

Ulmer Ventures Value

www.ulmerventures.com

202.596.2492

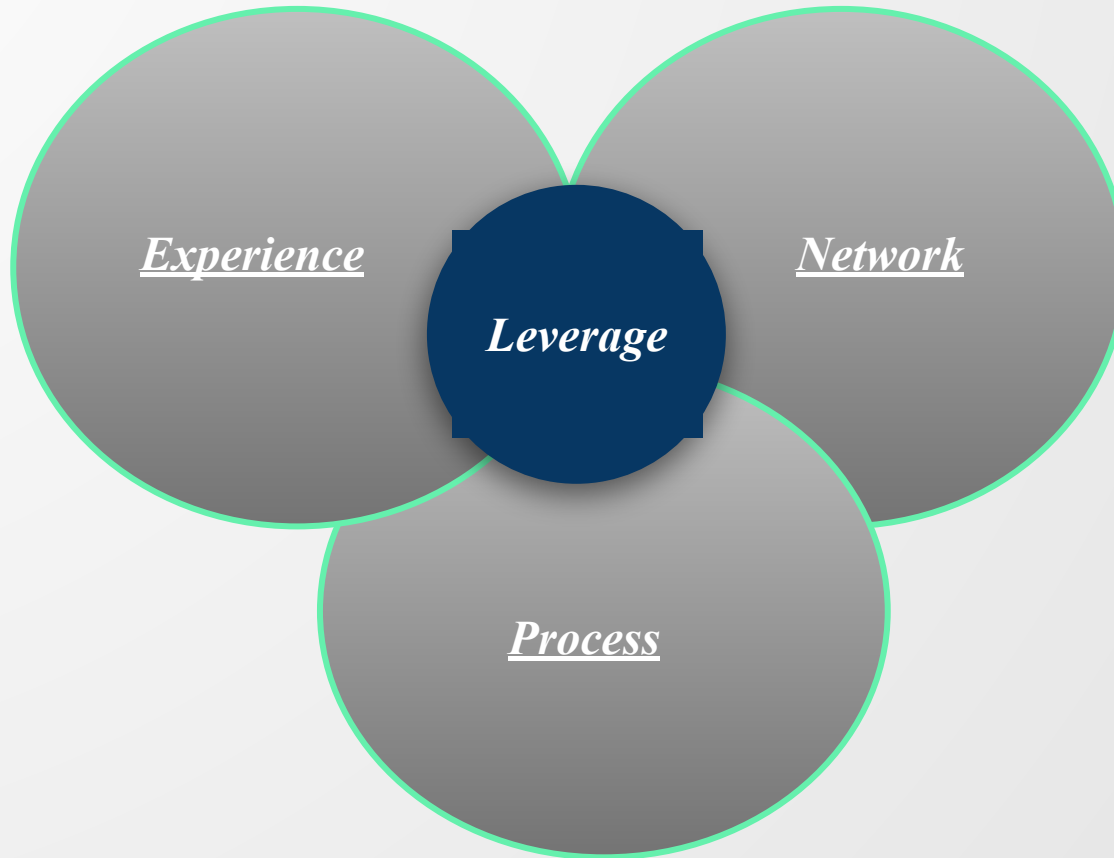
info@ulmerventures.com

Experience

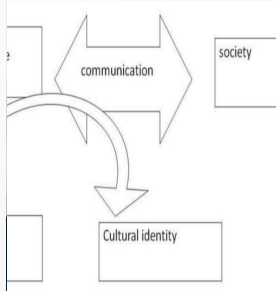
- Over a decade @FDA (Former Deputy Division Director)
- Expertise: Cardiovascular, Ophthalmology, General Hospital, Infection Control, Dental, Anesthesia, Respiratory
- Vice President Regulatory Affairs / Quality Assurance @Danaher (Fortune 150 Company)
 - Initiated reorganization of department
 - Led major compliance effort
 - Successful FDA inspection (no observations)



Differentiators



Services



Regulatory Strategy

- RAQA
- Organizational Structure
- Regulatory Pathway



FDA Communications

- Deficiency Response
- Application Review



Interim Executive Leadership

- Compliance Remediation
- Accelerated Product Registration



Training

- FDA Communication
- MDR Reporting

Experience to Provide...

Executive Application Review

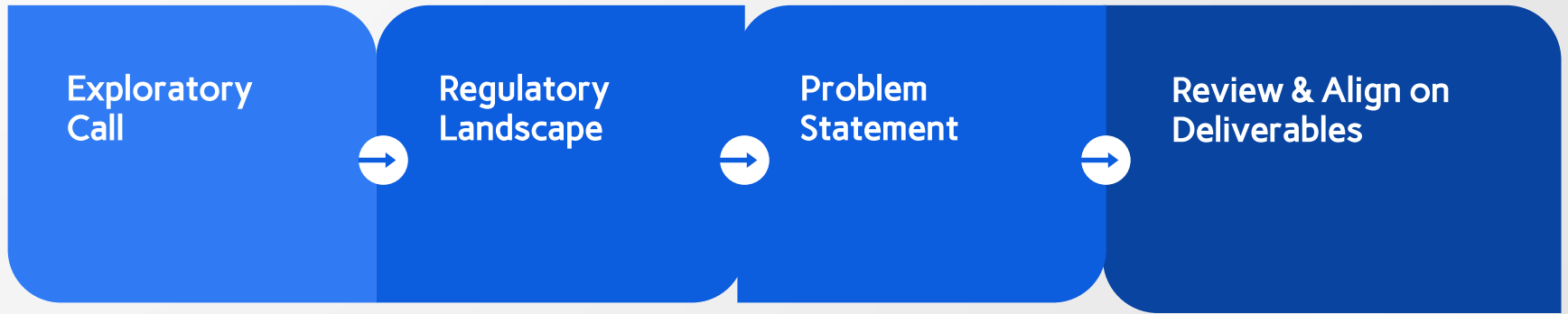
- Examples include: Presubmission, IDE, 510(k), 513(g), PMA, Refuse to Accept, Hold letter
- Troubleshooting

Strategic Advice & Diligence to Investors

- Validate & Verify Founder Milestones
- Diligence portfolio company Regulatory and Quality systems



Efficient Process



Valued Partner Network



Ulmer Ventures Value

Extensive Experience

Efficient Process

Valued Network

www.ulmerventures.com

202.596.2492

info@ulmerventures.com