REGULATORY COMPLIANCE, MS CLINICAL RESEARCH SPECIALIZATION

Students specializing in clinical research are given a solid framework from which to understand clinical research. A graduate’s understanding of clinical study design, drug development and regulatory requirements allows them to manage many facets of the clinical research endeavor, whether developing and implementing clinical research protocols or overseeing GCP, compliance and financial matters at an individual or multi-site level.

Curriculum

Core Courses (6 units)

<table>
<thead>
<tr>
<th>Course</th>
<th>Title</th>
</tr>
</thead>
<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>
</tr>
<tr>
<td>or MSRC 590-0</td>
<td>Thesis Research</td>
</tr>
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Specialization Courses (4 units)

<table>
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<tr>
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</thead>
<tbody>
<tr>
<td>CLIN_RES 400-DL</td>
<td>Essentials of Initiating Clinical Research</td>
</tr>
<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>QARS 450-DL</td>
<td>Medical Device Regulations</td>
</tr>
<tr>
<td>or QARS 460-DL</td>
<td>Drug and Biologics Regulations</td>
</tr>
</tbody>
</table>

Cross Specialization Elective (1 unit)

<table>
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<tbody>
<tr>
<td>HC_COM 410-DL</td>
<td>Healthcare Regulatory Environment</td>
</tr>
<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>
<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>
</tr>
<tr>
<td>or QARS 460-DL</td>
<td>Drug and Biologics Regulations</td>
</tr>
</tbody>
</table>

1 Whichever of the two courses (450 or 460) that was not taken as part of the specialization

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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