quality management system**
    - **Necessary roles** in local affiliates
    - **Preparation of applications** for authorisations, mock-up inspections and inspection support

### Approach

- **Greenhouse meeting** with senior management of client and experts from Deloitte to identify, select, define future organisational structure
- Gap analysis of quality management system to **cover requirements of EU GMP/GDP regulations**
- Preparation of entities **for application for local authorisations**, including:
  - Local SOPs
  - Roles and responsibilities
  - Adaptation to specific national set-ups (e.g. Exploitant in France)

### Results

- **Optimised entity structure in Europe**, with service providers integrated into supply chain
- **Authorisations adapted to requirements** of countries (e.g. Exploitant in France, Reseller in Germany, no licence in Italy)
- **Global quality management system** with regional and national extensions
- Readiness for supply of products **including national codes and recycling**

### Deliverables

Identification of critical capabilities, open questions/decisions

Alignment on priority design choices for European operating model

Functional implementation roadmap

# Expanding into the European market

## Case study 5: Tax-driven changes to supply chain

### Context

- In the **client's business operating model**, shipment of an API is delivered into Europe for inward processing and exported back to the US
- Importation is done via Italy, where:
  - VAT is paid when importing
  - VAT is not recovered when exporting

    This led to high outstanding amounts with the Italian tax authority
- Key objectives for the project included:
  - Choosing a **new importation location** outside Italy
  - Reviewing **necessary licenses** along the proposed importation route
  - Preparing **contracts and quality agreements** to be aligned with new transportation route

### Approach

- Reviewed the existing supply chain set up and related licenses
- Identified potential options for **service providers** along the supply chain
  - Reviewed existing licenses and sites in Italy and other countries
  - Evaluated legal and regulatory requirements
  - Reviewed service level requirements with third party service providers

### Results

- Implemented **new supply chain operating model** with the Netherlands as entry point for Europe
- **Agreed blueprint** for future supply chain with service level definitions
- Defined contracts and quality agreements for:
  - **Importation via Dutch customs**
  - **Contracts and quality agreements** with service providers
  - **Set-up of VAT processes** to pay and obtain reimbursed in the Netherlands

### Deliverables

European licenses required for complete supply chain business model

Defined roles & responsibilities for service providers

Fully licensed supply chain operating model

# Contacts


Barri Falk
Monitor Deloitte life sciences
Partner
barrifalk@deloitte.ch

Jacqueline Hess
Tax & Legal
Partner
jahess@deloitte.ch

Carlo Verri
Monitor Deloitte life sciences
Director
cverri@deloitte.ch


Deloitte.




Designed by CoRe Creative Services. RITM0356122