



## Take Your Big Ideas and Make Them Reality

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Katrina Rogers Consulting provides contract services for innovators, entrepreneurs, and investors working in the medicine and medical device spaces. Providing custom-designed services is our specialty. Our team has a wide range of experience and a depth of area-specific knowledge and skills that you can draw on to move your medical product rapidly through development. We confidently provide services in the following areas.

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*Planning and Strategy* - We are experts in pharmaceutical and medical device business and regulatory strategy. We evaluate your product for feasibility, outline a structure of development stage gates, and identify the requirements to complete each stage. Our experience with discovery/preclinical development, analytical laboratory operations, and chemistry, manufacturing, and controls (CMC) gives you a broad perspective on your products' current and future needs.

*Operations and Outsourcing* - Modern medical products companies make considered choices on what parts of their operations must use in-house expertise and what can be effectively outsourced. Cost is not the only consideration; the novel science or technology of your product will present unique business and regulatory risks that require an adaptive approach to operations.

*Lifecycle* - Planning and developing a new medicine or medical device requires a coordinated leadership team capable of balancing their strengths and learning new skills, especially as your business scales. We provide objective assessments for your executive personnel, recommendations for individual and team growth, and custom training and coaching to enhance skills and team cohesion.

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### *About our CEO*



Katrina Rogers is a change expert with over 25 years of experience in the discovery, development, and manufacture of medicines and related technology. An expert in laboratory and technical operations, she is also an ASQ certified Manager of Quality/Organizational Excellence and Pharmaceutical GMP Professional. Her professional services firm specializes in dramatically decreasing the cost and time of bringing new therapies to market.

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Schedule a meeting with me using  
my calendar app!  
<https://calendly.com/katrinarogers>

## Services Summary

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### **Planning and Strategy**

We provide expertise to innovators and investors on:

- Review or development of your strategic mission, vision, and values
- Internal competency or outsourcing assessments
- Operational and Regulatory strategy for discovery, development, and production
- Market strategy
- Stage gate readiness assessment
- Data package evaluation
- Risk assessment and mitigation
- Periodic strategy reassessments
- Business scorecards and metrics

### **Operations and Outsourcing**

Whatever your development stage, we can help you with our experience in the following areas:

- Operational and Regulatory tactics
- Study direction
- Project management
- Brokering expertise
- IND-enabling data assessments for new medicines
  - Analytical chemistry
  - Absorption, Distribution, Metabolism, Elimination (ADME)
  - Drug-Drug Interaction (DDI)
- Vendor/Service Provider audits and relations
- Inspection support
- Quality best practice
- Process analysis and improvements
- Deviation investigations
- Corrective and preventative actions
- Laboratory start- and scale-up

### **Lifecycle**

We have helped other leaders and teams with the following deliverables:

- Key Hires strategy
- Building trust relationships
- Succession planning
- Leadership assessment/training/coaching
- Skills development
- Interim leadership roles
- Change management
- Leading cross-functional and geographically separated teams

**Speaking Engagements** - see our website for topics or choose your own

### **Expert Witness Services**

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