



LSHC in Europe

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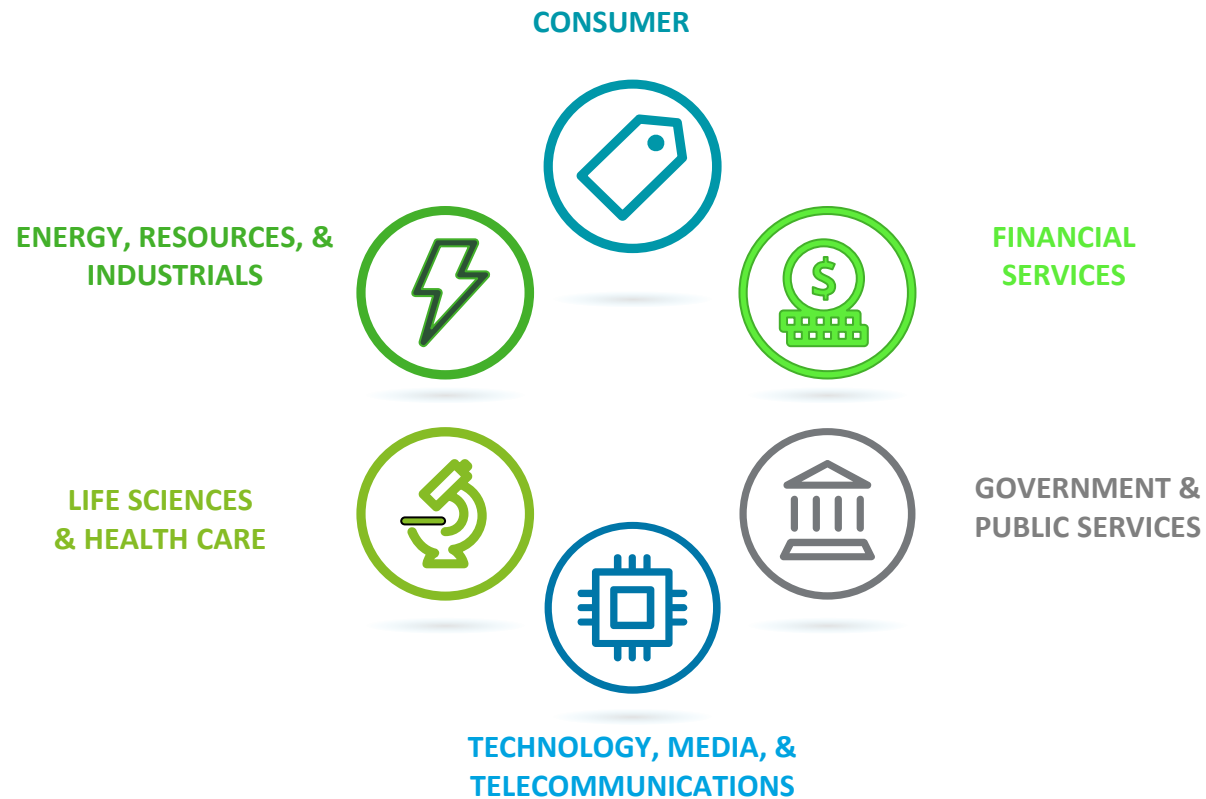
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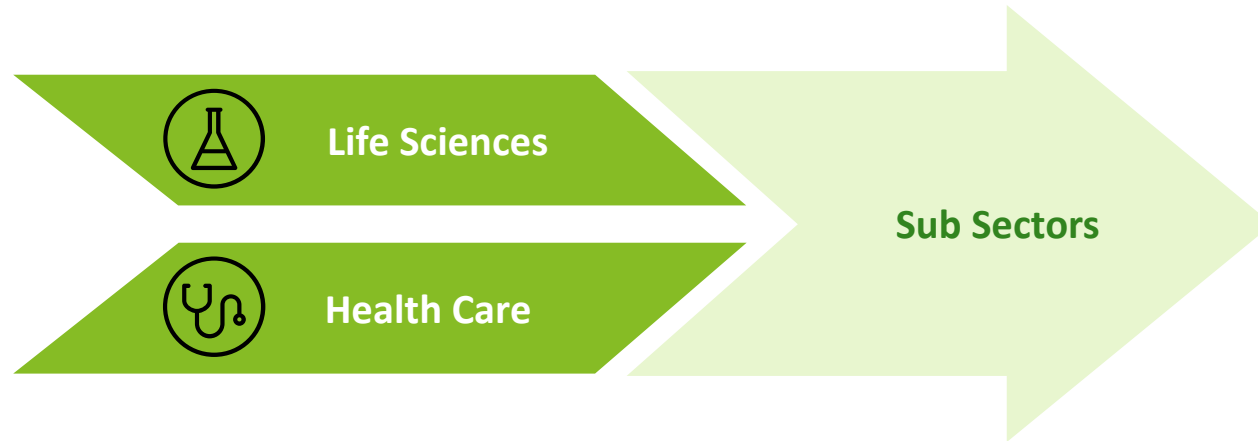
About Deloitte

Deloitte is the brand under which over 345,374 people in more than 150 countries and 700+ offices throughout the world collaborate to provide Audit, Consulting, Financial Advisory, Risk Advisory, and Tax and Legal services to selected clients.



Deloitte's Industry Focus

-  Consumer
-  Energy, Resources. & Industrials
-  Financial Services
-  **Life Sciences & Health Care**
-  Government & Public Services
-  Technology, Media & Telecommunications





Life Sciences

- BioPharma
- Generics and Biosimilars
- Medical Technology
- Commercial and market access
- Finance
- Information Technologies
- Regulatory, Compliance and Legal
- R&D
- Human resources
- Supply Chain



Health Care

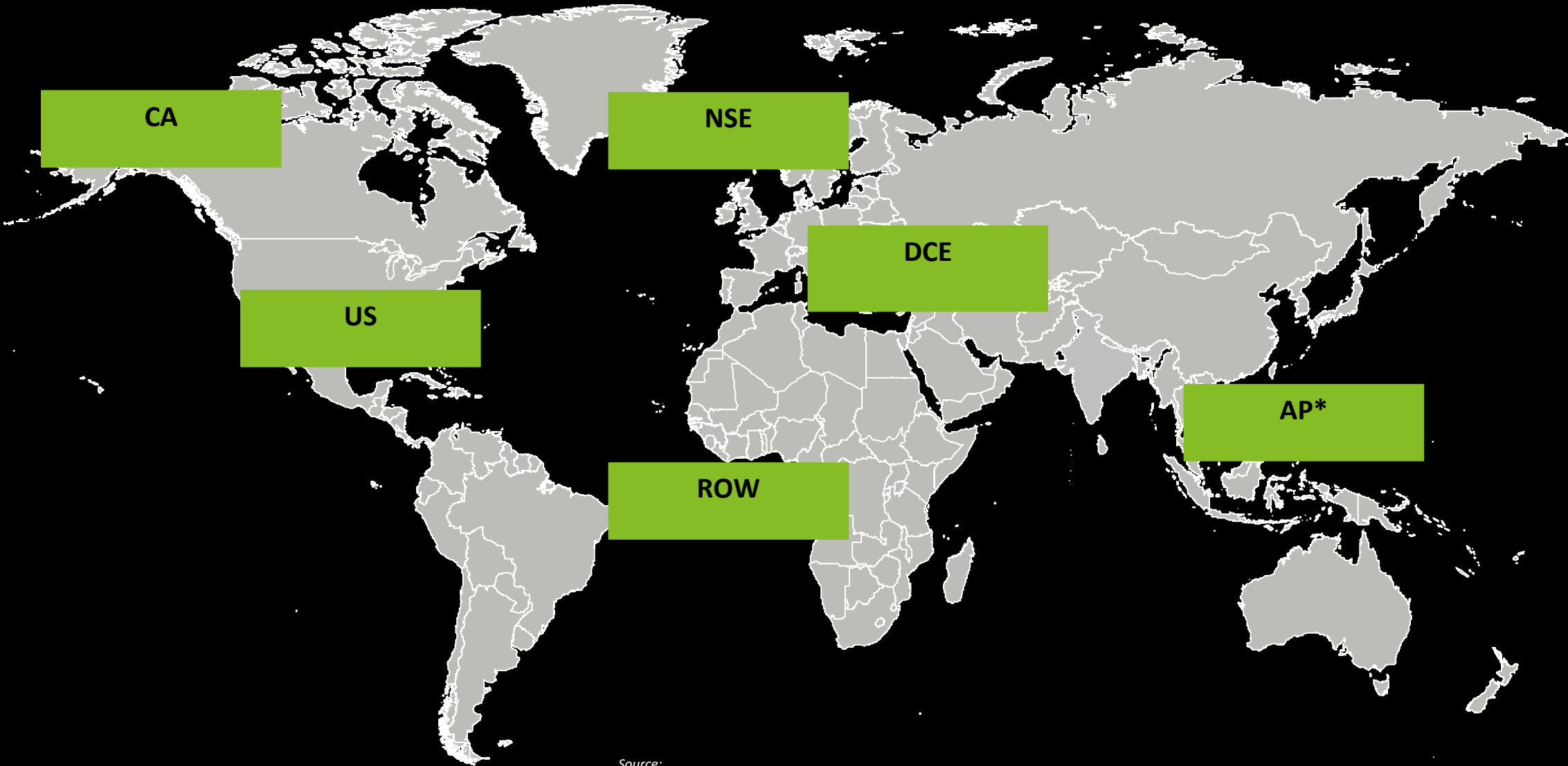
Health Care Providers

- Academic Medical Organizations
- Home Health Agencies
- Hospitals and Health Systems:
- Long Term Care
- Other Providers
- Physician Groups

Health Plans and Payers

- Commercial Health Plans and Payers
- Government Health Plans and Payers
- Other Health Administrators

Global Life Sciences and Health Care



LS: Advisory product revenue is mapped to Risk advisory
HC/H&HS: For US and CA, data includes P3 revenues (as per periodic cycle)

Source:
LS: CIR + PE + Product revenues
HC/H&HS: Revenue reported by Tier-1 MFs + ROW revenues from CIR

Life Sciences at Deloitte

Practice Overview

Deloitte's Global Life Sciences Practice is comprised of more than 17,200 professionals with over 75 years of proven life sciences experience. With a dedicated group of practitioners of this size, Deloitte offers clients comprehensive, integrated solutions from strategy to implementation, while also developing leading solutions for today's biggest opportunities and challenges in digital transformation, new regulatory climates, and increased patient engagement.

Deloitte's Life Sciences practice realizes that not all Life Sciences companies are the same. Biopharmaceutical, medical technology, generics, and mid-cap companies all face distinct opportunities and challenges. Deloitte's LS practice contains teams of practitioners dedicated to each of these segments.



BioPharma



Medical Technology



Generics



Medical Wholesale

Priority Offerings



Commercial and Market Access



Finance



Information Technology



Regulatory, Compliance and Legal



Corporate



Human Resources



Research & Development



Supply Chain

Top Client Issues



Redesigning work, workplace, and workforce



New customer-centric commercial models



Shortening development / review timelines



Cross-border reliance: supply chain visibility and reshoring options



Accelerated digitization



Collaborations/clinical trials reshaping R&D



Advancing humanity: ESG imperatives

Health Care at Deloitte

Practice Overview

Deloitte's Global Health Care Practice is comprised of more than 17,100 professionals, including on and offshore delivery centers and more than 100 clinicians professionals, and over 350 principals and managing directors who serve clients across the health care value chains.

We are the leading professional services firm serving health plans, providers, and PBMs with integrated offerings and solutions, deep expertise, and proven approaches. Deloitte's Health Care practice contains teams of practitioners dedicated to each of these segments. Integrated insights are drawn from cross-sector collaborations with providers, life sciences, state health, federal health, and retail sector practices and clients.



Health Care Providers



Health Plans and Payers

Priority Offerings



Care Delivery Models of the Future



Virtual Care



Transaction Services



Human Resources



Digital Transformation, Interoperable Data & AI



Financial Operations and Performance Improvement

Top Client Issues



Consumers and the human experience



Health Care Delivery Models of the Future / Shift to Virtual Care



Digital transformation and interoperable data



Socioeconomic shifts



Collaboration—Future of Public Health / Intersection of Govt. & Commercial Health



Future of Work and talent

What can we do for you?



What will we do and sell?

Product-Regulatory Affairs & Compliance

Currently working with DT firms

New and existing topics of product offerings



Regulatory Affairs consultancy

- Pre & post marketing activities
- Drug development plans
- Regulatory affairs strategy
- Support in regulatory affairs for clinical trials
- Due diligence, Commercialization and Market Access



Regulatory Compliance and Quality management system

- Set up a quality management system
- Implementation of digital systems for quality management across different providers Veeva, Flex etc.
- Regulatory information management



Pharmacovigilance services

- Set up of vigilance system for drugs
- Process assessment/ optimization
- Audit
- Due diligence

What will we do and sell?

Medical Devices and Digital Therapeutics

Currently working
with DT firms

New and existing topics of product
offerings



Digital Therapeutics
(DTx)

- SaMD classification
- Clinical validation and Technical validation
- Quality Management System Implementation
- Commercialization and Market Access
- DiGA listing
- Post Market Surveillance



Medical Devices and
IVD

- Cyber security
- *In vitro* Diagnostics (IVD)
- NewGen Therapies

What are our existing and target partners?

We build upon the existing relationship and also intend to create new ones with specific regulatory Life-science offering

1

Becoming a long-lasting partner in Regulatory & Compliance topics to our clients

Strategic partners: a focus on companies in CE region and existing clients of Deloitte



2

Expanding

Regional mid-cap pharma & Startups



3

Helping QMS and RIMs vendors to successfully implement

Delivering content to the tools Industry "ready made"



Our Life Science Team

Our Deloitte experts bring a depth of Life science expertise across segments



Pavel Nevicky

**Senior Manager
Life Science**

- Pavel has over 7 years of life science experience, leading the engagements in **regulatory, digital and strategy topics**.
- He regularly works with corporate leaderships to identify **new market opportunities and market access pathways**
- He specifically has deep experience in digital health and CNS therapeutical area



Vera Valesova

**Senior Manager
Life Science**

- Neuroscientist by background working in pharmaceutical industry for +10 years.
- She held **various positions within pharmaceutical industry** (in Biotechnology companies; regulatory agency as well as in CRO) as **senior regulatory manager**, quality system and regulatory compliance manager
- Vera brings **broad experience in regulatory/business consulting** and strategic services to Pharmaceutical companies.

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