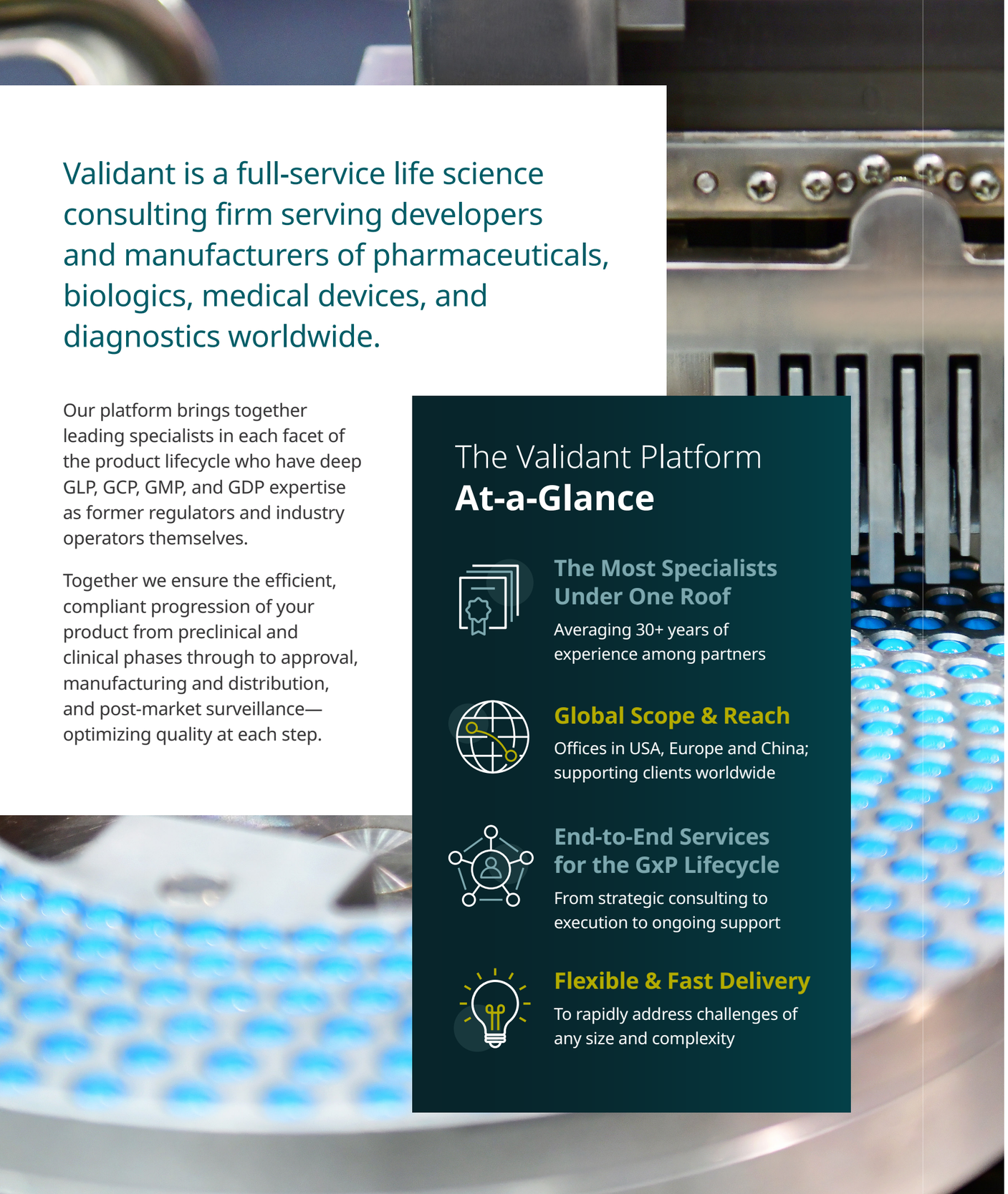
ABOUT OUR PLATFORM

VALIDANT

Your Full-Service **Global Regulatory, Compliance & Quality** Consultancy

Specializing in Life Science Consulting for the Entire GxP Lifecycle



Validant is a full-service life science consulting firm serving developers and manufacturers of pharmaceuticals, biologics, medical devices, and diagnostics worldwide.

Our platform brings together leading specialists in each facet of the product lifecycle who have deep GLP, GCP, GMP, and GDP expertise as former regulators and industry operators themselves.

Together we ensure the efficient, compliant progression of your product from preclinical and clinical phases through to approval, manufacturing and distribution, and post-market surveillance—optimizing quality at each step.

The Validant Platform **At-a-Glance**

The Most Specialists Under One Roof

Averaging 30+ years of experience among partners

Global Scope & Reach

Offices in USA, Europe and China; supporting clients worldwide

End-to-End Services for the GxP Lifecycle

From strategic consulting to execution to ongoing support

Flexible & Fast Delivery

To rapidly address challenges of any size and complexity

A Full-Service Approach for **Turnkey Problem-Solving**

One element that makes Validant unique as a regulatory, compliance, and quality consultancy is our ability to go beyond just strategic services. We offer:

Strategic Consulting

We apply our deep experience gained from thousands of engagements to your unique project realities, creating an action plan that is both practical and drives needed results.

Ongoing Support

We provide training, monitoring, process reviews, and staff for maintenance support to help you maintain compliance and quality within your operations over time.

Execution Services

We deploy boots-on-the-ground talent and Validant's program leaders to oversee successful implementation of your defined strategies, anywhere in the world.

A Partner for the **Full Product Lifecycle**

We apply our strategic, execution, and ongoing support services to virtually any regulatory, compliance, or quality requirement across the GxP product lifecycle.

DataRevive
A VALIDANT COMPANY

Validant is able to deliver expert services for regulatory pathways through DataRevive, which specializes in Regulatory Affairs for small molecule and biological products as well as advanced therapies.

Below are some examples of services we provide to support pharmaceutical biologics, medical device, and diagnostics clients:

Strategic Consulting

- Regulatory Strategy
- Process Development Strategy
- Quality Management Systems (QMS) Strategy
- Data Integrity Strategy
- In-House vs. Contract Supplier Strategy
- M&A Strategy
- Product Portfolio & Global Compliance Strategy

Execution Services

- Regulatory Meeting Representation
- Dossier Writing & Review (FDA, EMA, MHRA, etc.)
- Product Submissions & Maintenance [IND, BLA, NDA, PMA, 510(k) & Global Product Registrations]
- QMS Design & Optimization
- Due Diligence & Audits
- Data Integrity Solution Implementation
- Health Authority Response & Remediation
- Implementation of New/Revised Standards and Regulations
- Design Review

Ongoing Support

- Regulatory Monitoring
- Mock Inspections
- Process Monitoring
- Compliance Training
- Independent QA Reviews and Support
- Supplier Qualification
- Audit Trail Review Methodologies
- Inspection Readiness Reviews
- Qualification/Validation
- Support for Ongoing Standards and Regulation Changes

Not sure exactly what you need?
That is where our team can help the most.

We will help you define the optimal path forward, applying our specialized expertise and proven methodologies to fit the distinct nuances of your product, team, geographic region, and specific initiative.

Global Strategies, **Delivered Anywhere**

Validant is able to deliver our breadth of consulting, execution, and support services in the right place, at the right level, and in the right combination to meet your exact need. How?

Unmatched Range of Talent

We have curated an extensive and diverse global network of consultants to help execute strategies worldwide. We will hand-select the talent with the technical credentials and region- or language-specific skills to match your requirements.

Unparalleled Deployment Speed

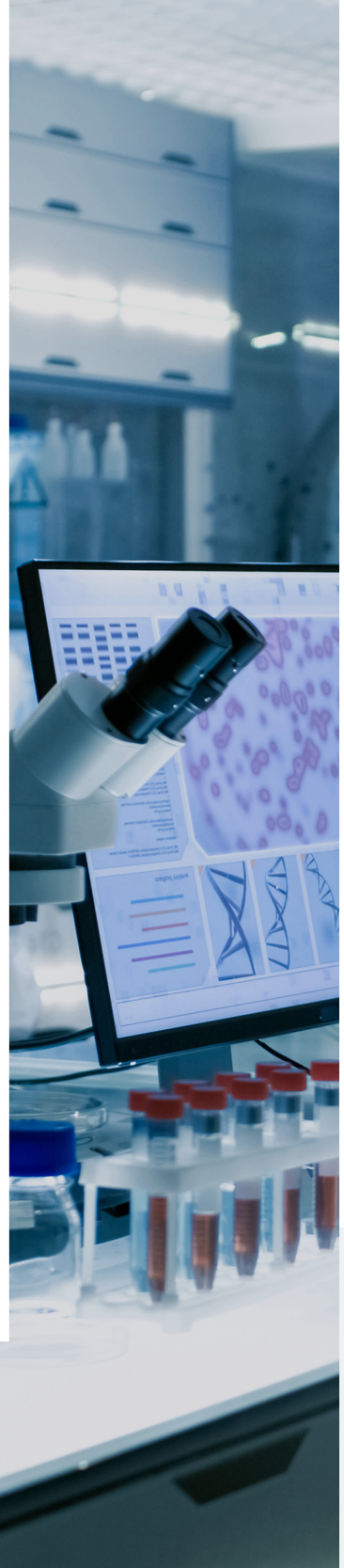
Validant consultant teams of any size can be mobilized around the world in as little as one week. To streamline deployment, we handle all global work-related compliance requirements for you.

Borderless Delivery

With offices in USA, Europe, and China, Validant can easily access all major global markets and is steeped in the nuanced regulatory, compliance, and quality requirements of the different global health agencies.

Equally Equipped for Local or Remote Engagements

While we can deploy on-site teams virtually anywhere in the world, we are also proven at successfully delivering services through remote work models using advanced technologies and virtual reality tools.



Guided by **Seasoned Experts**

Validant's partners average 30+ years in the life science industry as former FDA and EMA regulators and as leaders in major global pharma, medical device, and diagnostics organizations.

Brian Burns
Chief Executive Officer

Robert Rhoades
Managing Partner

Stephanie Colotti
Senior Partner

A differentiator of Validant's model is that our partners provide not only strategic direction, but also active hands-on support to put those strategies into action.

Tony McDonagh
Partner

Kurt Moerck
Partner

Janet Whipple
Partner

Audrey Jia, M.D., Ph.D.
Regulatory & CMC Principal Consultant, DataRevive

Michele Dougherty, Ph.D.
Vice President, CMC Biologics, DataRevive

Wayne Hutman, M.D.
Managing Director, DataRevive

Validant's team members have held top positions at leading companies including:

Abbott · Baxter · Beckman Coulter · Boston Scientific · EMD Serono · Fresenius Medical Care · Genentech · Haemonetics · Pfizer · Roche · Shire · Solvay

How can **we help *you?***

Through specialized and comprehensive regulatory, compliance, and quality consulting, we have empowered thousands of customers to efficiently navigate the life science product lifecycle from end to end. We're ready to support you too.

Tell us about your distinct requirements today by visiting **www.validant.com/need** or by calling **+1.844.VALIDANT.**

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