

## 2024 Student Academic Calendar

### Note to students:

To become a Certified Medicines Development (CMD) professional, a student must successfully complete and pass six Modules made up of ten lessons each and the End of Program Assessment. Lessons are comprised of online lectures, post lecture assignments, discussion forums, feedback, and assessments. Two lessons are released each week. Each week typically requires **5-12 hours** of home study.

Some assignments, such as webinars and examinations **must be completed during specific dates and times to receive credit**. Students are responsible for logging in to the classroom and completing all assignments on time. **Late submissions will not be accepted**. If you are unable to complete an assignment on time, due to an emergency, please contact GMDP Academy administrators as soon as possible notifying them of the situation.

GMDP Academy sends weekly student announcements about upcoming dates, calendar updates, and other important information. However, it is the responsibility of the student to be aware of these communications, as well as upcoming assignments, webinars, exam dates, etc.

- **All listed times are U.S. Eastern Time (New York).**
- Assignments and lessons are posted in the classroom each week on Friday at 12:01 AM (ET), all responses are due by next Sunday at 11:59 PM (ET). The exception is the first day of each Module which is always a Monday.
- Pages 2-3 contain a summary of each module. Pages 5-10 show a detailed view of each lesson, including weekly assignments. Pages 4 & 11 provide information about the EPA (End of Program Assessment)
- The GMDP Academy strives to notify students of exact dates and times of webinars as soon as possible. Each webinar will be held twice to allow for more flexibility in student schedules. Typically, the two offerings are available on separate days; however, due to the nature of these live events, webinar scheduling is dependent on the availability of the presenter.
- Module exams are offered on two separate dates. Students that do not receive a passing score on the first offering can retake the exam during the 2<sup>nd</sup> offering. Exams are available for 24 hours on the scheduled day. Students have 60 minutes to complete the exam.
- All dates are subject to change. The GMDP Academy will notify students of all updates/changes to the *Student Academic Calendar*.

## Orientation Week: January 8 – January 14

**This week includes orientation lectures, how-to guides for navigating the classroom, and an opportunity to meet and network with fellow students. Orientation Webinar Date: TBA**

### Module 1

#### **10 Lessons – January 15 to February 25**

Webinar 1 – Wk. of Jan 22

Webinar 2 – Wk. of Jan 29

Webinar 3 – Wk. of Feb 5

Webinar 4 – Wk. of Feb 12

Team Assignment Presentations: Feb 19<sup>th</sup> & 20<sup>th</sup> @ 8a EST

Final Exam (2 Offerings) – **1<sup>st</sup> Offering:** Thursday, Feb 22 | **2<sup>nd</sup> Offering:** Sunday, Feb 25

### Module 2

#### **10 Lessons – February 26 to April 7**

Webinar 1 – Wk. of Mar 4

Webinar 2 – Wk. of Mar 11

Webinar 3 – Wk. of Mar 18

Webinar 4 – Wk. of Mar 25

Team Assignment Presentation: April 1<sup>st</sup> & 2<sup>nd</sup> @ 8a EST

Final Exam (2 Offerings) – **1<sup>st</sup> Offering:** Thursday, April 4<sup>th</sup> | **2<sup>nd</sup> Offering:** Sunday, April 7<sup>th</sup>

### Module 3

#### **10 Lessons – April 8 to May 19**

Webinar 1 – Wk. of April 15

Webinar 2 – Wk. of April 22

Webinar 3 – Wk. of April 29

Webinar 4 – Wk. of May 6

Team Assignment Presentation: May 13<sup>th</sup> & 14<sup>th</sup> @ 8a EST

Final Exam (2 Offerings) – **1<sup>st</sup> Offering:** Thursday, May 16<sup>th</sup> | **2<sup>nd</sup> Offering:** Sunday, May 19<sup>th</sup>

## Module 4

<b>10 Lessons – May 20<sup>th</sup> to June 30<sup>th</sup></b>	
Webinar 1 – Wk. of May 27	Webinar 2 – Wk. of June 3
Webinar 3 – Wk. of June 10	Webinar 4 – Wk. of June 17
Team Assignment Presentation: June 24 <sup>th</sup> & 25 <sup>th</sup> @ 8a EST	
Final Exam (2 Offerings) – <b>1<sup>st</sup> Offering:</b> Thursday, June 27 <sup>th</sup>   <b>2<sup>nd</sup> Offering:</b> Sunday, June 30 <sup>th</sup>	

## Module 5

<b>10 Lessons – July 1<sup>st</sup> to August 11<sup>th</sup></b>	
Webinar 1 – Wk. of July 8	Webinar 2 – Wk. of July 15
Webinar 3 – Wk. of July 22	Webinar 4 – Wk. of July 29
Team Assignment Presentation: Aug 5 <sup>th</sup> & 6 <sup>th</sup> @ 8a EST	
Final Exam (2 Offerings) – <b>1<sup>st</sup> Offering:</b> Thursday, Aug 8 <sup>th</sup>   <b>2<sup>nd</sup> Offering:</b> Sunday, Aug 11 <sup>th</sup>	

3-Week Recess (no classroom activities) – August 12<sup>th</sup> to September 1<sup>st</sup>

## Module 6

<b>10 Lectures – September 2<sup>nd</sup> to October 13<sup>th</sup></b>	
Webinar 1 – Wk. of Sept 9	Webinar 2 – Wk. of Sept 16
Webinar 3 – Wk. of Sept 23	Webinar 4 – Wk. of Sept 30
Team Assignment Presentation: Oct 7 <sup>th</sup> & 8 <sup>th</sup> @ 8a EST	
Final Exam (2 Offerings) – <b>1<sup>st</sup> Offering:</b> Thursday, Oct 10 <sup>th</sup>   <b>2<sup>nd</sup> Offering:</b> Sunday, Oct 13 <sup>th</sup>	

## **Office Hours**

Check the classroom for available office hours during the program. We will have regular office hours available for students. This will be a virtual zoom session in which you can meet fellow students, faculty, or ask any questions you might have. These sessions must be registered for in advance. If there are no registrations for a particular office hour, we will not hold that session.

## **End of Program Assessment (EPA): October 14th - November 17th**

The End of Program Assessment is the last educational activity for GMDP Academy-King's College London's Certification in Medicines Development (CMD) Program. It is a formative assessment aimed to promote learning through the development of self-evaluation, provide high-quality information to students about their learning while encouraging communication, and provide opportunities to close the gap between current and desired performance.

Only students who have successfully passed Modules 1-6 are eligible to participate.

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## **Optional Modules**

- **Module 7: Leadership in Medical Affairs (Chair: Ana B. Salgado)**

Tufts Center for the Study of Drug Development (Tufts CSDD) has partnered with GMDP Academy to offer *Leadership in Medical Affairs*. This module has a separate cost and registration process. Additional information on module availability and timeline will be available shortly.

Available 4<sup>th</sup> Quarter 2024

- **Module 8: Digital in Medicines Development (Chair: Mark Lightowler)**

Available October 2023

## Module 1: The Fundamentals of Medicines Development

**Chairs:** Honorio Silva and Nirvana Raghubir

Week of	Lecture/Webinar	Lesson Title	Faculty	Deliverables
<b>Jan 15</b>	Lecture 1	Current Trends and Challenges in Pharmaceutical R&D	Kenneth Kaitin	<ul style="list-style-type: none"> <li>Lecture 1 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 2	The Purpose and Identity of Medical Affairs	Pol Vandenbroucke	<ul style="list-style-type: none"> <li>Lecture 2 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jan 22</b>	<b>Webinar 1</b>	<b>Ongoing issues in Medicines Development</b>	<b>Kenneth Kaitin</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 3	Principles of Clinical Pharmacology	Sandor Kerpel-Fronius	<ul style="list-style-type: none"> <li>Lecture 3 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 4	Principles of Health Economics	Laurent Pacheco	<ul style="list-style-type: none"> <li>Lecture 4 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jan 29</b>	<b>Webinar 2</b>	<b>Patient Reported Outcomes</b>	<b>Laurent Pacheco</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 5	Overall Regulations and Harmonization	TBD	<ul style="list-style-type: none"> <li>Lecture 5 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 6	The Discovery Process and Non-Clinical Development	Sandor Kerpel-Fronius	<ul style="list-style-type: none"> <li>Lecture 6 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Feb 5</b>	<b>Webinar 3</b>	<b>Emerging issues in Exploratory Development</b>	<b>Sandor Kerpel-Fronius</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 7	From Portfolio Management to Real World Evidence	Tamas Suto	<ul style="list-style-type: none"> <li>Lecture 7 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 8	Clinical Trials and Regulations	Domenico Criscuolo	<ul style="list-style-type: none"> <li>Lecture 8 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Feb 12</b>	<b>Webinar 4</b>	<b>Confirmatory Development</b>	<b>Kam Thakker</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 9	Patient Centered Medicines Development	Roslyn Schneider	<ul style="list-style-type: none"> <li>Lecture 9 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 10	Principles of safety and clinical toxicology	TBD	<ul style="list-style-type: none"> <li>Lecture 10 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Feb 19 &amp; 20</b>	Team Assignment Presentations	8am EST Via Zoom		
<b>Thursday, Feb 22</b>	Module 1 Examination 1 <sup>st</sup> Offering	Online Synchronous	H Silva/N Raghubir	30 Multiple Choice Questions 60 minutes to complete
<b>Sunday, Feb 25</b>	Module 1 Examination 2 <sup>nd</sup> Offering	Online Synchronous	H Silva/N Raghubir	30 Multiple Choice Questions 60 minutes to complete

## Module 2: Medical Affairs and Health Economics

**Chairs:** Edward Power

Week of	Lecture/Webinar	Lesson Title	Faculty	Deliverables
<b>Feb 26</b>	Lecture 1	Principles and Practice of Marketing	Brenda Raphael	<ul style="list-style-type: none"> <li>▪ Lecture 1 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 2	Advertising-Promotion and Promotional Review	Peter Sajben	<ul style="list-style-type: none"> <li>▪ Lecture 2 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Mar 4</b>	<b>Webinar 1</b>	<b>MSL Strategy and Practice</b>	<b>Nik Karkanias</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 3	The MSL Function	Nik Karkanias	<ul style="list-style-type: none"> <li>▪ Lecture 3 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 4	Generics and biosimilars	John Kelton	<ul style="list-style-type: none"> <li>▪ Lecture 4 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Mar 11</b>	<b>Webinar 2</b>	<b>Marketing strategy: A Case Study</b>	<b>Brenda Raphael</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 5	Lifecycle Management Planning: the TPP	Demian Largier	<ul style="list-style-type: none"> <li>▪ Lecture 5 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 6	Applying Principles of Healthcare Economics: PE analysis, market access and pricing	Laurent Pacheco	<ul style="list-style-type: none"> <li>▪ Lecture 6 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Mar 18</b>	<b>Webinar 3</b>	<b>Strategy for Mature Products</b>	<b>Seema Haider</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 7	Introduction to Health Technology Assessment	Ahmed Shelbaya	<ul style="list-style-type: none"> <li>▪ Lecture 7 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 8	Value Generation and Communication	Seema Haider	<ul style="list-style-type: none"> <li>▪ Lecture 8 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Mar 25</b>	<b>Webinar 4</b>	<b>Digital Technology and Behavioral changes</b>	<b>Mark Lightowler</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 9	Systems Thinking in Medicines Development	Eddie Power	<ul style="list-style-type: none"> <li>▪ Lecture 9 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 10	Effective use of digital technology to leverage Medicines Development	Mark Lightowler	<ul style="list-style-type: none"> <li>▪ Lecture 10 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Apr 1 &amp; 2</b>	Team Assignment Presentation	8am EST Via Zoom		
<b>Thursday, Apr 4</b>	Module 1 Examination 1 <sup>st</sup> Offering	Online Synchronous	E Power/N Karkanis	30 Multiple Choice Questions 60 minutes to complete
<b>Sunday, Apr 7</b>	Module 1 Examination 2 <sup>nd</sup> Offering	Online Synchronous	E Power/N. Karkanis	30 Multiple Choice Questions 60 minutes to complete

## Module 3: Drug Discovery and Development

**Chairs:** Sandor Kerpel-Fronius and Domenico Criscuolo

Week of	Lecture/Webinar	Lesson Title	Faculty	Deliverables
<b>Apr 8</b>	Lecture 1	Overview of Drug Discovery	Sandor Kerpel-Fronius	<ul style="list-style-type: none"> <li>▪ Lecture 1 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 2	Principles of Non-Clinical Testing	Jacqui Piner	<ul style="list-style-type: none"> <li>▪ Lecture 2 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Apr 15</b>	<b>Webinar 1</b>	<b>Applied Pharmacodynamics and Toxicology</b>	<b>Jacqui Piner</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 3	Pharmaceutical Development	Jeff Duke	<ul style="list-style-type: none"> <li>▪ Lecture 3 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 4	<b>Statistical Principles 1</b>	David Morgan	<ul style="list-style-type: none"> <li>▪ Lecture 4 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Apr 22</b>	<b>Webinar 2</b>	<b>Pharmaceutical Development Scenarios</b>	<b>Jeff Duke</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 5	Statistical Principles II	David Morgan	<ul style="list-style-type: none"> <li>▪ Lecture 5 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 6	Study Design	David Morgan	<ul style="list-style-type: none"> <li>▪ Lecture 6 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Apr 29</b>	<b>Webinar 3</b>	<b>Study Design Issues and controversies</b>	<b>David Morgan/Domenico Criscuolo</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 7	Development of Vaccines	Otfried Kistner	<ul style="list-style-type: none"> <li>▪ Lecture 7 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 8	Exploratory Development	Sandor Kerpel-Fronius	<ul style="list-style-type: none"> <li>▪ Lecture 8 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>May 6</b>	<b>Webinar 4</b>	<b>Fraud and Misconduct</b>	<b>Mike Collins</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 9	Confirmatory Development	Kamlesh Thakker	<ul style="list-style-type: none"> <li>▪ Lecture 9 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 10	Evidence Based Medicine	Penny Ward	<ul style="list-style-type: none"> <li>▪ Lecture 10 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>May 13 &amp; 14</b>	Team Assignment Presentation	8am EST Via Zoom		
<b>Thursday, May 16</b>	Module 3 Examination 1 <sup>st</sup> Offering	Online Synchronous	S. Kerpel/D. Criscuolo	30 Multiple Choice Questions 60 minutes to complete
<b>Sunday, May 19</b>	Module 3 Examination 2 <sup>nd</sup> Offering	Online Synchronous	S. Kerpel/D. Criscuolo	30 Multiple Choice Questions 60 minutes to complete

## Module 4: Clinical Trials: From Concept to Study Report

**Chairs:** Domenico Criscuolo and Cristina Mamedio

Week of	Lecture/Webinar	Lesson Title	Faculty	Deliverables
<b>May 20</b>	Lecture 1	Ethical Aspects in Clinical Research	Greg Koski	<ul style="list-style-type: none"> <li>▪ Lecture 1 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 2	The Clinical Trial Protocol	Kamlesh Thakker	<ul style="list-style-type: none"> <li>▪ Lecture 2 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>May 27</b>	<b>Webinar 1</b>	<b>Ethics and the Publication of Study Results</b>	<b>Chieko Kurihara</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 3	The Research Site	Mike Collins	<ul style="list-style-type: none"> <li>▪ Lecture 3 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 4	Adverse Event Reporting	Stefano Bonato	<ul style="list-style-type: none"> <li>▪ Lecture 4 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jun 3</b>	<b>Webinar 2</b>	<b>Investigator Initiated Protocols</b>	<b>Kamlesh Thakker</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 5	Study Monitoring	Roberto Vallalta	<ul style="list-style-type: none"> <li>▪ Lecture 5 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 6	Project Management	Mike Collins	<ul style="list-style-type: none"> <li>▪ Lecture 6 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jun 10</b>	<b>Webinar 3</b>	<b>Risk Based and Patient Centered Monitoring</b>	<b>Mike Collins</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 7	Data Management	Susy Davis	<ul style="list-style-type: none"> <li>▪ Lecture 7 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 8	Quality Management	Shoibal Mukherjee	<ul style="list-style-type: none"> <li>▪ Lecture 8 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jun 17</b>	<b>Webinar 4</b>	<b>The Role of DSMB &amp; CEC in Medicines Development</b>	<b>Kamlesh Thakker</b>	<ul style="list-style-type: none"> <li>▪ <b>Scheduled Webinar</b></li> <li>▪ <b>Recording available in Classroom</b></li> </ul>
	Lecture 9	Study Report	Domenico Criscuolo	<ul style="list-style-type: none"> <li>▪ Lecture 9 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 10	Overall Issues in Medicines Development and Virtual Trials	Domenico Criscuolo	<ul style="list-style-type: none"> <li>▪ Lecture 10 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jun 24 &amp; 25</b>	Team Assignment Presentation	8am EST Via Zoom		
<b>Thursday, Jun 27</b>	Module 4 Examination 1 <sup>st</sup> Offering	Online Synchronous	D Criscuolo/C Mamedio	30 Multiple Choice Questions 60 minutes to complete
<b>Sunday, Jun 30</b>	Module 4 Examination 2 <sup>nd</sup> Offering	Online Synchronous	D Criscuolo/C Mamedio	30 Multiple Choice Questions 60 minutes to complete



## Module 5: Regulatory Affairs, Drug Safety and Pharmacovigilance

**Chairs:** Sam Salek and Chloé Garay

Week of	Lecture/Webinar	Lesson Title	Faculty	Deliverables
<b>Jul 1</b>	Lecture 1	Regulatory Processes in Key Countries	Beate Schmidt	<ul style="list-style-type: none"> <li>Lecture 1 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 2	ICH and the CTD	Petra Doerr	<ul style="list-style-type: none"> <li>Lecture 2 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jul 8</b>	<b>Webinar 1</b>	<b>Regulatory Differential Issues Between the FDA and the EMA</b>	<b>Beate Schmidt</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 3	Regulatory Issues in ROW	Tariro Sithole/Larry Kennedy/J. Leong	<ul style="list-style-type: none"> <li>Lecture 3 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 4	Principles of Medical Devices	Shayesteh Furst-Ladani	<ul style="list-style-type: none"> <li>Lecture 4 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jul 15</b>	<b>Webinar 2</b>	<b>Controversial Issues in Medical Devices</b>	<b>Shayesteh Furst-Ladani</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 5	Off-label Use, Controlled Drug Regulations, Falsified and Counterfeit Medicines	Zaide Frias	<ul style="list-style-type: none"> <li>Lecture 5 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 6	Safety Reporting Requirements	Jan Petracek	<ul style="list-style-type: none"> <li>Lecture 6 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jul 22</b>	<b>Webinar 3</b>	<b>Analysis of Serious Post-Marketing Safety Issues</b>	<b>Jan Petracek</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 7	Risk Management Plans and Risk Evaluation and Mitigation Strategies	Saad Shakir	<ul style="list-style-type: none"> <li>Lecture 7 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 8	Specialized Regulatory Procedures	Larry Liberti	<ul style="list-style-type: none"> <li>Lecture 8 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Jul 29</b>	<b>Webinar 4</b>	<b>Critical Points When Navigating Through Regulations</b>	<b>Xavier Luria</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 9	Advanced Therapies/ATMPs	Chris Schneider	<ul style="list-style-type: none"> <li>Lecture 9 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 10	Integration of Regulatory Affairs in Pre-and-Post Marketing Activities	TBD	<ul style="list-style-type: none"> <li>Lecture 10 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Aug 5 &amp; 6</b>	Team Assignment Presentation	8a EST Via Zoom		
<b>Thursday, Aug 8</b>	Module 5 Examination 1 <sup>st</sup> Offering	Online Synchronous	S Salek/C Garay	30 Multiple Choice Questions 60 minutes to complete
<b>Sunday, Aug 11</b>	Module 5 Examination 2 <sup>nd</sup> Offering	Online Synchronous	S Salek/C Garay	30 Multiple Choice Questions 60 minutes to complete

## Module 6: Medical Affairs as a Strategic Business Partner

**Chairs:** Pravin Chopra and Cristina Mamedio

Week of	Lecture/Webinar	Lesson Title	Faculty	Deliverables
<b>Sept 2</b>	Lecture 1	The Future of Medical Affairs	Charlotte Kramer	<ul style="list-style-type: none"> <li>Lecture 1 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 2	Ethical Framework in Medicines Development	Sandor Kerpel-Fronius	<ul style="list-style-type: none"> <li>Lecture 2 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Sept 9</b>	<b>Webinar 1</b>	<b>Ethical Challenges for Medical Affairs Professionals</b>	<b>Sandor Kerpel-Fronius</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 3	Quality Management	Larry Kennedy	<ul style="list-style-type: none"> <li>Lecture 3 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 4	Real World Evidence and Medical Affairs	S. Ramagopalan	<ul style="list-style-type: none"> <li>Lecture 4 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Sept 16</b>	<b>Webinar 2</b>	<b>Embedding Quality as a Process</b>	<b>Larry Kennedy</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 5	Public Access to Information	Edward Power	<ul style="list-style-type: none"> <li>Lecture 5 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 6	The Evolving Role of External Medical Education	Maureen Doyle	<ul style="list-style-type: none"> <li>Lecture 6 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Sept 23</b>	<b>Webinar 3</b>	<b>Medical Strategy and Inputs to Operating Plans</b>	<b>Helene Schluep</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 7	Introduction to Organizational Effectiveness	Helene Schluep	<ul style="list-style-type: none"> <li>Lecture 7 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 8	Public and Professional Relations	Lisa Egbuonu-Davis	<ul style="list-style-type: none"> <li>Lecture 8 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Sept 30</b>	<b>Webinar 4</b>	<b>Reinforcing the Value of Medical Affairs in Building Trust</b>	<b>Pravin Chopra</b>	<ul style="list-style-type: none"> <li><b>Scheduled Webinar</b></li> <li><b>Recording available in Classroom</b></li> </ul>
	Lecture 9	The Value of Strategic Alliances	Christine A. Carberry	<ul style="list-style-type: none"> <li>Lecture 9 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
	Lecture 10	How to Assess a Clinical Research Paper	Alan Boyd	<ul style="list-style-type: none"> <li>Lecture 10 Lesson</li> <li>✓ Quiz, Feedback, Discussion Forum/Lecture Guide</li> </ul>
<b>Oct 7 &amp; 8</b>	Team Assignment Presentation	8am EST Via Zoom		
<b>Thursday, Oct 10</b>	Module 6 Examination 1 <sup>st</sup> Offering	Online Synchronous	PChopra/C Mamedio	30 Multiple Choice Questions 60 minutes to complete
<b>Sunday, Oct 13</b>	Module 6 Examination 2 <sup>nd</sup> Offering	Online Synchronous	PChopra /C Mamedio	30 Multiple Choice Questions 60 minutes to complete

## End of Program Assessment

Week of	Lecture/Webinar	Deliverable	Faculty	Guidelines
<b>Oct 14</b>	Special Webinar	Announcement of End of Program Assessment (EPA)	GMDP Academy Faculty	<ul style="list-style-type: none"> <li>Eligible students must attend this webinar.</li> </ul>
<b>Oct 14</b>	End of Program Assessment	Individual Assignments	GMDP Academy Faculty	<ul style="list-style-type: none"> <li>The EPA consists of a single essay with 3 items.</li> <li>Students must attain 50% or better to pass</li> <li>The markers (examiners) will provide feedback as deemed appropriate so that the student can take advantage of this formative experience.</li> </ul>
<b>Nov 17</b>	End of Program Assessment Submissions	Individual Assignments Submission	GMDP Academy	<ul style="list-style-type: none"> <li>Students must submit their answers via the EPA Classroom course inside the LMS (Canvas)</li> <li>Students must include their name at the top of each document.</li> <li>Students must submit by the deadline and use the following format for naming the document: LASTNAME_FIRSTNAME_EPA2024</li> </ul>