

**SCSU at Plymouth  
9750 Rockford Road  
Plymouth, MN 55442**

**SCSU Regulatory Affairs & Services (RAS) Graduate Program  
Summer 2023, Fall 2023, Spring 2024 Course Schedule –  
Updated April 25, 2023**

| Semester    | Subj | #   | Title  | Dates         | Days | Time            | Cr/Hr | Instructor                    |
|-------------|------|-----|--|---------------|------|-----------------|-------|-------------------------------|
| Summer 2023 | RAS  | 627 | Intl Regulatory Affairs: European Union, East Europe, Australia & Canada | 05/11 - 05/11 | Th   | 5:00pm - 9:00pm | 3     | Bolton, Jennifer              |
|             |      |     |  | 05/15 - 05/15 | M    | 5:00pm - 9:00pm |       | Ertl, Donald                  |
|             |      |     |  | 05/18 - 05/18 | Th   | 5:00pm - 9:00pm |       | Sardeson, Scott               |
|             |      |     |  | 05/25 - 05/25 | Th   | 5:00pm - 9:00pm |       | Krier, Cathleen               |
|             |      |     |  | 06/01 - 06/01 | Th   | 5:00pm - 9:00pm |       | Larson, Belinda               |
|             |      |     |  | 06/08 - 06/08 | Th   | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 06/15 - 06/15 | Th   | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 06/22 - 06/22 | Th   | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 06/29 - 06/29 | Th   | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 07/10 - 07/10 | M    | 5:00pm - 9:00pm |       |                               |
| Summer 2023 | RAS  | 643 | Reimbursement & Cost Management for Medical Technology                   | 05/17 - 05/17 | W    | 5:00pm - 9:00pm | 3     | Mischke, Jennifer             |
|             |      |     |  | 05/22 - 05/22 | M    | 5:00pm - 9:00pm |       | Krier, Cathleen               |
|             |      |     |  | 05/24 - 05/24 | W    | 5:00pm - 9:00pm |       | Collis-Prather, Will          |
|             |      |     |  | 05/31 - 05/31 | W    | 5:00pm - 9:00pm |       | Kessinger-Sobcinski, Mary Kay |
|             |      |     |  | 06/05 - 06/05 | M    | 5:00pm - 9:00pm |       | Fautsch, Mary                 |
|             |      |     |  | 06/07 - 06/07 | W    | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 06/12 - 06/12 | M    | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 06/14 - 06/14 | W    | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 06/21 - 06/21 | W    | 5:00pm - 9:00pm |       |                               |
|             |      |     |  | 06/26 - 06/26 | M    | 5:00pm - 9:00pm |       |                               |
| Summer 2023 | RAS  | 644 | Internship in Regulatory Affairs and Services                            | 05/15 - 08/03 | n/a  | n/a             | Vari. | Krier, Cathleen               |
| Summer 2023 | RAS  | 699 | Capstone Culminating Project - Initial                                   | 05/15 - 08/03 | n/a  | n/a             | 1     | Sardeson, Scott               |
|             |      |     |  |               |      |                 |       | Krier, Cathleen               |
| Summer 2023 | RAS  | 699 | Capstone Culminating Project - Final                                     | 05/15 - 08/03 | n/a  | n/a             | 1     | Sardeson, Scott               |
|             |      |     |  |               |      |                 |       | Krier, Cathleen               |

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|-----------|------|-----|---|---------------|------|-----------------|-------|-----------------|
| Fall 2023 | RAS  | 621 | Legal Basis for Medical Device Product Regulation | 09/12 - 09/12 | T    | 5:00pm - 9:00pm | 3     | TBD             |
|           |      |     |   | 09/19 - 09/19 | T    | 5:00pm - 9:00pm |       | Krier, Cathleen |
|           |      |     |   | 09/26 - 09/26 | T    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/03 - 10/03 | T    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/10 - 10/10 | T    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/17 - 10/17 | T    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/24 - 10/24 | T    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 11/07 - 11/07 | T    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 11/14 - 11/14 | T    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 11/21 - 11/21 | T    | 5:00pm - 9:00pm |       |                 |
| Fall 2023 | RAS  | 625 | Regulatory Routes to Market: PMA's                | 09/11 - 09/11 | M    | 5:00pm - 9:00pm | 3     | TBD             |
|           |      |     |   | 09/18 - 09/18 | M    | 5:00pm - 9:00pm |       | Novak, Brian    |
|           |      |     |   | 09/25 - 09/25 | M    | 5:00pm - 9:00pm |       | Krier, Cathleen |
|           |      |     |   | 10/02 - 10/02 | M    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/09 - 10/09 | M    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/16 - 10/16 | M    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/23 - 10/23 | M    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 11/06 - 11/06 | M    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 11/13 - 11/13 | M    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 11/20 - 11/20 | M    | 5:00pm - 9:00pm |       |                 |
| Fall 2023 | RAS  | 633 | Quality Systems for Regulated Industries          | 08/30 - 08/30 | W    | 5:00pm - 9:00pm | 3     | TBD             |
|           |      |     |   | 09/06 - 09/06 | W    | 5:00pm - 9:00pm |       | Krier, Cathleen |
|           |      |     |   | 09/13 - 09/13 | W    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 09/20 - 09/20 | W    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 09/27 - 09/27 | W    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/04 - 10/04 | W    | 5:00pm - 9:00pm |       |                 |
|           |      |     |   | 10/11 - 10/11 | W    | 5:00pm - 9:00pm |       |                 |



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|-------------|------|-----|--|------------------|-------|------------------|
| Spring 2024 | RAS  | 623 | Regulatory Routes to Market: 510(k)s                                       | To Be Determined | 3     | To Be Determined |
| Spring 2024 | RAS  | 631 | IDE Regulations and Clinical Trial Design                                  | To Be Determined | 4     | To Be Determined |
| Spring 2024 | RAS  | 635 | Regulatory Affairs Compliance  | To Be Determined | 3     | To Be Determined |
| Spring 2024 | RAS  | 644 | Internship in Regulatory Affairs and Services                              | To Be Determined | Vari. | To Be Determined |
| Spring 2024 | RAS  | 651 | Regulation of Combination Products   | To Be Determined | 3     | To Be Determined |
| Spring 2024 | RAS  | 695 | Special Topics in Combination Products                                     | To Be Determined | 1     | To Be Determined |
| Spring 2024 | RAS  | 695 | Special Topics in IVDR - New Medical Device In Vitro Diagnostic Regulation | To Be Determined | 1     | To Be Determined |
| Spring 2024 | RAS  | 699 | Capstone Culminating Project - Initial                                     | To Be Determined | 1     | To Be Determined |
| Spring 2024 | RAS  | 699 | Capstone Culminating Project - Final                                       | To Be Determined | 1     | To Be Determined |