Make Quality an attractive first step in your career

**Plan**
- High Level Implementation Plan
  - Assess the inventory of Quality programs
  - Develop partnerships with University engineering programs and the FDA
  - Create framework for Quality curriculum
  - Create a pilot program for Quality Day and Undergraduate recruiting programs

**Accelerate**
- Accelerate with Pathway Elements in place:
  - Key Focus Areas
  - Rigor of Program
  - Curriculum
  - Success Factors
  - Pathway advisory board (Jun)

**Program Pilot**
- Xavier will pilot course fall 2019
- Internships with industry
- Industry SMEs as faculty
- Evaluate success factors for university, industry, and students
- Develop project plan with gate checks (Apr)
- Create Intern Guidelines Policy (May)
- Networking portal for interns (TBD)

**Achieve**
- Establish a Quality discipline at the College/University level
- Educate students to the benefits of making Quality a foundational start to a successful career
Quality Science Education

**Governance/ Structure**
- Advisory Board formed May 2019, Kick off meeting June 2019
- Engagement developed with MDIC, FDA, Industry and Pathway

**Curriculum**
- 6 courses identified for curriculum
- Full curriculum development for Regulatory course is underway
- Curriculum for validation course set for Fall 2019
- Curriculum for Risk course set for Spring 2020
- Novo Nordisk and Danish Association want Denmark universities on board
- Paid internship opportunities

**University Relations**
- Calls to 39 universities completed June 2019
- Conducted First virtual info sessions for 6 universities
- Pilot launch at Xavier University – August 2019
- Development of student/industry portal
- 550 emails sent to Xavier conference attendees to connect with alma maters
- Advisories Board formed May 2019, Kick off meeting June 2019

**Student Support**
- Evaluating flexibility in non-major science course
- Establish ways to evaluation student performance on internship
- Curriculum taught by industry and government SME’s
- Web-recording career interviews to be posted on Pathway site
- Career examples posted on Pathway site

**CQO Forum**
- Support offered through SME teaching
- Endorsed Quality Science Education Curriculum

**Mobilizing Enterprise-wide Quality Effectiveness Through Next Generation Development**
- Support university implementation
- F&P to engage Univ. of Auckland
- Student certification
- Paid internship opportunities

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# Quality Science Education

## Key Focus Areas
- Data Integrity
- Risk and Failure Analysis
- Process Validation
- Understanding “why”

## Rigor of Program

**Designed with:**
- Chief Quality Officers across pharma, device, biotech, consumer goods and animal health industries
- Regulators from North America and Europe
- Academia

## Success Factors
- Complimentary resources and support for academia
  - Subject matter experts to teach industry-focused content
  - Internships offered to students for hands-on immersion
- Certification Board to certify academic rigor and faculty credentials
- Certification of student learning
- Linkage made between graduating students and industry employers
- Designed for science students, but also compliments any field with career paths into the health science industries

## Courses that Comprise the Curriculum

1. **Global Regulatory and Legal Requirements of Quality** focused on “why” global regulations were adopted, and the evolution of the quality systems grounded in science.
2. **Business Acumen** to teach financial concepts and applications, such as operating and capital expenses, fixed assets and liabilities, cash flow, profit and net worth.
3. **Product Development, Specifications, Process and Validation**, to include criticality of inputs, risk controls and assessment, specifications, testing, clinical trials, transfer, scalability, yield and validation.
4. **Risk and Failure Analysis**, Investigation Processes and writing scientifically justified conclusions linked to laboratory experiments.
5. **Microbiology and Laboratory** courses focused on controls, testing, and aseptic techniques. [Working to expand this to any relevant non-major science course]
# Case for Quality: Quality as a career – Project Milestones

<table>
<thead>
<tr>
<th>Key Deliverable</th>
<th>Dependency</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identify Candidates</td>
<td>1</td>
<td>Job Description</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>No. of Internships</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Candidate Resumes</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>Total No. of Candidates</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Networking Portal</td>
</tr>
<tr>
<td>Identify Interns</td>
<td>1</td>
<td>Candidate Interviews</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Acceptance Letters</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>List of Interns</td>
</tr>
<tr>
<td>Onboarding</td>
<td>1</td>
<td>Onboard Interns</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Housing</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Mentors / Coaches</td>
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<tr>
<td>Offboarding</td>
<td>1</td>
<td>Exit Interviews</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Intern Analysis</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Acceptance Letters</td>
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<tr>
<td>Intern Evaluation Report</td>
<td>1</td>
<td>Return on Investment (ROI)</td>
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<tr>
<td></td>
<td>2</td>
<td>Growth &amp; Fitment</td>
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<tr>
<td></td>
<td>3</td>
<td>Feedback Survey</td>
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</tbody>
</table>
Backup Slide
<table>
<thead>
<tr>
<th>Knowledge and Skills</th>
<th>Key observable behaviors</th>
<th>Business, University, Student Results</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>▪ Global Regulatory and Legal Requirements of Quality</td>
<td>1. Passion for Quality</td>
<td>a. Improved Operational Efficiency and Effectiveness (B) {Behaviors:1,2,3,4,5}</td>
<td>Accelerate the next generation of critical-thinking professionals grounded in the science of quality by immersing students in real-world experiences</td>
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<tr>
<td>▪ Business Acumen</td>
<td>2. Proactive risk mitigation</td>
<td>b. Reduction in cost of poor quality (B) {Behaviors: 1,3,4,6}</td>
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<tr>
<td>▪ Product Development, Specifications, Process and Validation</td>
<td>3. Confidence builder</td>
<td>c. Reduce on-boarding training by 1-3 years for new employees (B) {Behavior: 3}</td>
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<tr>
<td>▪ Risk and Failure Analysis</td>
<td>4. Adaptability</td>
<td>d. Accelerated path for job placement (U, S) {Behaviors: 1,3,4,5,6}</td>
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</tr>
<tr>
<td>▪ Microbiology and Laboratory Courses</td>
<td>5. Stakeholder savvy</td>
<td>e. Increased student recruiting and enrollment at lower cost (U) {Behaviors: 3,4}</td>
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<td></td>
<td>6. Innovative systems thinker</td>
<td>f. Exposure to senior leaders (S) {Behaviors: 2,4,5}</td>
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<tr>
<td>Methods for Delivery</td>
<td></td>
<td>g. Increased hiring and career success (B, U, S) {Behaviors: 1,2,3,4,6}</td>
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<tr>
<td>✓ On-campus coursework</td>
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<td>✓ On-line learning with SMEs</td>
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<td>✓ Hands on Internship</td>
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<tr>
<td>✓ Engagement with Industry Leaders</td>
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</table>
Co-operative Quality Science Model

- **Quality Science Education**
  - Microbiology Course
  - Regulatory and Legal Framework
  - Business Acumen
  - Microbiology Laboratory
  - Failure and Risk Analysis
  - Product Development and Validation

- **Industry Support**
  - Online learning live
  - On-Demand learning
  - Co-ops/internships
  - On-Campus teaching

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