

Ulmer Ventures Value

www.ulmerventures.com

202.596.2492

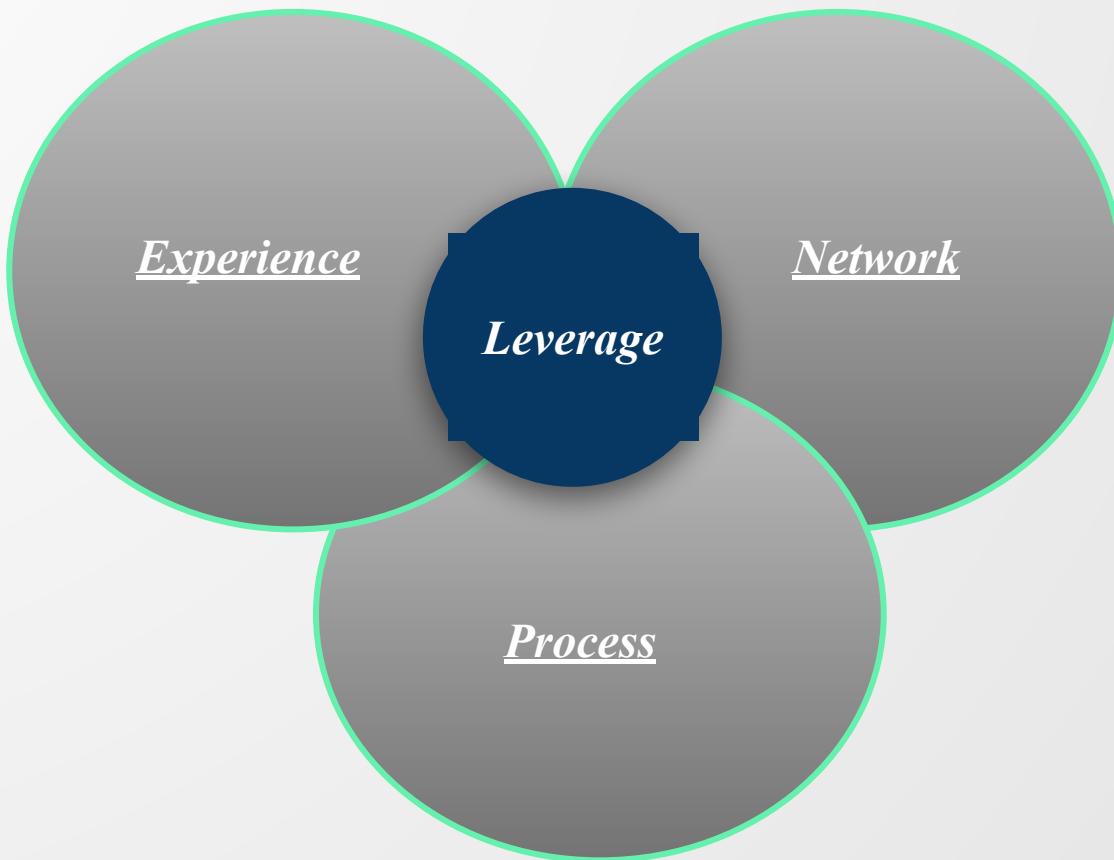
info@ulmerventures.com

Experience

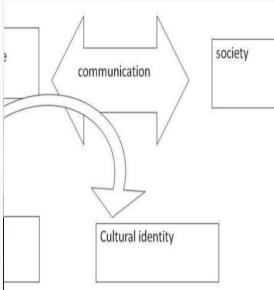
- Over a decade @FDA (Former Deputy Division Director)
- Expertise: Cardiovascular, Ophthalmology, General Hospital, Infection Control, Dental, Anesthesia, Respiratory
- Vice President Regulatory Affairs / Quality Assurance @Danaher (Fortune 150 Company)
 - Initiated reorganization of department
 - Led 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

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