Blue Stream
Bring Medical Devices to Market Faster!

UCLA CS Class Presentation
Who Are We

Blue Stream provides software platform to reduce the time and cost to navigate regulatory pathway for launching Medical Devices.

Benefits:

• Patients get life-saving devices sooner
• Reduce the cost of health care delivery

The TurboTax for Medical Device FDA Submissions!
Experienced Team

Deep Domain Expertise (Healthcare, IT, Medical Device Regulatory and Start-Up Operations)

Soumya Mahapatra, Founder
Software and process re-engineering in Healthcare

Anna Libman, Co-founder
Regulatory Strategy Consulting for Medical Device firms

Tae Macias
Seasoned CPA and CFO, Startup operations

Ross Lu
Marketing Strategy, Brand and Product Management for Medical Products

Frank Mikel
Operations, Healthcare Technology & Facility Management
Why is it complicated?

**Regulatory search & strategy**

1. Meet with Regulatory Consultancy (1-2 days)
2. Gather Device Information (1 day)
3. Search FDA Databases (3-4 weeks)
4. Search relevant, websites, google (1 day)
5. Develop Strategy (1-2 weeks)
6. Regulatory Professional (multiple iterations)

**FDA Submission Management**

- Standards
- Word Templates
- Protocols
- Regulatory guidelines
- Project Manager
- Clinical
- Engineering
- Bio-comp.
- R&D
- Quality Assurance

- Poor Quality
- High Turn Around Time
- Labor-intensive
- Steep Learning Curve
- Siloed Teams
- Manual Submission
Blue Stream Software for Regulatory

A platform that leverages advanced analytics and intuitive user design to streamline manual processes, reducing time and cost of FDA submissions.

Regulatory Strategy Builder + Regulatory Submission Manager

1. Data Entry
2. Create Strategy
   - Medical Device Founder
   - Strategy Builder
   - 1 day
   - 2-5 days

1. Gather Device Information
2. Search FDA Databases
3. Search relevant websites
4. Confidential
5. Iterative

Submission Manager

- Regulatory Professional
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Product Suite

Integrated Solutions

Regulatory Search
- Search device type, use and technology
- Competitors products, risk classification
- Device recalls and registration information

Strategy Builder
- Workflow Tool with integrated search capability
- Consistent information flow from search
- Decision making and easy-selection options
- Determine resources and time

Strategy Manager
- Collaboration tool to manage submission prep
- Custom task assignment, tracking
- Automate validation, alerts and notifications
- 360 degree view of submission progress
- Automate 510k sections & submission

❤ Develop easy-to adopt products that users will fall in love with!
# Value to Customers

<table>
<thead>
<tr>
<th></th>
<th>Search</th>
<th>Reg. Strategy</th>
<th>Submission Mgt.</th>
<th>Overall Process</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Today</strong></td>
<td>2-4 Weeks</td>
<td>4-6 Weeks</td>
<td>4-6 months</td>
<td>Siloed</td>
</tr>
<tr>
<td><strong>Blue Stream</strong></td>
<td>✔️ 5 Days</td>
<td>✔️ 5 days</td>
<td>✔️ 1-2 months</td>
<td>✔️ Transparent</td>
</tr>
<tr>
<td><strong>Value</strong></td>
<td>• Predictable • Consistent</td>
<td>• Quicker turn around time</td>
<td>• Cost-Effective • Greater Control</td>
<td>• Collaborative • User-friendly</td>
</tr>
</tbody>
</table>
Product Development Principles

Develop easy-to adopt products that users will fall in love with!

**Design**
- User-centric, simple front-end designs
- HL solution and architecture
- Refine UXD based on user feedback

**Discover**
- Discover user needs with real-time feedback
- Discover database types, access methodology, sync process

**Develop**
- Lean development methodology
- Proof of concept to full-scale product
- Iterate to add incremental features
Project Execution Methodology

1. IMMERSE
2. PLAN & PREPARE
3. INNOVATE/DESIGN
4. PROTOTYPE
5. ASSESS & REFLECT
6. PILOT & LEARN

DELIVER A GREAT USER EXPERIENCE!
## A Full-Stack Product Development

<table>
<thead>
<tr>
<th>Components</th>
<th>Skill Category</th>
<th>Learning Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>UI screen design</td>
<td>UX designer</td>
<td>Wireframes, themes, Visuals</td>
</tr>
<tr>
<td>Front end development</td>
<td>Web developer</td>
<td>HTML, UI pages, Styles, js</td>
</tr>
<tr>
<td>Back end development</td>
<td>Backend dev</td>
<td>API development, DB- SQL, No SQL integration, Full text search</td>
</tr>
<tr>
<td>Core functionality</td>
<td>Natural Language processing</td>
<td>Full text search, parsing, relevance, ranking</td>
</tr>
<tr>
<td>Analytics/ ML (future)</td>
<td>Data Analyst/ Scientists</td>
<td>Relevance based on datasets</td>
</tr>
<tr>
<td>Databases</td>
<td>Database Designer</td>
<td>DB modelling, NO SQL schema design, integration with API and front end.</td>
</tr>
</tbody>
</table>

Access to Prototyping Tools and AWS for the best learning experience!
What to expect from the Project

• Solve real-world problems in healthcare in U.S.
• Gain hands-on expertise on emerging tech
• Full-scale software development lifecycle
• Real-time user feedback from primary research
Thank You