



Building the Best Regulatory Affairs Curriculum



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Learning Outcomes

- Appraise the drivers for course development or restructure
- Create your own plans for course restructure
- Describe the steps involved in course restructure
- Perform a gap analysis of your own course

Program Transformation



**UNSW**
SYDNEY

School of Medical Sciences
Faculty of Medicine

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PHAR9101-Introduction to the Therapeutics Indus..  [Turn editing on](#)[UNSW - University of New South Wales](#) > [MED - Faculty of Medicine](#) > [APPP - School of Medical Sciences](#) > [PHAR9101-5174_00411](#)

Your progress

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General Information



Welcome to PHAR9101 Introduction to the Therapeutics Industry

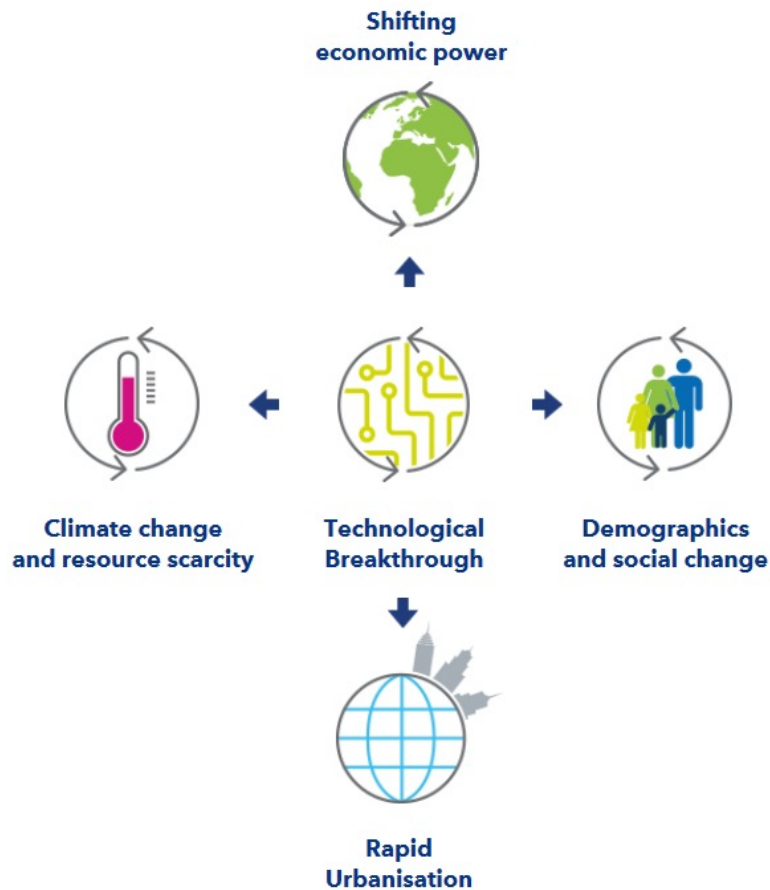
This course introduces you to the pharmaceutical industry both globally and locally and forms the basis for all other courses in your program of learning. It will focus on the role of therapeutics in improving health outcomes, the history of the industry, how companies are created and structured, current and future strategies for therapeutics development, the role of trade, global harmonisation and the evolution of new funding models in future therapeutics development.

 **Announcements**
General news and announcements from your lecturers will be posted here **Class Introductions**
Please introduce yourself to your fellow class members. Provide some info as to why you have enrolled in this course, what your goals are for the course, where you are currently working and your career goals.
Note: You will not be able to view posts from other students until you have posted your own introduction. You will not have access to the course sections until you have posted your introduction. **Question and Answer Forum**
This forum is for any general questions about the course. **Glossary of Terms**
This is a glossary of terms that you have discovered through your readings for this course. Please feel free to add a new term and its definition as you come across them so that you can share your learning with your colleagues. All entries are moderated by the course convenor before inclusion in this glossary. **Getting Started** **Meet Your Lecturers** **View feedback on Student Surveys**
 Actions taken in response to evaluation feedback in Student Surveys **Experience** is our new student survey.

What I did



REVIEW Global Megatrends



SUSTAINABLE DEVELOPMENT GOALS
17 GOALS TO TRANSFORM OUR WORLD



REVIEW The Future of Work

THE FIVE TRENDS SHAPING THE FUTURE OF WORK



© Chess Media Group

Top 10 skills of 2025

Type of skill

- Problem-solving
- Self-management
- Working with people
- Technology use and development

-  Analytical thinking and innovation
-  Active learning and learning strategies
-  Complex problem-solving
-  Critical thinking and analysis
-  Creativity, originality and initiative
-  Leadership and social influence
-  Technology use, monitoring and control
-  Technology design and programming
-  Resilience, stress tolerance and flexibility
-  Reasoning, problem-solving and ideation

Source: Future of Jobs Report 2020, World Economic Forum.

REVIEW

Trends in Health and the MTP Sector

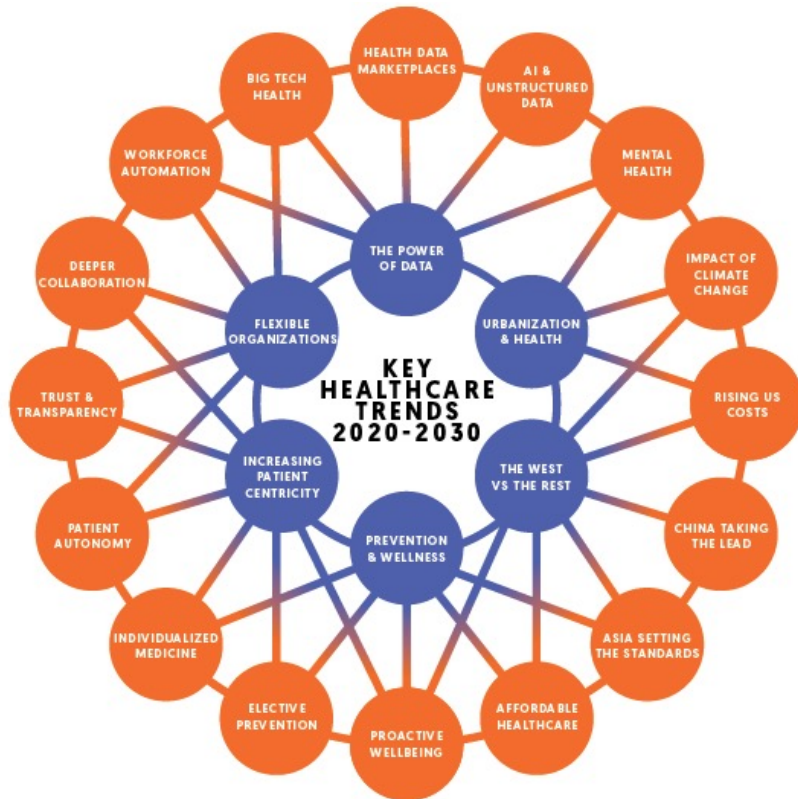
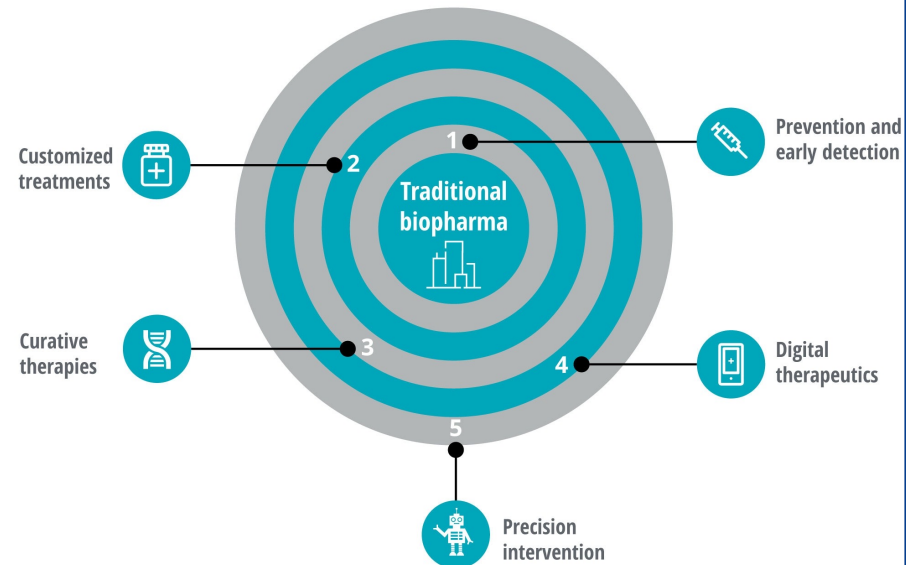


FIGURE 1

Five forces of potential disruption to the biopharma industry



Source: Deloitte analysis.

Deloitte Insights | deloitte.com/insights

MTP=medical technology and pharmaceutical

<https://www.deloitte.com/au/insights/trends-of-healthcare>, <https://www.deloitte.com/au/insights/trends-of-healthcare/insights-of-pharmaceutical-industry.html>

Shaw, B. and Chisholm, O. (2020) Creeping through the backdoor: disruption in medicine and health. *Frontiers in Pharmacol* 11: article 818;

<https://www.frontiersin.org/articles/10.3389/fphar.2020.00818/full>

REVIEW

Trends in Regulatory Affairs Profession



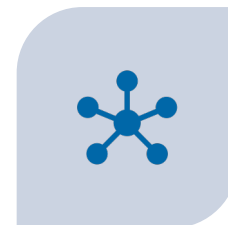
Leveraging real-world evidence in regulatory processes



Leveraging AI in regulatory processes



Opportunities for global harmonization of e-submissions



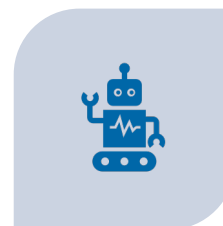
Global harmonization, convergence and reliance



Real-time regulation



Integrating the patient voice in regulatory decision-making



Automation of routine tasks including regulatory intelligence, regulatory information management

REVIEW

Strategic placement

- The Medical Technology and Pharmaceutical Sector is constrained in growth through lack of appropriately skilled and experienced workforce participants
- The projected growth for the industry sector equates to an extra 28,000 skilled employees required by 2025
- Skills required include: clinical research, regulatory affairs, translation of drug discovery
- 21st Century skills required: negotiation, collaboration, creative problem-solving, communication, analytical thinking

REVIEW

Trends in Higher Ed



Borderless

Competitors will be offering programs within the territory assumed in others' catchment areas, and the opportunity is there to do the same. Increasingly this means overseas delivery, as cultural and regulatory resistance diminishes to programs offered online by foreign institutions.

Shorter courses and degrees

Fewer students will wish to undertake full-service degrees. However, more students will be interested in micro-credentialing, competency-based education, nano-degrees and curated degrees. Unbundling will be prominent, with tuition fees itemized separately for teaching, campus experience and so on. Students will be able to opt out of some aspects of university life and not pay for them.



Digitally native cohorts

As the proportion grows of young people who are digital natives, with good access to connectivity, interest will grow in borderless education and new kinds of courses, thus accelerating the above two features.

Experiential learning

Demand will grow for learning by doing. This will challenge the traditional university model. With the exception of teaching and health courses, and perhaps some institutions deliberately set up with this mission, extensive periods in practice are not part of many degrees. Work-integrated learning is hard to scale up in the standard business and operating model of a university, but that is where the demand will be; from students themselves, and their prospective employers.



A likely development in post-secondary systems is a greater integration of higher and vocational education, to create new blends of abstract and applied learning.

Lifelong learning

Fueled by the dislocation of workers due to automation and new ways of working, demand will be high for upskilling, reskilling and retraining. Some estimate that almost all growth in formal hours of learning within static populations will be with adult learners who are older than the typical graduate.

Some universities may move towards a subscription model, whereby for a regular payment, people will have access to a range of programs, thus potentially retaining the loyalty of their students across their lifespan.



Competing at scale

One of the extraordinary developments in today's economy has been the rise of the platform business. Seven of the 10 largest organizations in the world can be described in this way.²⁰ The institution that can provide on-demand learning, at scale and personalized to the needs and wishes of the student, is the organization which can build resilience into its future.

We may now see new forms of business model which draw on the entertainment industry, whereby some universities relay and quality assure content and assessment that is actually provided by others, as well as offering their own programs.



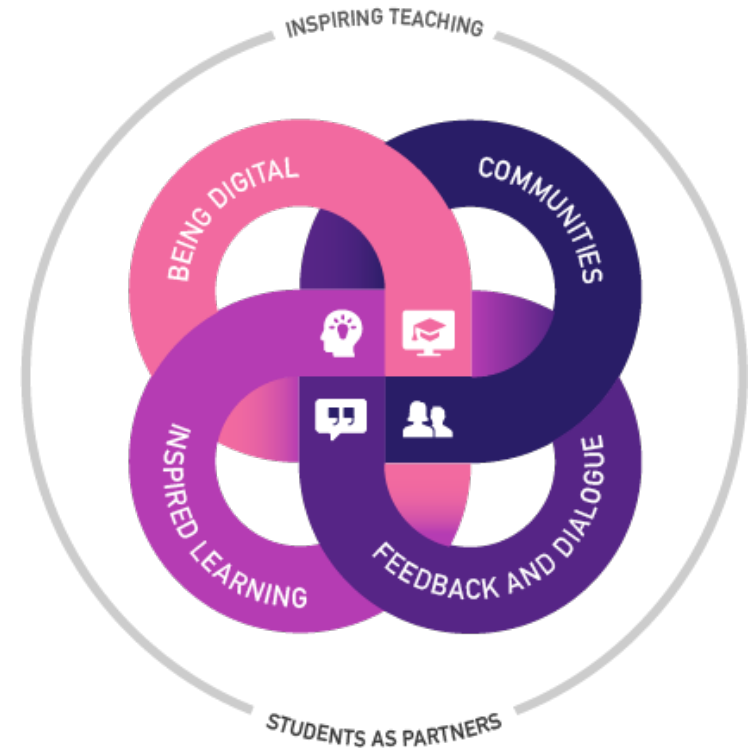
Lifestyle integration

Although not necessarily reducing in absolute numbers, the cohort of young people seeking the immersive, rite-of-passage, full-time, on-campus, bachelor education will reduce as a proportion of the whole student body. More students will be working part-time, undertaking family responsibilities and wanting to integrate learning into their lives rather than interrupt their lives for an immersive experience.




REVIEW

UNSW 2025 Strategy



BENCHMARK

www.pme-institute.com/index.php?id=112



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So sind wir für Sie da!

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Master of Science (MSc) in Pharmaceutical Medicine

Course duration: 2 years (4 semester)

Degree: Master of Science (MSc)
Several possibilities are offered leading to a different title.

Language: English

Credits: 60 ECTS

Fees: € 14.850,- (€ 7425,- per year)

Schedule: The next study course will start in April 2017.



THE FACULTY OF PHARMACEUTICAL MEDICINE

of the Royal Colleges of Physicians of the United Kingdom



Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Faculties and Schools Courses

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Courses

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Postgraduate

A-Z Listing of Taught Courses

POSTGRADUATE

Pharmaceutical Medicine (M.Sc. / P.Grad. Dip.)

2 years part-time



HOSPITAL SIRIO-LIBANÊS
BORDO LÉZOUS

PORTAL IEP

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Medicina Farmacêutica - Ciência do Desenvolvimento de Medicamentos e Medical Affairs



International Federation of Associations
of Pharmaceutical Physicians &
Pharmaceutical Medicine



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MASTER OF MEDICINE (PHARMACEUTICAL AND MEDICAL DEVICE DEVELOPMENT)



Homepage Description Organisation Registration Practical information ASFODEMP Contacts F.A.Q Private E

MASTER 2 OF HEALTH AND PHARMACEUTICAL ENGINEERING specialized in Clinical Evaluation - Pharmaceutical Medicine



INTERNAL

PROSPECTIVE STUDENTS STUDENT SERVICES RESEARCH & INNOVATION FACULTIES GIVING TO KING'S ALUM COM

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PHARMACEUTICAL MEDICINE

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SHORT COURSES
HOW TO APPLY
COURSE DATES
CONTACT US



A NEW PERSPECTIVE
FLEXIBLE PROFESSIONAL TRAINING FOR PHYSICIANS AND SCIENTISTS IN PHARMACEUTICAL MEDICINE



ABOUT MEMBERSHIP COMMUNITY CONFERENCES & C



MSc Regulatory Affairs

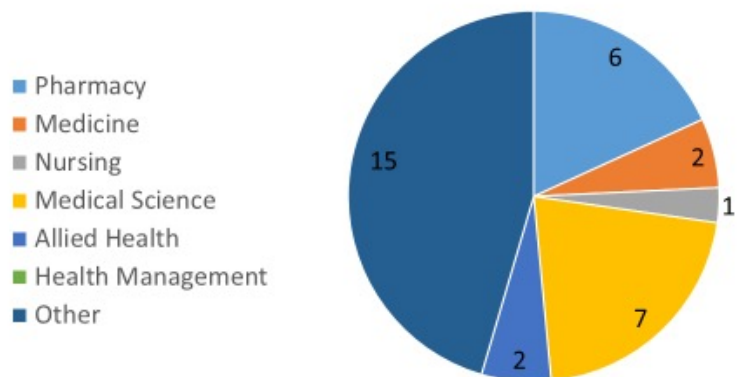


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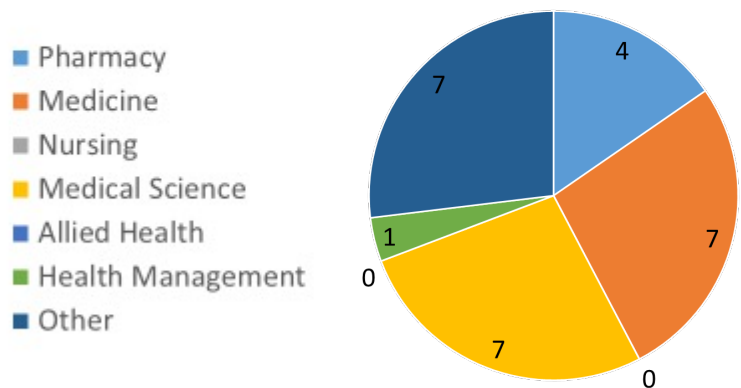
STAKEHOLDER SURVEY

Demographics

Background of students and alumni (n=33)



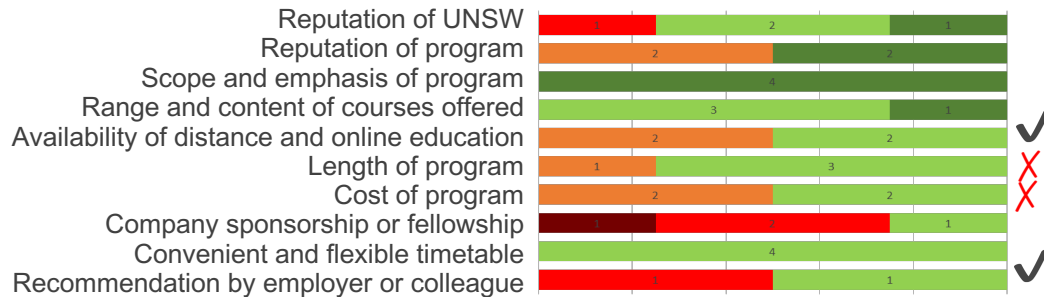
Background of stakeholders (n =26)



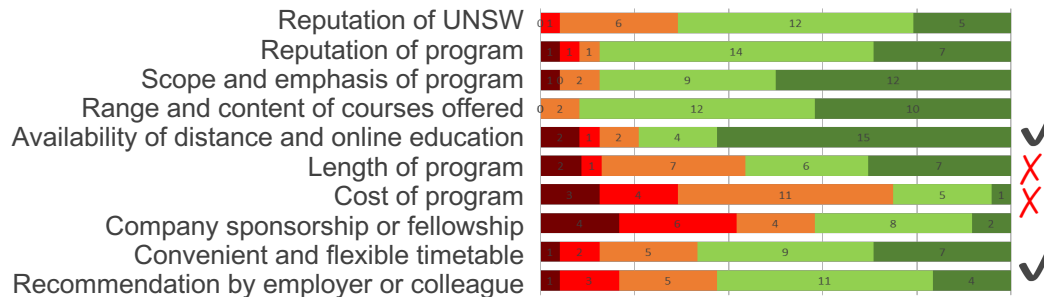
| Characteristics | Total N (%) |
|-----------------|-------------|
| Gender | |
| Female | 29 (54%) |
| Male | 22 (41%) |
| Other | 3 (6%) |
| Age | |
| 25-35 years | 9 (12%) |
| > 35 years | 46 (84%) |

STAKEHOLDER SURVEY Reasons to study

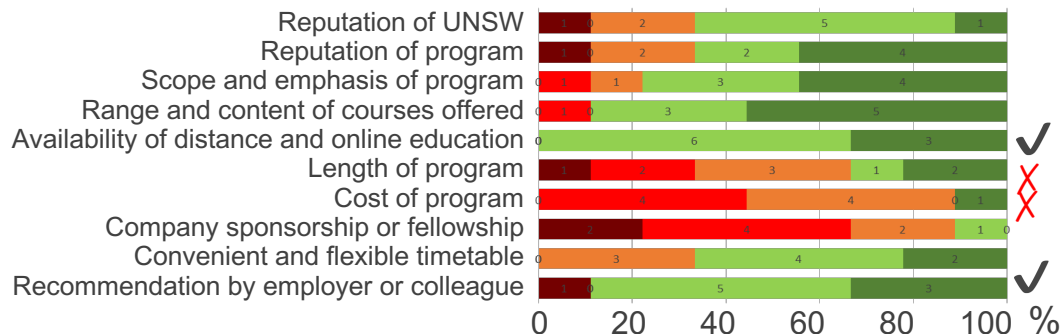
1996-1999 (n=4)



2000-2009 (n=24)



2010-current (n=9)



✓
- Online availability
- Recommendation by colleague

✗
- Length of program
- Cost of program

■ Strongly Disagree
 ■ Disagree
 ■ Neither agree nor disagree
 ■ Agree
 ■ Strongly Agree

STAKEHOLDER SURVEY

Student Feedback

“Really contributed to my competencies and actually enabled me to gain more confidence and credibility in my professional career”

“Great that there was industry/academic/government aligned tutors/lecturers”

“After completing the MMed.Sc from UNSW, the Pharma companies here started looking at me with respect; I got plenty of good job offers”

“I thought it was an excellent course..I would recommend it to someone who wanted to enter the pharmaceutical industry or do clinical research and who did not have any background or experience in these areas”

“Offer specialisation such as Regulatory Affairs, Manufacturing, Clinical Trials, Pharmacovigilance”

“Critical that course content is kept current with industry requirements constantly evolving at a rapid pace”

“Greater connection between students to promote knowledge sharing and to clarify uncertainties”

“Globalising the course content with more international (i.e. non-Australian-specific material) would make it attractive”

“Reduce the course length to 1 year full-time or 2 years part-time”



GAP ANALYSIS



Mission

Vision

Teaching Philosophy

Program learning outcomes

Course learning outcomes

Alignment

Fully online delivery

Industry engagement

Internationalisation of content

Updated/revised content

Authentic assessment tasks

Relevance to workplace

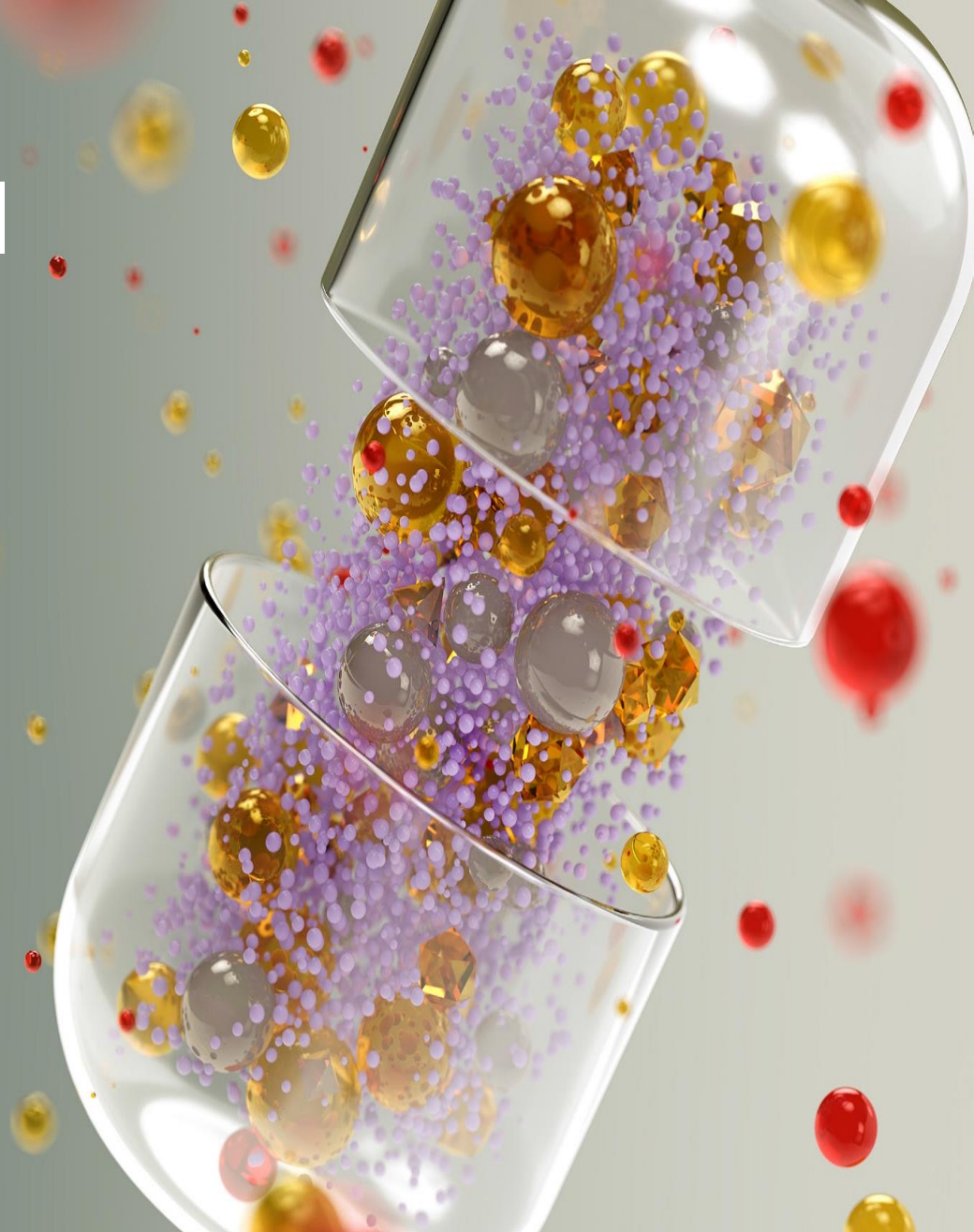
Compliance

Communities of Practice

Career planning

Master of Pharmaceutical Medicine

To produce graduates with the knowledge and skills to make a meaningful contribution to medicines research, development and access, working across the pharmaceutical industry, academia and government, with the goal of improving the health and wellbeing of the community.



Advisory Board



David Grolman

- MBBCh FCS(SA)
- Medical Director, Pfizer Pharmaceuticals
- President, APPA



Victoria Elegant

- MBBS DRCOG FFPM
- Vice President and JAPAC Region Head Medical, Amgen



Liz de Somer

- BN MMedSc(Drug Develop)
- Director, Policy and Advocacy, Medicines Australia



Ric Day

- MBBS MD FRACP
- Professor of Clinical Pharmacology UNSW & St Vincent's Clinical School UNSW



John Skerritt

- BSc (Hons 1, Univ. Medal) PhD FTSE FIPAA (Vic)
- Deputy Secretary for Health Products Regulation, Australian Department of Health
- Adjunct Professor, Universities of Queensland and Canberra



Eugene Salole

- PhD MPH
- Principal and CEO, Value-Based Access Pty Ltd, Sydney
- Conjoint Professor, UNSW Medicine



Sarah Clark

- BPharm
- Medical Liaison Manager, Biogen Idec
- Student Advisor

Teaching Philosophy

- Student-centred learning
- Authentic activities: real-world, case-studies
- Constructivist: connections between new and existing knowledge
- Connectivist: learning from each other's perspectives
- Brookfield's 4 lenses: self, peers, literature, students
- Analytics

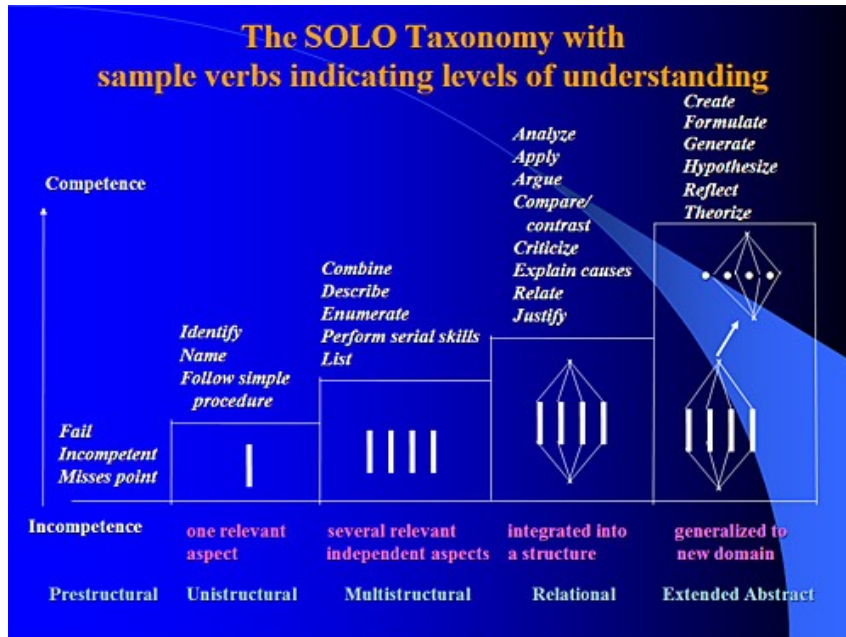
Brookfield lenses

Stephen Brookfield's Lenses Model Of Reflection

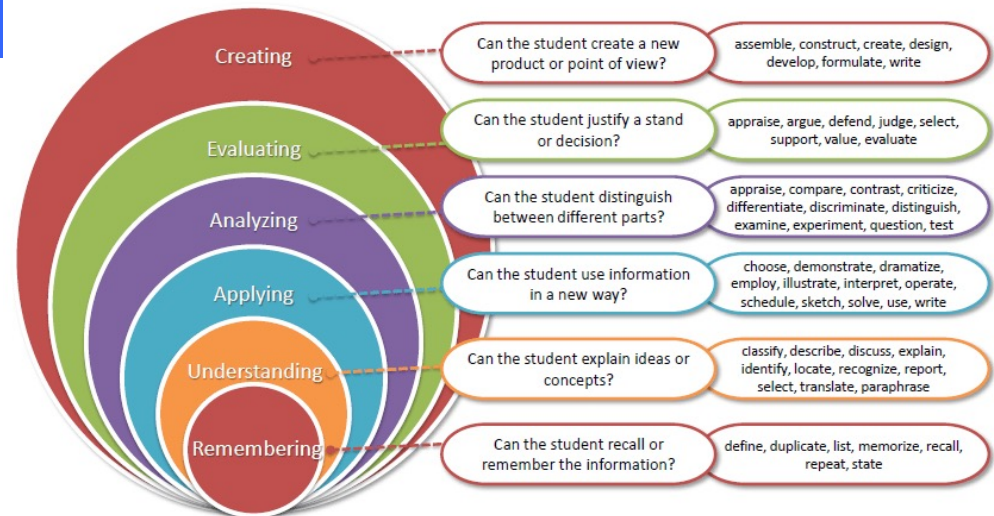
Brookfield's Lenses Model Of Reflection



SOLO taxonomy/Revised Bloom's taxonomy



Bloom's Taxonomy (Revised)



COURSE DEVELOPMENT

**Academic
Program Director**

Industry Experts

**Academic
Course Coordinator**



**Educational
Developers**

Current Students

Alumni

Program Learning Outcomes (PLO)

1. *Advanced disciplinary knowledge and practice*

Graduates will be able to demonstrate an advanced understanding of pharmaceutical medicine and the development process for new therapeutic products and apply their knowledge to new developments and approaches within this area.

2. *Enquiry-based learning*

Graduates will have the ability to ask the appropriate questions, find relevant information using their digital and information literacy skills and develop the required plans and documents to facilitate their contributions to the development and maintenance of therapeutic products.

3. *Cognitive skills and critical thinking*

Graduates will be able to understand, critically appraise and apply information and literature in the field of pharmaceutical medicine to inform development of new therapeutic products or strategies for success of new and existing products.

4. *Communication, adaptive and interactional skills*

Graduates will demonstrate the ability to effectively communicate complex, relevant subject matter relating to pharmaceutical medicine to diverse audiences. They will have the appropriate skills of flexibility and adaptability in working collaboratively with others in teams to achieve specified outcomes in a time-bound environment. Graduates will show leadership and initiative in areas of their focus within pharmaceutical medicine.

5. *Global Outlook*

Graduates will have a thorough knowledge and understanding of the global arena in which therapeutic products are developed, regulated, priced and marketed.

6. *Ethics*

Graduates will reflect on and critique the role of ethics in the therapeutics industry and develop a personal ethical framework for working within the area of pharmaceutical medicine.

Alignment

PLO: Advanced disciplinary knowledge and practice



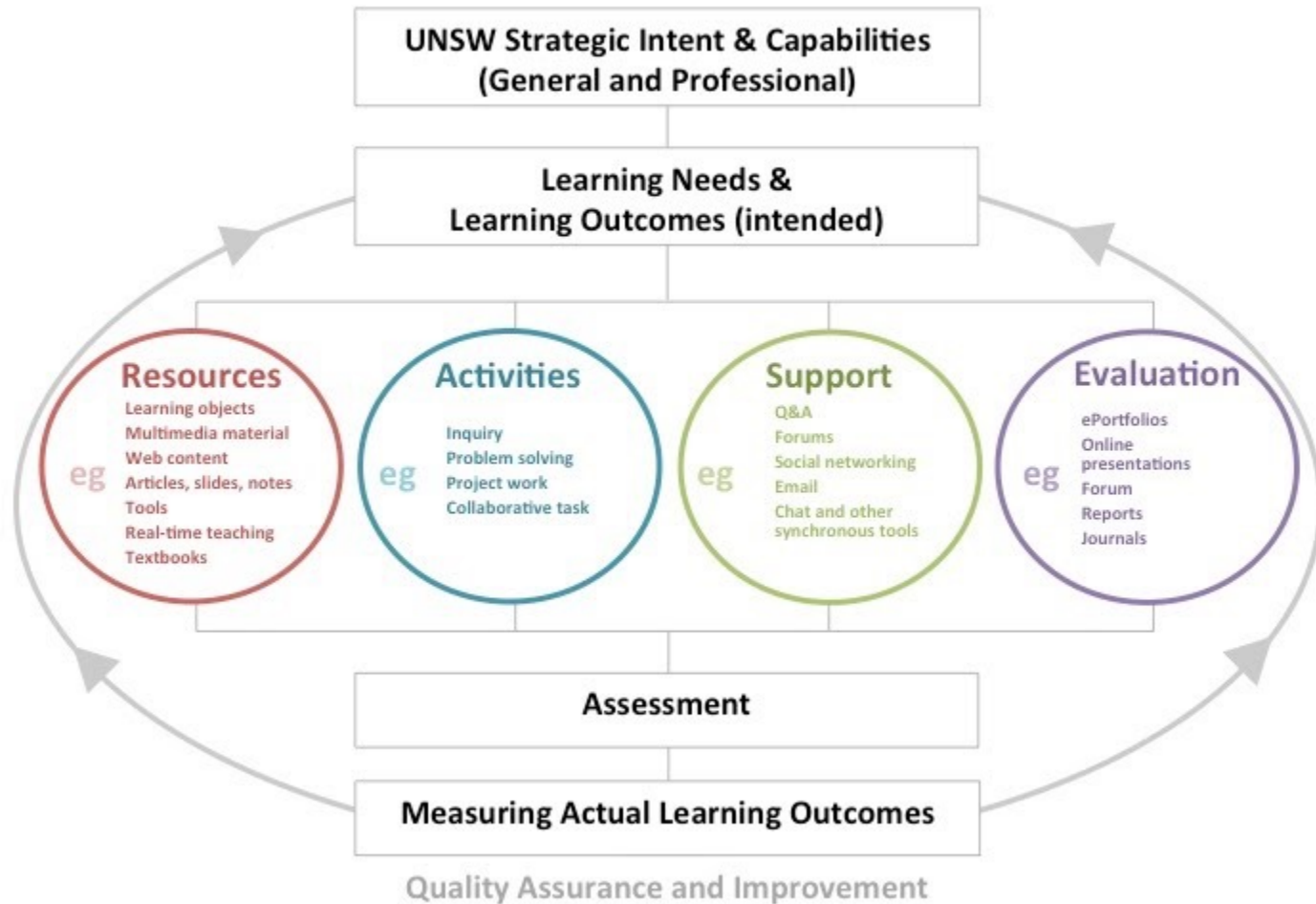
CLO: Formulate an appropriate strategy for the registration of a new therapeutic product



Assessment task: Students are provided with a scenario about a new product in development and asked to prepare a report to their managing director on the regulatory strategy they will pursue to obtain registration of the product in Australia

COURSE DEVELOPMENT

RASE Model



Reference

Mirriahi, Alonzo & Fox, 2015, Research in Learning Technology, 23: 28451

FORMAL APPROVAL

Admission to coursework programs, v 2.0, effective 11 Mar 2016
Assessment design procedure, v 1.0, effective 20 Feb 2017 (implementation due by Feb 2018)
Assessment implementation procedure, v 1.0, 20 Feb 2017
Assessment Policy, v 4.0, effective 20 Feb 2017
Code of Conduct, v 2.1, effective 18 Feb 2016
Education Quality Policy, v 2.0, 6 May 2017
Education Quality Procedure, v 1.0, effective 4 May 2017
myExperience survey procedure, v 1.0, effective 20 Feb 2017
Plagiarism policy statement, v 1.3, effective 17 Aug 2016
Managing plagiarism for students procedure, v 1.3, effective 3 Aug 2016
Program level learning outcomes for honours and postgraduate coursework programs guideline v 1.1, effective 18 Feb 2016
Recognition of prior learning (coursework programs) policy, v 2.1, effective 18 Feb 2016
Recognition of prior learning (coursework programs) procedure, v 2.1, effective 18 Feb 2016
Structure of Postgraduate Coursework Programs Policy, v 2.1, effective 29 Feb 2016
Structure of Postgraduate Coursework Programs Procedure, v 2.3, 13 Mar 2017
Student complaint procedure, v 3.3, effective 29 Feb 2016
Student misconduct procedure, v 2.6, effective 16 Aug 2016

IMPLEMENTATION

Communities of Practice

Class Introductions

Please introduce yourself to your fellow class members. Provide some info as to why you have enrolled in this course, what your goals are for the course, where you are currently working and your career goals.

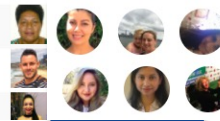
Discussion

History and Structure of Therapeutics in PNG from Medicines Regulatory System point of view

Big Pharma Outlook to 2025

Re-scheduling of all codeine products to S4

Started by



Replies

5

16

8



Discussion Forum: Roles in the Pharma Industry

KW: Hi All, some thoughts on what has worked for me.....

JL: As someone who is not working in the industry I'm very interesting in learning from all of you on how to navigate through it and you have provided some very valuable advice.... Some more questions....

NT: Hi JL, Thank you for your questions. Here are my answers regarding my role....

IMPLEMENTATION

Connections and Collaboration

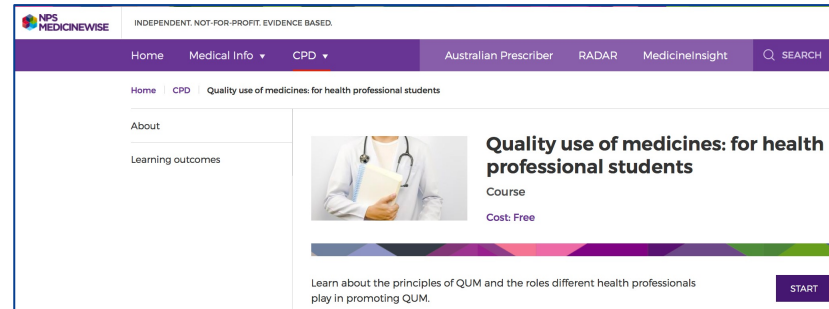


Blackboard
collaborate™

 Wikispaces part of tes

IMPLEMENTATION

Integrated Activities



 **NPS QUM online tutorial** 1.1MB PDF document

 **Quality Use of Medicines Discussion Forum**

Complete the NPS QUM and submit your certificate to the Pharm.med@unsw.edu.au email box by 19 March.
Discuss what you learned from completing this online tutorial here.

| Discussion |
|---|
| QUM vs RUM from PNG perspective |
| QUM - can technology help? |
| QUM – Opting for 'Lifestyle Prescription' |
| NPS QUM- take home messages |
| Digital revolution in healthcare |
| Rights and responsibilities of pharmaceutical companies |
| What is medical affairs |
| MedicineList+: A QUM initiative in educating consumers |
| Tarceva indications |

60 posts; 20 students

IMPLEMENTATION

Career support

Pharmaceutical Medicine Program 2015

UNSW - University of New South Wales > MED - Faculty of Medicine > Pharmaceutical Medicine Program 2015

People

Participants

Search forums

Go

Advanced search

Latest news

Add a new topic...

Entry level regulatory compliance associate position
2 Jun, 11:26 On Chisholm

Entry level CTA positions at INC Research
10 May, 10:41 On Chisholm

S/CRA Position at George Clinical
2 May, 11:40 On Chisholm

Industry positions
21 Apr, 10:55 On Chisholm

CRA position at Abbvie
12 Apr, 14:19 On Chisholm

Older topics ...

Upcoming events

There are no upcoming events

Go to calendar...

New event...

Recent activity

Activity since Sunday, 3 July 2016, 3:13 PM

Full report of recent activity...

No recent activity

Course Information

This site contains general program-wide and career progression information. It also offers an opportunity for you to connect with each other by sharing a brief profile. Networking and making connections with people is critically important to your career progression in the pharmaceutical industry and this site allows you to begin making these critical connections with your fellow students.

Announcements

Pharmaceutical Medicine on the School of Medical Sciences website

UNSW Graduate Attributes

Pharmaceutical Med Programs Intro

Open all Close all

Instructions: Clicking on the section name will show / hide the section.

Introductions

Career Information

In this section please find links and tips for your careers; from finding your first role in the pharma/biotech/medical devices industry to moving up the career ladder.

Career Discussion Forum

Please use this Discussion Forum to post jobs available in your company that fellow students may wish to apply for or to discuss careers with fellow students.

Career Advice

Recruitment Agencies

UNSW website career information

Mid-career professional advice

Adroit 2013 Pharmaceutical Salary Survey

UK Diplomas in Pharmaceutical Medicine for medically-qualified students

APICS Australia

DA

Autobiotech

Medical Science Liaison Society

International Society of Pharmacovigilance

Pharmaceutical Information and Pharmacovigilance Association

Regulatory Affairs Professionals Society

The Organisation for Professionals in Regulatory Affairs

Australasian Medical Writers Association

Careers in the Industry

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- 1 Early-stage R&D
- 2 Clinical Research
- 3 Video - Clinical Researcher
- 4 Medical Information/Communication
- 5 Medical Affairs
- 6 Pharmacovigilance
- 7 Regulatory Affairs
- 8 Video - Regulatory Affairs Consultant
- 9 Video - Regulator
- 10 Quality Assurance
- 11 Manufacturing
- 12 Supply Chain
- 13 Pharmacoeconomics
- 14 Video - Consultant Health Economist
- 15 Sales
- 16 Marketing
- 17 Video - Marketing Consultant
- 18 Customer Service
- 19 Business Development
- 20 Legal
- 21 Video - Patent Attorney
- 22 References

Roles of Therapeutics Industry Employees

9 Video - Regulator



Turn Theatre Display On

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- 1 Your job search
- 2 Your CV
- 3 Your cover letter
- 4 Your interview
- 5 Useful career books

Space to share job adverts and CV

Discussion

- Entry level regulatory compliance associate position
- Entry level CTA positions at INC Research
- S/CRA Position at George Clinical
- Industry positions

IMPLEMENTATION

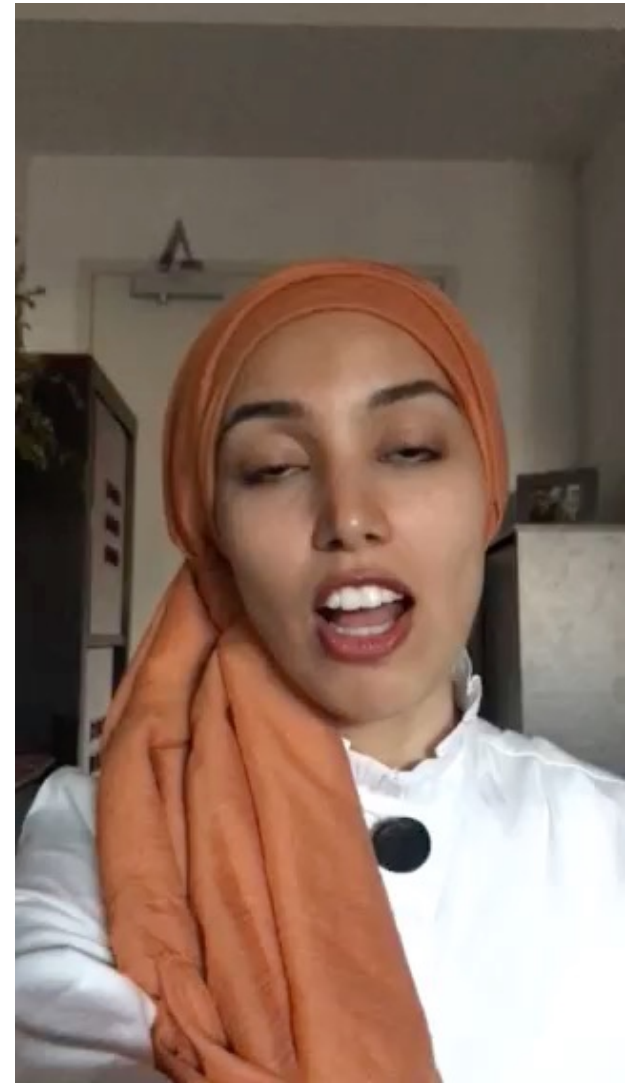
Internships

Providing authentic learning opportunities

Regulatory Affairs Associate

You will have:

- Experience with the registration of medical devices in Australia and New Zealand.

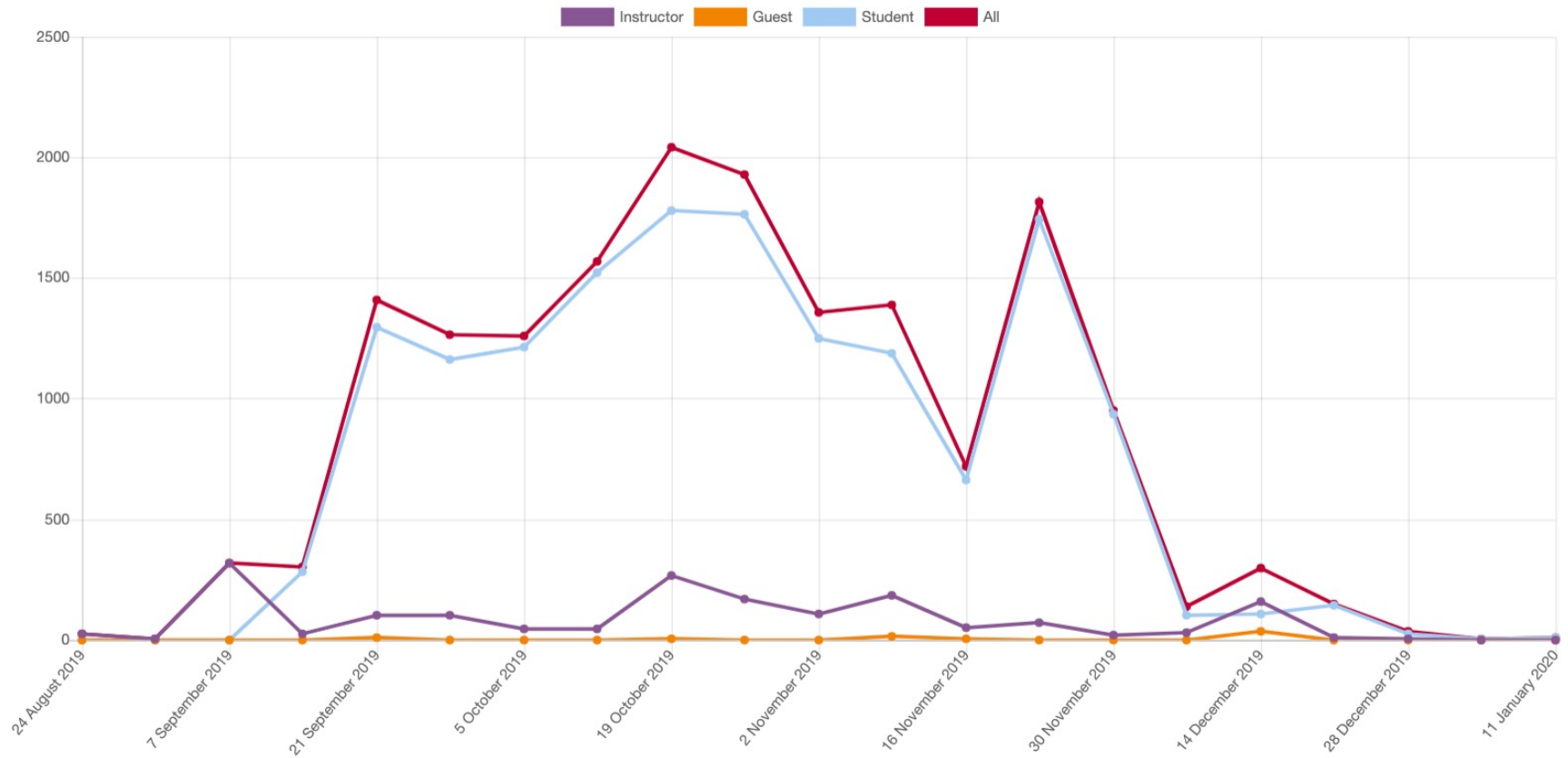


Student voice:
Maedeh Najafi

IMPLEMENTATION

Analytics

PHAR9104-5199_00192 - All activity (all roles)



REVIEW

Reflective Practice



“I am currently in the process of developing a training module with my Senior Regulatory Affairs Associate at work...and I was able to apply the knowledge I have learnt ...into ...training module.”

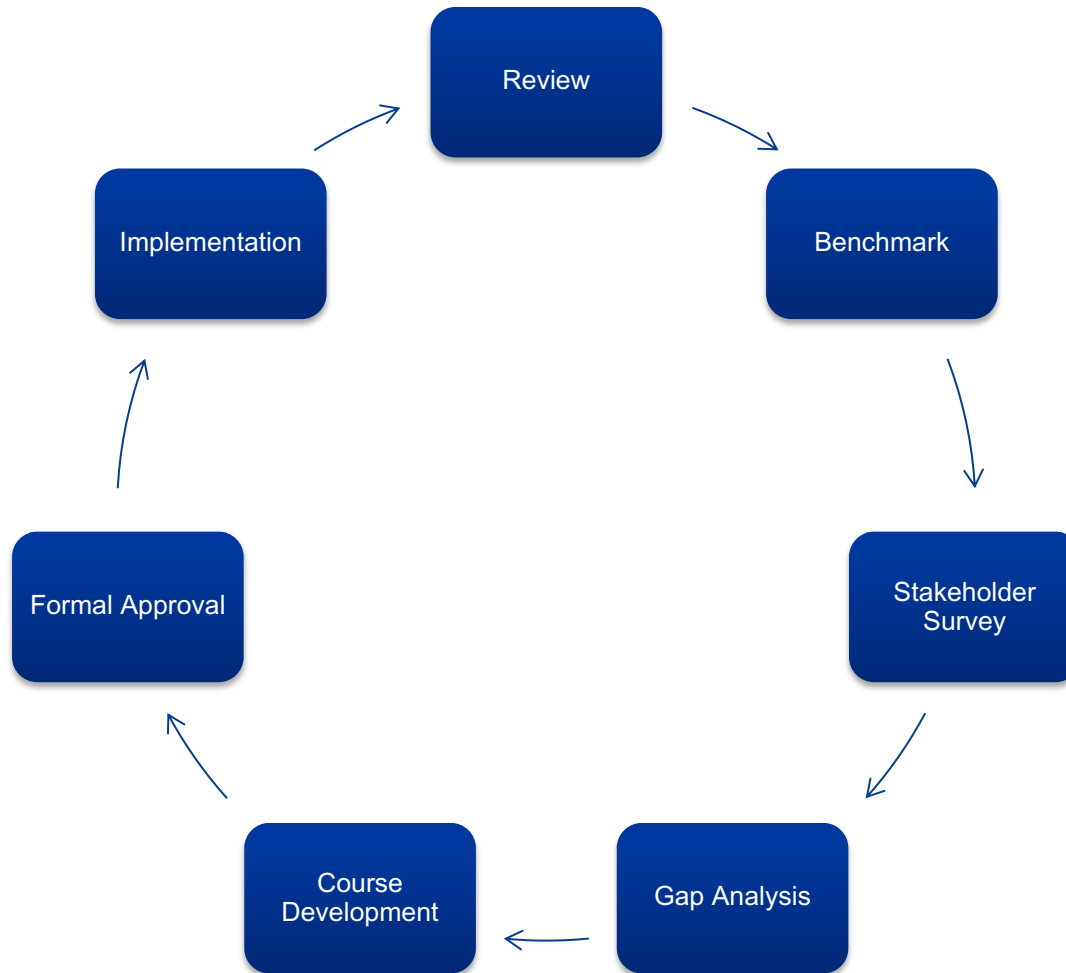
I was able to note down techniques from all the other groups' presentations to help me with my own presentation skills....

REVIEW

Impact

“I have gained so much from this course, on many levels and am applying my learnings in everyday life at work. The course has enriched my level of understanding in areas pertinent to my regulatory role... Thank you for continually improving the course material and including excellent, knowledgeable speakers in industry who are willing to share their experiences - is truly wonderful. The course has changed and I find that education does not stand still and the course is innovative and moving with time.”

PROGRAM TRANSFORMATION CYCLE



My education publications

Chisholm, O. (2019) Professional Development: Benefits of Obtaining Professional Qualifications. *Regulatory Focus*. August 2019. Regulatory Affairs Professionals Society.

Chisholm, O. (2019) Curriculum Transformation: from didactic to vocational programs in Pharmaceutical Medicine. *Frontiers Pharmacol*
<https://www.frontiersin.org/articles/10.3389/fphar.2019.00278/full>

Allen, G. and **Chisholm, O.** (2018) Postgraduate Education in Pharmaceutical Medicine in Australia: Evaluation and Evolution to a Global Program Over 20 Years. *Therapeutic Innov. Regulat. Sci.* Oct 5:2168479018793129. doi: 10.1177/2168479018793129.

Chisholm, O. (2017) Program transformation: reimagining distance education in the digital world. *Research and Development in Higher Education: Curriculum Transformation* 40: 61-72; <http://www.herdsa.org.au/research-and-development-higher-education-vol-40-61>