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## HEALTH CARE & LIFE SCIENCES LAW

Health Care and Life Sciences have been central to the work of Maynard Nexsen for more than 60 years. Today, our legal practice supports clients located throughout the Southeast and beyond with a team of attorneys dedicated to protecting health care providers and serving innovators in the life science community.

Our attorneys are experienced in all areas of the law regarding the regulation, delivery, and financing of health care and life sciences services and products. We work with providers, practitioners, investors, scientists, manufacturers, suppliers, and vendors -- all who need the support of a legal team that is knowledgeable and understands the ever-changing regulatory environment that they work within.

### Expansive health care and life sciences experience:

- Payor/patient/provider relationships and contracts
- False claims analysis and defense
- Health care fraud and abuse, investigations and litigation
- Alternative dispute resolution
- Physician/hospital dealings
- Stark/Anti-kickback laws
- Mergers, acquisitions and consolidations
- Survey and certification
- Employment law
- Relationships with pharmaceutical vendors
- Compliance due diligence
- Managed care issues
- Licensure and provider application assistance
- Professional disciplinary proceedings
- Medical staff/credentialing advice
- Requirements for prescribing opioid and controlled substances
- HIPAA privacy and security

### Our clients span the life sciences spectrum including:

- Pharmaceutical
- Biopharmaceutical
- Medical Devices
- Drug Delivery
- Neurotech
- Diagnostic
- Bioagriculture
- Biotech
- Research Institutions



Learn more about Maynard Nexsen and our health care and life sciences law practice.



*Taking The Pulse* is dedicated to one of America's largest industry sectors - talking with leaders in Health Care and Life Sciences to bring key issues to the forefront every week.

Health care is one of the fastest evolving industries and its complexities can be difficult to keep up with, let alone navigate. Join Matthew Roberts and Lauren DeMoss, Maynard Nexsen Health Care Attorneys, with co-host Heather Matthews, for *Taking the Pulse: A Health Care and Life Sciences Podcast*, a weekly series that takes a current look at one of America's largest industry sectors.



Filmed on-site at NCLifeSci's Annual Meeting!





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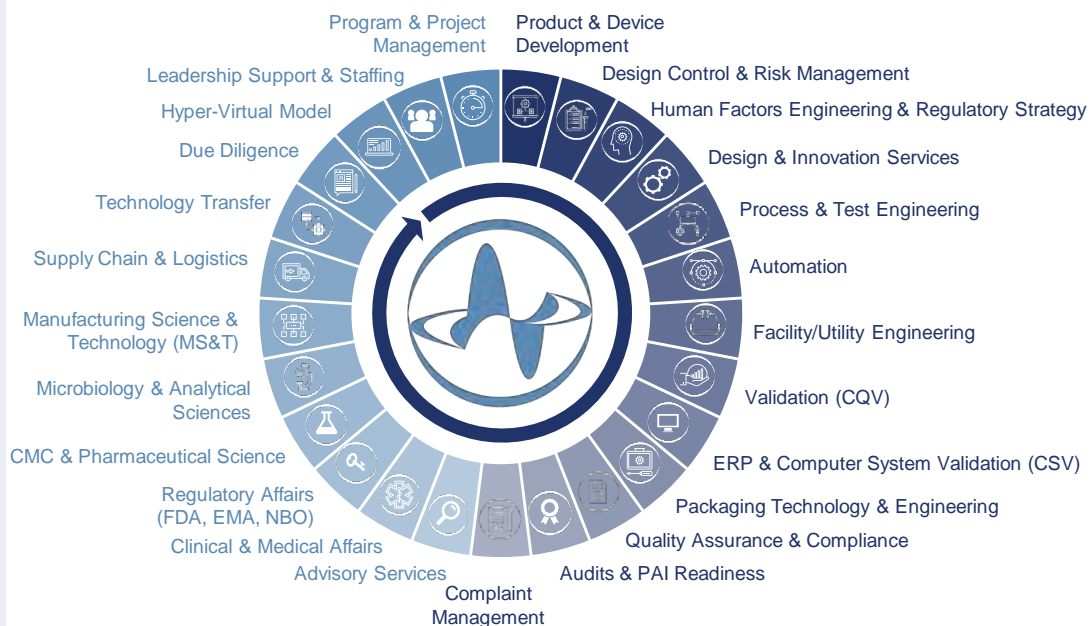
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Kymanox provides integrated, end-to-end solutions throughout the product lifecycle – from **development** through **commercialization** and **post-market support**.



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### STRATEGIC SOLUTIONS

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## OUR COMBINED TEAMS



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MASTERS and PhD LEVELS



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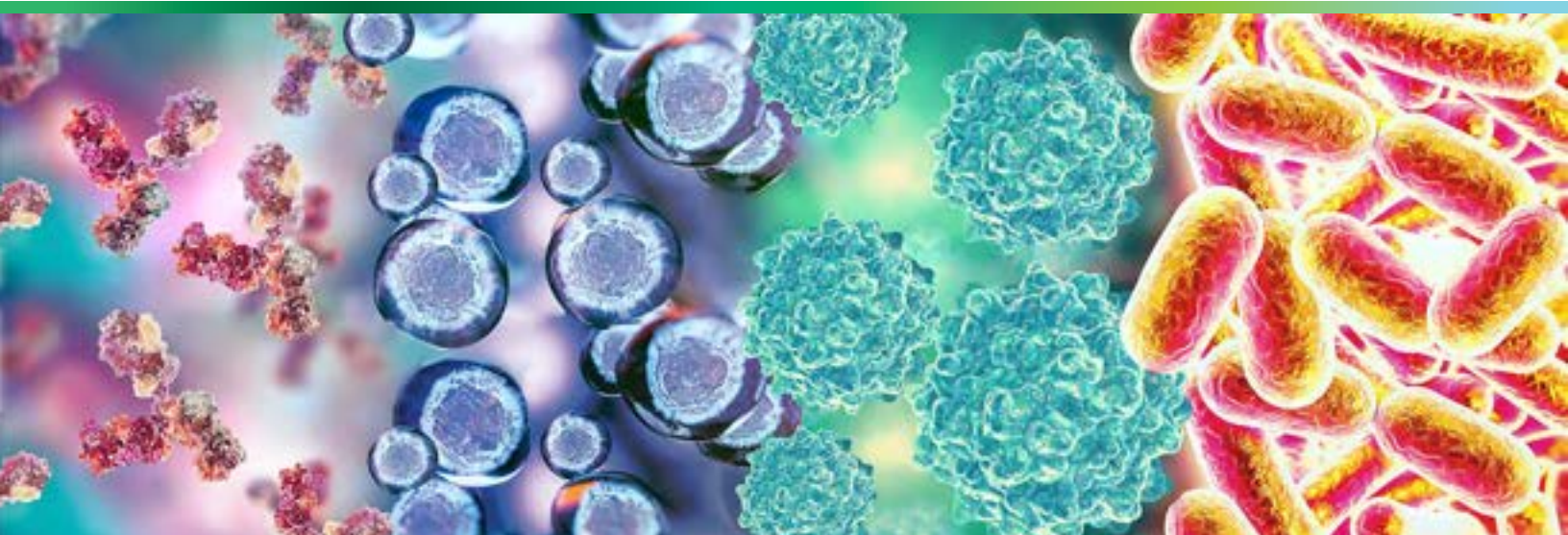
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**Grifols** is a leading global healthcare company that develops plasma-derived medicines and other innovative biopharmaceutical solutions that enable millions of patients around the world to lead more productive lives.



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**GRIFOLS**

# Our purpose is to innovate to transform the lives of patients and their families.

We are dedicated to developing life-changing medicines for people with serious diseases — often with limited or no therapeutic options — so they can live their lives more fully.



**PATIENT-CENTRIC INNOVATION DRIVES OUR STRATEGY**

We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development in two therapeutic areas:

**Neuroscience.**

We are an industry leader in treating sleep disorders and epilepsy.

**Oncology.**

We innovate and deliver medicines for hard-to-treat malignancies and solid tumors.

We actively explore new options for patients, including novel compounds, small molecule advancements, biologics and innovative delivery technologies.



**WE EACH PLAY OUR PART TO TURN PASSION INTO ACTION**

We strive to put patients first as we know that the symptoms and conditions that our therapies treat are often lifelong and disruptive to a person's everyday life. That is why we are focused on creating an environment where employees are encouraged to bring new ideas and question the status quo, infusing innovation into all that we do for patients.

Our people are fundamental to everything we do. We are committed to creating a company where the culture embodies our corporate purpose to innovate to transform the lives of patients and their families and reflects our key goals:

- 1



Be a great place to work; and
- 2

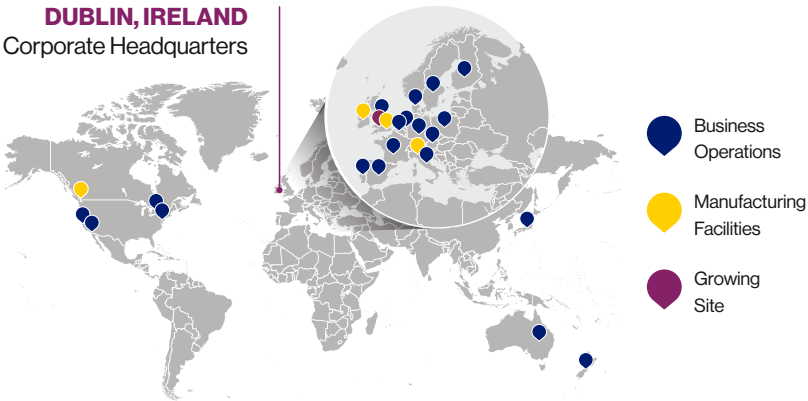


live our core values of Integrity, Collaboration, Passion, Innovation and Pursuit of Excellence.



**OUR GLOBAL FOOTPRINT**

Our medicines are available in nearly 100 countries around the world and our talented team members are embedded in North America, the UK, Europe, Australia, and Japan. In addition to our owned and operated manufacturing facilities in Ireland, Italy and the UK, Jazz partners with a network of manufacturers with whom we have had long-standing relationships, allowing us to rapidly advance and scale our medicines.



Figures above as of December 31, 2023, except for the number of countries served and R&D programs which have been updated as of July 2024

## Specialized Life Science Consulting

PSC Biotech® is a specialized life science consulting firm with **26 years of experience**, having collaborated with over **1,000+ clients** across **52 countries**.

### Professional Services Offered:



#### Computer Systems Validation (CSV)

- Manufacturing and Lab Equipment Software Validation
- Enterprise Resource Planning (ERP) Systems
- Electronic Quality Management Systems (eQMS)
- Laboratory Information Management Systems (LIMS)
- Automation Systems
- Calibration Management Software Implementation & Validation



#### Quality Assurance & Compliance

- QA Review (GLP, GMP, GCP)
- 483/Warning Letter Remediation
- Risk Assessments
- EM Program Analysis/Creation
- Quality Control Laboratory Consulting
- Training Management



#### Audits

- Supplier Quality Audits
- Regulatory Gap Assessment
- IT Gap Assessment/ Data Integrity
- Internal Audits
- Turn-Key Supplier Qualification Program



#### Technical Writing

- Documentation Gap Assessment
- SOP and Policy Development
- Document Harmonization, Simplification, and Consolidation
- Document Compliance with Industry Standards
- Regulatory Body Submission Development



#### Engineering

- Engineering Drawings
- Process Design and P&ID
- Facility Optimization
- Quality Engineering Support
- Equipment Selection

PSC Biotech® offers expert consulting services that enhance client success and ensure regulatory compliance, including supplier audits and greenfield facility startups. Contact us to discover how we can adapt our services for you!



#### Commissioning, Qualification, and Validation (CQV)

- CQV Plans & Documentation
- ISPE Risk-Based C&Q Approach
- Greenfield CQV Projects
- Paperless Validation
- Clean Room IQ/OQ/EMPQ
- Manufacturing Equipment
- Analytical Instrumentation



#### Project Management

- Validation Team Leadership
- Schedule Development and Oversight
- Project Coordination Support
- Risk Management
- Budget Management
- Lifecycle Management



#### Metrology

- In-Lab Calibrations at PSC
- Field and In-Place Instrument Calibrations
- NIST-Traceable Calibrations
- Test Equipment Rental
- Thermal Validation/Temperature Mapping Support
- Asset Management



#### Regulatory Affairs

- Regulatory Strategy Development
- Global Submission Management
- eCTD Submission Support
- Risk Benefit Analysis
- Post-Approval Product Compliance

### Official Partner Programs



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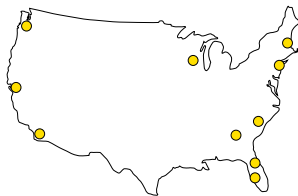
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**10**

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### Building Design + Construction Giants

**#2** Laboratory  
Architecture, 2024

**#4** Science &  
Technology, 2023

### Science & Technology Project Stats

**7.5m** sq ft of drug processing &  
manufacturing facilities (cGMP)

**60m** sq ft of science & technology  
space designed



## Directly Reducing Costs with **Foreign Trade Zone**

Move time- and temperature-sensitive life science materials in significantly shorter timeframes, with fewer touchpoints, less risk, and greater sustainability.



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Tarmac Time



# Our Promise



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BUT OUR QUEST HAS EVOLVED  
—IT'S BIGGER AND BOLDER.  
OUR FOCUS IS EVEN GREATER THAN MEDICINE,  
IT'S ALSO ABOUT SERVING SOCIETY.

TO SOLVE THE WORLD'S MOST  
COMPLEX HEALTH CHALLENGES,  
WE WILL NEED COURAGE AND ADAPTABILITY.

WE WILL CULTIVATE AND UNIFY THE GREATEST MINDS,  
WITHIN AND BEYOND OUR DIVERSE NETWORK,  
TO IMPROVE THE LIVES OF ALL PATIENTS.

**MAKE NEW MEDICINE  
LIKE A LIFE DEPENDS ON IT.**





From preservation to **cell proliferation**,  
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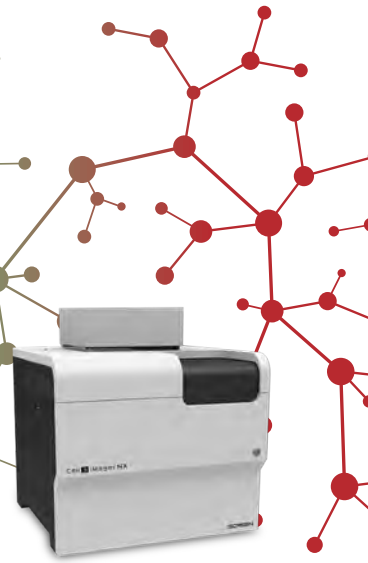
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\*Research Use Only

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LABS



**Saya**, UCB researcher

# UCB in the U.S.

**Inspired by patients.  
Driven by science.**

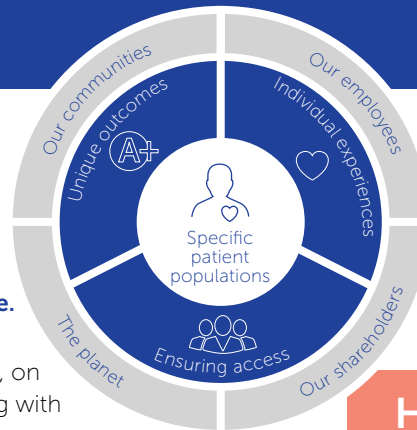
# About UCB

UCB is a global biopharmaceutical company committed to developing innovative solutions to address significant unmet needs for people living with severe, chronic diseases. By putting patients at the heart of everything we do, we enable people to live their best lives, delivering impactful solutions patients value, now and into the future.

At UCB, we come together every day to work, laser-focused, on a simple question: How will this create value for people living with severe diseases?

Patient value is not just what we say, but how we live. It is our culture of care, embodied by our patient value strategy. That's because how we do business – from discovery to development to delivery – has been transformed and redesigned around people and their individual experience. We amplify scientific innovation through digital transformation and commit to making solutions as accessible as possible in ways that are sustainable for people impacted by severe diseases, for UCB, and for society. By keeping people at the heart of everything we do, we push scientific boundaries, seeking to solve the tough challenges to create tangible improvements in care.

As UCB's largest affiliate, we have **more than 1,700** U.S.-based employees.

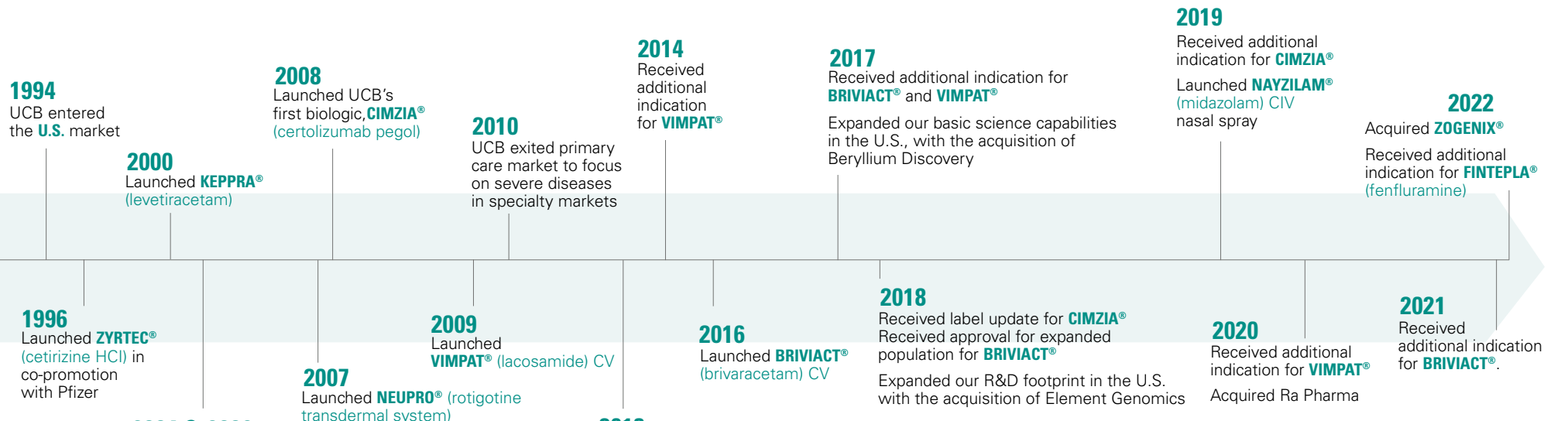
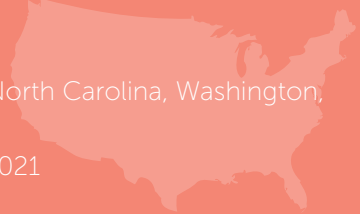


Our people, with their diversity, unique strengths, and talents, enable us to fulfill our commitment. With a team of approximately 8,600 employees and operations in nearly 40 countries, we invest about a quarter of our revenue annually in cutting-edge scientific research to meet unmet patient needs. Global headquarters are in Brussels, Belgium, with U.S. headquarters in Atlanta, Georgia, and additional U.S. sites for R&D in Raleigh and Durham, North Carolina, Bedford and Cambridge, Massachusetts, and Seattle, Washington, and a policy office in Washington, D.C..

## HOW WE DELIVER VALUE IN THE U.S.

UCB has more than 1,700 employees across the United States working in research, development, and operations.

- 2021 U.S. Economic Footprint: **\$775 million**
- **7 UCB offices** across Georgia, Massachusetts, North Carolina, Washington, and Washington, D.C.
- **14% increase** in U.S. employees from 2019 to 2021
- **More than 100** active clinical studies
- **On average, 25% of our global revenue** is invested every year in R&D
- About **25%** of our U.S.-based employees are dedicated to R&D



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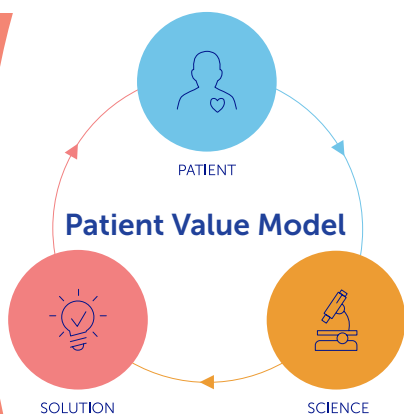
# U.S. Innovation

## DISEASE AREAS

At UCB, we want to help people live their best lives, whatever that means for them. We're focused on severe, chronic, neurological and immunological conditions. And we're blazing a path integrating new technologies like machine learning and data analytics into how we work today to unlock a healthier tomorrow.

Beyond medicines, we support patients in the community through additional services and with online resources for patients and their families.

At UCB, we are driven by our commitment to people living with severe diseases who inspire our research and development across neurology, immunology, and other areas where our expertise, innovation, and ambition align with unmet needs. We are dedicated to the development of transformative solutions. Our Digital Business Transformation approach aims to use data and technology with purpose throughout the whole value chain, for both drug and non-drug solutions.



Our future has never been brighter and the opportunities to provide patients with solutions they value has never been more urgent. By fulfilling our commitment, driving innovation, and providing patients a meaningful experience, solutions are on the horizon to help more patients managing severe diseases live their best lives, now and in the future.

As long as there are unmet needs, our mission continues. We are inspired by patients and driven by science to deliver what patients value.

**For More Information:**

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Inspired by **patients.**  
Driven by **science.**

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