REGULATORY COMPLIANCE, MS QUALITY SYSTEMS SPECIALIZATION

Rapid technological advances and increased globalization have spurred government and industry regulations. The changing environment has transformed job and performance expectations for chemists, scientists, technicians, and managers. The quality systems specialization is designed for students to explore concepts and problems in quality assurance and regulatory affairs that span life science industries, thus encouraging a cross-pollination of best practices and systems.

Quality Systems specialization students will have the knowledge they need to sit for the ASQ Six Sigma Green Belt (https://asq.org/cert/six-sigma-green-belt/) certification exam after completing the degree. ASQ certification increases the potential for a higher salary and demonstrates proficiency in the quality and regulatory science fields.

Curriculum

Core Courses (6 units)

<table>
<thead>
<tr>
<th>Course</th>
<th>Title</th>
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<tbody>
<tr>
<td>MSRC 401-DL</td>
<td>Quality Systems</td>
</tr>
<tr>
<td>MSRC 405-DL</td>
<td>Applied Research and Writing</td>
</tr>
<tr>
<td>MSHA 409-DL</td>
<td>Statistical Analysis</td>
</tr>
<tr>
<td>MSRC 435-DL</td>
<td>Risk and Decision Management</td>
</tr>
<tr>
<td>MSRC 481-DL</td>
<td>Leadership in the Regulatory Environment</td>
</tr>
<tr>
<td>MSRC 498-DL</td>
<td>Capstone</td>
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<tr>
<td>or MSRC 590-0</td>
<td>Thesis Research</td>
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Specialization Courses (4 units)

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<tr>
<th>Course</th>
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<tbody>
<tr>
<td>QARS 420-DL</td>
<td>Practical Quality Management</td>
</tr>
<tr>
<td>QARS 421-DL</td>
<td>Applied Quality &amp; Regulatory Practices</td>
</tr>
<tr>
<td>QARS 425-DL</td>
<td>Quality Assurance Project Management</td>
</tr>
<tr>
<td>QARS 450-DL</td>
<td>Medical Device Regulations</td>
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<tr>
<td>or QARS 460-DL</td>
<td>Drug and Biologics Regulations</td>
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Cross-Specialization Elective (1 unit)

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<tr>
<td>Choose one</td>
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<tr>
<td>CLIN_RES 400-DL</td>
<td>Essentials of Initiating Clinical Research</td>
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<tr>
<td>CLIN_RES 401-DL</td>
<td>Responsible Conduct of Research</td>
</tr>
<tr>
<td>CLIN_RES 403-DL</td>
<td>Clinical Research Design &amp; Methodology</td>
</tr>
<tr>
<td>HC_COM 410-DL</td>
<td>Healthcare Regulatory Environment</td>
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<tr>
<td>HC_COM 411-DL</td>
<td>Healthcare Programs and Enforcement</td>
</tr>
<tr>
<td>HC_COM 413-DL</td>
<td>Healthcare Billing Models &amp; Systems</td>
</tr>
<tr>
<td>HC_COM 415-DL</td>
<td>IT Systems Compliance</td>
</tr>
</tbody>
</table>

About the Final Project

Students pursue their capstone experience independently or as part of a team. As their final course, students take either the individual research project in an independent study format or the classroom final course in which students integrate the knowledge they have gained in the core curriculum in work assigned by the instructor. In both cases, students are guided by faculty in exploring the body of knowledge on regulatory compliance while contributing research of practical value to the field. The capstone independent project and capstone class project count as one unit of credit.

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