

Spring 2021

## **PHEN 604-852: Validation and Regulatory Issues in the Pharmaceutical Industry**

Paul Melamud

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# Validation and Regulatory Issues in the Pharmaceutical Industry

## MS PhEn604

Instructor: Paul Melamud, PMP

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### Part 1: About This Course:

#### Class and Instructor Information:

**Term:** Spring 2021

NJIT Course Title: Validation and Regulatory Issues in the Pharmaceutical Industry

NJIT Course Number: PhEn604

Course Day & Time: Online Section

Classroom: NJIT CANVAS @ <https://canvas.njit.edu/>

Course Prerequisites: Graduate Student Standing  
NJIT UCID & CANVAS Account (**IMPORTANT**)  
PhEn601 (*preferred, but not required*)  
Technical Writing & Formal Argument skills  
(**strongly recommended**)

Course Instructor: **Paul A. Melamud, PMP**

Grader: **TBD**

Instructor Contact: Message via CANVAS (**Primary**)  
E-mail via [pam7@njit.edu](mailto:pam7@njit.edu) (Secondary)

#### Instructor's Office Hours:

Your instructor is an industry professional who often works over 50 miles away from Newark, NJ, and does not have an office on campus. He therefore does not have in-person office hours. Instead, your teacher can be reached through NJIT's CANVAS and e-mail platforms. There are three "rules" the instructor asks:

- 1) If you have a general question about the class or a specific question regarding the lecture or reading materials (i.e. you don't understand something), or require clarification about an assignment, please post in the **DISCUSSIONS** area within CANVAS. The instructor strongly believes that if you have a question, so does at least one other person in the class, and this will allow everyone to benefit.
- 2) If you have a personal question (e.g. grading other personal issue), please use a private message through the CANVAS **INBOX** (CANVAS is preferred vs. e-mail). This way, the rest of the class will not see the discussion.

Note: you may be contacted by the instructor via one of his e-mail addresses, in which case you may respond directly, but if you start a new conversation, please do it through CANVAS or it may not be seen for some time.

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### **Course Description (from your Instructor):**

This class was designed to provide the students with as much of the background, fact, and interpretation of the pharmaceutical industry's underlying governmental regulations as can be possibly fit into a single semester.

That is a lot of material. The Code of Federal Regulations (CFR) is long and can be dull and confusing, even to a lawyer. Our government is not known for brevity. But as we will learn there are reasons for how they're written and we will cover the critical portions during this course as they relate to the pharmaceutical industry.

We'll try to make the regulations as painless as possible. It is not my goal that you become able to quote regulations "by the book" – there is plenty of time for that when you're working in the industry. It is much more important that you gain an appreciation for **WHY** we have and **HOW** we use the various regulations, guidelines, and standards that we follow in the pharmaceutical industry.

We will gain this understanding by viewing the entire industry, from drug discovery through post-marketing. We will highlight most of the major regulatory concepts, and their reasons for existence. And yes, there are times we will quote regulations, but we will try to digest together what they are really asking us to do.

This course is focused on the development of a working knowledge of Title 21 of the CFR and its interpretations and applications within the pharmaceutical and allied industries. In this pursuit, we shall study the history and role of the FDA, and the reasons underlying the regulations that now shape the way pharmaceutical companies do business. Of primary focus shall be the roles of "cGMPs" as we know (and are required to use) them today.

In addition, we shall discuss the concept of "Validation", primarily known to the pharmaceutical industry, but increasingly recognized by others as well – software developers, for example. As Validation is a primary activity for ensuring safety and efficacy of a pharmaceutical product, as well as the quality and integrity of the data supporting these assurances, we shall study this concept in such a manner that the student should be able to anticipate the requirements and apply sound principles for validation of any new process, system, equipment, or laboratory method.

Finally – for those of you taking this course as a cross-curriculum breadth requirement, or have no experience in the industry, I will provide you with enough supplemental reading and other resources to catch up with the full-time industry professionals that also take this course. We don't have time to repeat the material of the other PhEn courses, so I hope you ask lots of questions so everyone can benefit.

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### **Coursework & Grading Policy:**

Please ignore the CANVAS “overall grade” calculation – sometimes it is correct, sometimes it is not, and it is not something the Professor can control. You may track your grade manually as follows:

- 20% of your grade based on the homework and “in class” assignments
- 20% of your grade based on the quizzes
- 20% of your grade based on each of the Midterm Exam & Final Exam
- 5% of your grade based on Class Participation (Discussions on CANVAS, et al)
- 15% of your grade based on a validation project, if issued by the professor. Otherwise, this will be distributed evenly over the other grade elements.

You may expect the FINAL GRADE (not the Final Exam grade) to be “curved” utilizing the class final grade Mean and Standard Deviation. As a general rule of thumb, consider the Mean + 1 Standard Deviation to be the “B Range”, the Mean - 1 Standard Deviation = “C Range”, and “A” and “F” grades following suit (remember: there is no “D” grade in graduate courses).

Please note that this is a **general guideline only** – for instance, if everyone in the class achieves 75 or better in the course, then the grades can be expected to be curved from A-C, not A-F.

*Remember – you will get out of this class what you put into it. If you truly put in A-grade effort, there is little reason to expect you should not achieve an A-grade as a result.*

### **Attendance and Homework Submission Deadline Policies:**

As for all graduate courses at NJIT **attendance is not mandatory**, however, it is strongly recommended. Students are responsible for all material presented in class.

All work is due by the date and time specified, which is most often two weeks or more after the assignment is issued. This allows us at least one week to discuss any hurdles or questions that arise. It is therefore encouraged you begin the assignments within a few days of their being issued.

Please upload all assignments on CANVAS using a MS Word .DOC or a .DOCX file. This will allow the professor or grader to easily comment on assignments. A PDF file will work but is not preferred, as the instructor cannot readily make comments on your assignment.

**Extensions on assignment deadlines are not typically provided.** In the event you have an extenuating circumstance, you are required to notify the instructor as soon as possible with the reason and your expected submission date. Although all due considerations shall be made, the instructor reserves the right to deny anyone an extension for any reason. **Having “other work due” is not a reasonable excuse for requesting an extension.** And please be respectful – do not expect much leeway if you e-mail the instructor the night before an assignment when you could have done so a week or more previously.

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### **Exam Expectations:**

Exams for the online section shall be distributed online. Exams for the classroom section shall be distributed during a regularly scheduled class period.

Bring whatever resources you wish in order to take the exam. There is to be no collaboration with other people allowed, however – as noted on the next page, cheating and plagiarism can result in a zero for the assignment or expulsion from class.

It is expected that the Midterm shall focus primarily on basic concepts and vocabulary, while the Final shall focus more on interpretations and applications, though both shall have Case Studies. The Final will focus on the material presented after the Midterm.

### **“Textbook” & Reference Materials:**

*The “Good” News:* There is no textbook for this class

*The “Bad” News:* There is still a substantial amount of reading for this class

Lecture Notes, articles, and other materials shall be distributed via CANVAS.

Primary references that you should read and be familiar with will be provided as Pre-Reading or Mandatory Reading. It is expected that, by reviewing and understanding these documents, you will develop a working knowledge of the material to a degree similar to that of industry professionals. Where possible and within the time constraints of the class, this shall be supplemented and reinforced with application of the knowledge by way of “real-life” case studies, discussions, and activities in class.

The instructor also recognizes that not everyone taking this class has experience in the industry or in this degree program. Therefore, “Catch-Up” material will be provided to fill in gaps in the foundations of the topics that are not gone over in class (e.g. basics from PhEn601). The instructor may also assign “Optional” readings, which go into some topics in greater detail, or bring up other related topics that are not otherwise covered in class. All students are encouraged to read these at their discretion, especially if they are considering a career in the allied healthcare industries.

### **Lecture Notes:**

The instructor’s Lecture Notes are most often a distillation or focus on the material provided as Mandatory Reading in CANVAS. It is expected that the student reads these materials for a given class **PRIOR** to the classroom lecture, so the class time can be spent listening, discussing, and annotating, rather than writing down a lot of notes as the instructor speaks.

The instructor uses Adobe Acrobat for most of the files, but please note that some are formatted for the current version of Microsoft Office – if you have an older version of this software, the Microsoft website offers a free conversion tool.

*Please note: the class provides many hyperlinks to active internet sites, including those maintained by the US government. Sometimes, these links change. If you encounter*

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*broken references while studying, please try to find the correct link online and share with the class (CANVAS bulletin board) so the professor can correct them for next time. If you cannot find the correct link, please ask.*

### **Guidelines on Writing Assignments & Term Papers:**

As a graduate student, you should already know how to write an academic paper or research-based homework assignment. However, if you have any doubts, please refer to the following link which provides some information:

[http://www.gale.cengage.com/free\\_resources/term\\_paper/index.htm](http://www.gale.cengage.com/free_resources/term_paper/index.htm).

Here is another, which focuses on the “MLA Format” – this shall show you one “proper way” to cite your resources and to format your papers: <https://style.mla.org/>.

If you have ANY doubts or questions about what constitutes a “proper” assignment, please consult with the NJIT library in advance of your assignment deadlines – they have wonderful and numerous literary resources and personnel to help you.

### **Reminders of Relevant NJIT Academic Policies & Programs:**

- <http://catalog.njit.edu/graduate/frontmatter/academicpolicy.php> - Academic policies and procedures
- <http://www.njit.edu/education/pdf/academic-integrity-code.pdf> - NJIT Honor Code, including the school’s “no tolerance” position on plagiarism
- <https://ist.njit.edu/support/contactus.php> - Help for using CANVAS

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### **Part 2: General Course Outline:**

*Note: lecture units will be issued through CANVAS 1-2 per week (some units are larger than others).*

<b>Lecture Unit #</b>	<b>Anticipated Topic(s)</b>
Lecture 1 Regulatory History	<ul style="list-style-type: none"><li>• Introduction</li><li>• International Regulatory Framework</li><li>• USC, CFR, USDHHS, &amp; FDA</li><li>• FDA Regulatory History</li></ul>
Lecture 2 R&D: Pre-Clinical	<ul style="list-style-type: none"><li>• Definitions of FDA Regulated Products</li><li>• R&amp;D, GLPs, &amp; Non-Clinical Trials</li><li>• INDs (CDER/CBER), IDE (CDRH) &amp; DMFs/VMFs</li></ul>
Lecture 3 R&D: Clinical & Approval	<ul style="list-style-type: none"><li>• GCPs &amp; Clinical Trials</li><li>• Informed Consent &amp; IRBs</li><li>• NDA (CDER), BLA (CBER), NADA (CVM), &amp; PMN (510(k))/PMA (CDRH)</li><li>• APRs &amp; Pharmacovigilance</li></ul>
Lecture 4 Manufacturing	<ul style="list-style-type: none"><li>• Adulteration &amp; Misbranding</li><li>• USP-NF</li><li>• FDA GMPs</li><li>• ICH Q7: GMPs for BPCs &amp; APIs</li><li>• SUPAC &amp; the PAS, CBE, or Annual Reportable</li></ul>
Lecture 5 Validation Program	<ul style="list-style-type: none"><li>• VMPs &amp; PVPs</li><li>• Protocols and Reports</li><li>• Discrepancies &amp; Deviations</li><li>• GDPs</li></ul>
Lecture 6 C&Q	<ul style="list-style-type: none"><li>• RS, FS, DS, and the Traceability Matrix</li><li>• GEP: DQ, Commissioning, FAT, &amp; SAT</li><li>• Equipment Qualification: IQ, OQ, PQ</li><li>• Handover &amp; Post-Handover Programs</li></ul>
Lecture 7 Facilities/Utilities	<ul style="list-style-type: none"><li>• Facility Design &amp; Validation (Overview)</li><li>• HVAC &amp; ISO 14644 Acceptance Criteria</li><li>• Utilities Design &amp; Validation (Overview)</li><li>• USP PW, WFI &amp; Compressed Air Acceptance Criteria</li></ul>
<i>Lecture 8 (if time allows)</i>	<ul style="list-style-type: none"><li>• <i>This lecture is a "float" that may be presented in either half of the class, depending on available time and class progression.</i></li><li>• <i>See next page for lecture details</i></li></ul>
<b>March 8</b>	<b>MID-TERM EXAMINATION WEEK begins (Lectures 1-7)</b>

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<b>Lecture &amp; Week Given (approx)</b>	<b>Anticipated Topic(s)</b>
Lecture 8 Process Validation	<ul style="list-style-type: none"><li>• SISPQ</li><li>• Process Validation &amp; FDA's new Guidance Document</li><li>• ICH Q8A Overview</li></ul>
Lecture 9 Environment	<ul style="list-style-type: none"><li>• Air Waste &amp; CFCs – CAA, Montreal Protocol</li><li>• Water &amp; Water Waste – CWA, SWDA, NPDES</li><li>• Solids &amp; Solid Waste – RCRA, DOT, RMW</li><li>• Emergencies &amp; CRTK – CERCLA, SARA, EPCRA</li></ul>
Lecture 10 CSV	<ul style="list-style-type: none"><li>• BMS, MRP/ERP, CDS, LIMS</li><li>• CSV and 21 CFR 11</li><li>• Spreadsheets</li><li>• Related SOPs</li></ul>
Lecture 11 Examples Applying Validation Statistics	<ul style="list-style-type: none"><li>• Cleaning Validation &amp; MACO</li><li>• Environmental Mapping Studies &amp; MKT</li><li>• Continuous Sampling: AQLs &amp; ANSI Z1.4</li></ul>
Lecture 12 AMV & Micro	<ul style="list-style-type: none"><li>• Analytical Testing “Figures of Merit”</li><li>• System Suitability</li><li>• Analytical &amp; Bio-analytical Method Validation</li><li>• Microbiology &amp; Sterility Testing</li><li>• Stability Testing</li></ul>
Lecture 13 Modern Initiatives: Inspections & QBD	<ul style="list-style-type: none"><li>• “GMPs for the 21st Century”</li><li>• ICH Q8-Q10: QbD, QbR, and Quality Risk Management</li><li>• The “QS Approach” &amp; PAIs</li><li>• Other Inspections and Audits</li></ul>
Lecture 14 Packaging Serialization	<ul style="list-style-type: none"><li>• International Overview of Serialization &amp; Product Tracking</li><li>• US DSCSA</li><li>• GS1 &amp; HDA</li></ul>
<b>May 7</b>	<b>FINAL EXAMINATION WEEK begins (Lectures 8-14)</b>

**Supplemental Lectures** – *the professor has prepared additional short presentations that cover other related topics; these shall be presented as class time and interest allow. Any/all supplements are fair game for exams and homework.*