

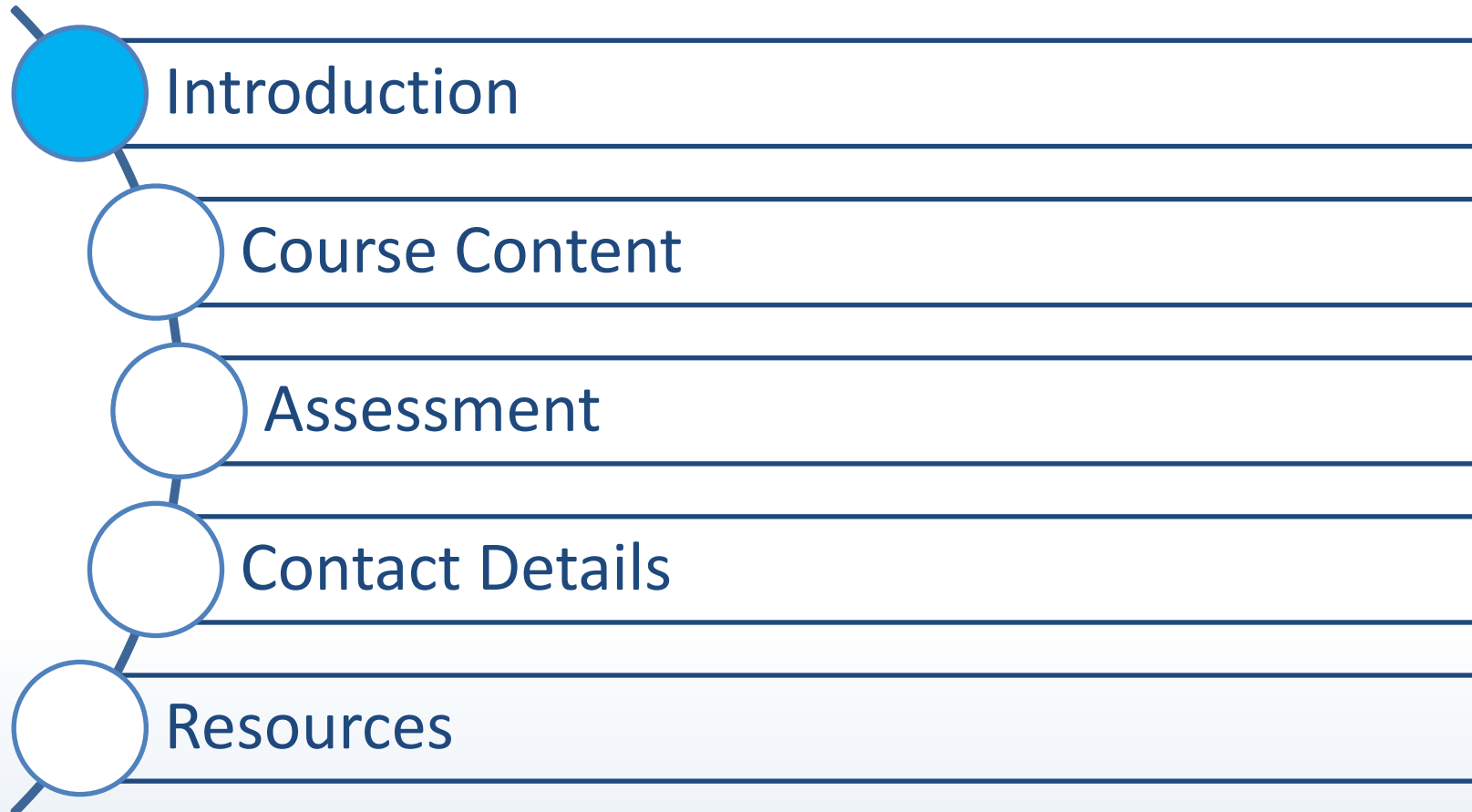
# Bioanalytical Techniques

## Lecture 1 – Course Overview





# Topics



# Introduction



M. Pharm.



Ph.D. Immunology

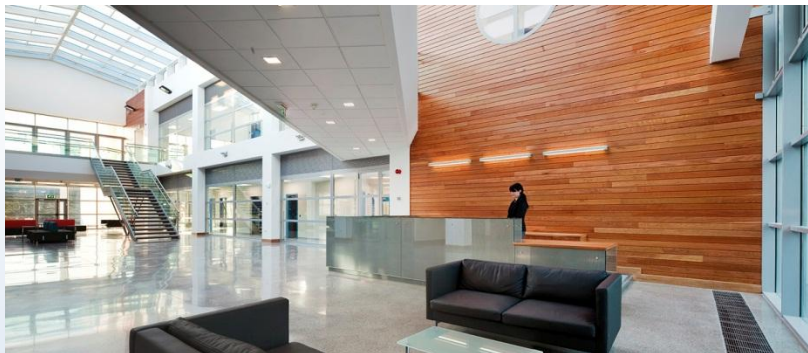


Senior Bioprocessing Trainer at NIBRT

- Quality Control and Characterisation of Biopharmaceuticals
- Cell Culture and Aseptic Processing
- Downstream Processing (Chromatography)



NIBRT provides training and research solutions for the biopharma industry in state-of-the-art facilities located in South Dublin







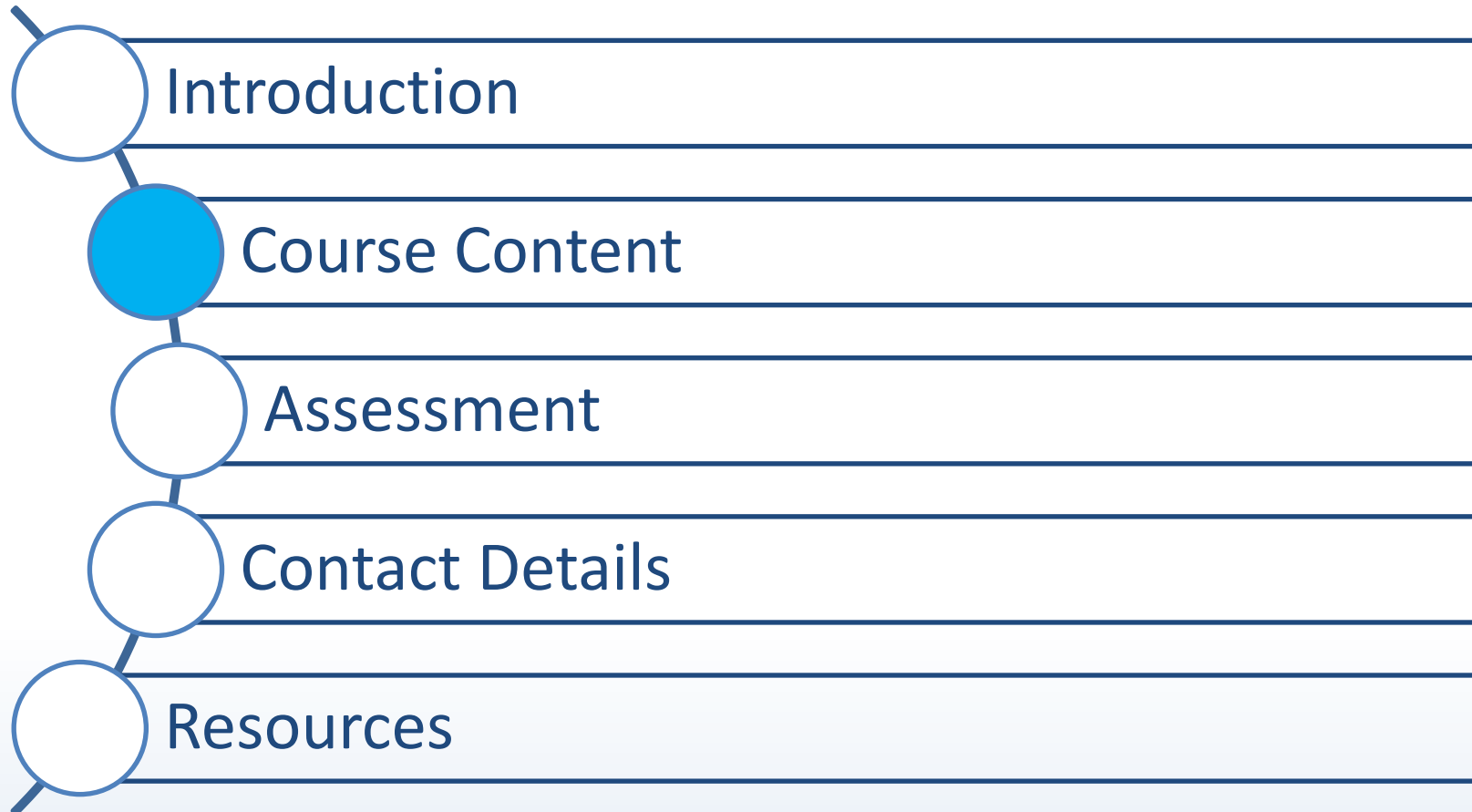
NIBRT offers clients unrivalled access to a fully operational manufacturing plant, in a simulated GMP environment which ensures that trainees gain experience with both the equipment and the regulations of a cGMP plant

NIBRT's training programmes are designed in partnership with industry to deliver flexible, competency based learning solutions that deliver immediate cost-effective benefits.





# Topics





# Description

- This module aims to provide students with a **detailed knowledge** and understanding of the various analytical test methods employed in the **analysis of biopharmaceuticals**.
- These analytical tests are used to assess the **raw material, in-process, bulk drug substance** and **finished product** quality attributes.



# Indicative Syllabus

- Introduction to QC
- Protein Estimation Assays
- Slab Gel Electrophoresis
- Capillary Electrophoresis
- Immunoassays and Bioassays
- Polymerase Chain Reaction (PCR)
- High Performance Liquid Chromatography (HPLC)
- Mass Spectrometry (MS)





# Schedule

L8 Bioanalytical Techniques Schedule			
Week of semester	Date	Lecture/Event	Additional info
1	22 <sup>nd</sup> January	Lecture 1	Begin assignment of projects
2	29 <sup>th</sup> January	Lecture 2	
3	5 <sup>th</sup> February	Lecture 3	
4	12 <sup>th</sup> February	Lecture 4	Finish assignment of projects
5	19 <sup>th</sup> February	MCQ 1 (10%)	Based on lectures 2-4
6	26 <sup>th</sup> February	Lecture 5	
7	5 <sup>th</sup> March	Lecture 6	
8	12 <sup>th</sup> March	Lecture 7	
9	19 <sup>th</sup> March	MCQ2 (10%)	Based on lectures 5-7
10	26 <sup>th</sup> March	Lecture 8	
11	2 <sup>nd</sup> April	Lecture 9	
12	9 <sup>th</sup> April	Reading week	No Live Lectures
13	16 <sup>th</sup> April	LAQ (30%)	Based on lectures 2-9
14	23 <sup>rd</sup> April	Final Project Report Due (40%)	
15	30 <sup>th</sup> April -	Project Presentation (10%)	Time to be arranged

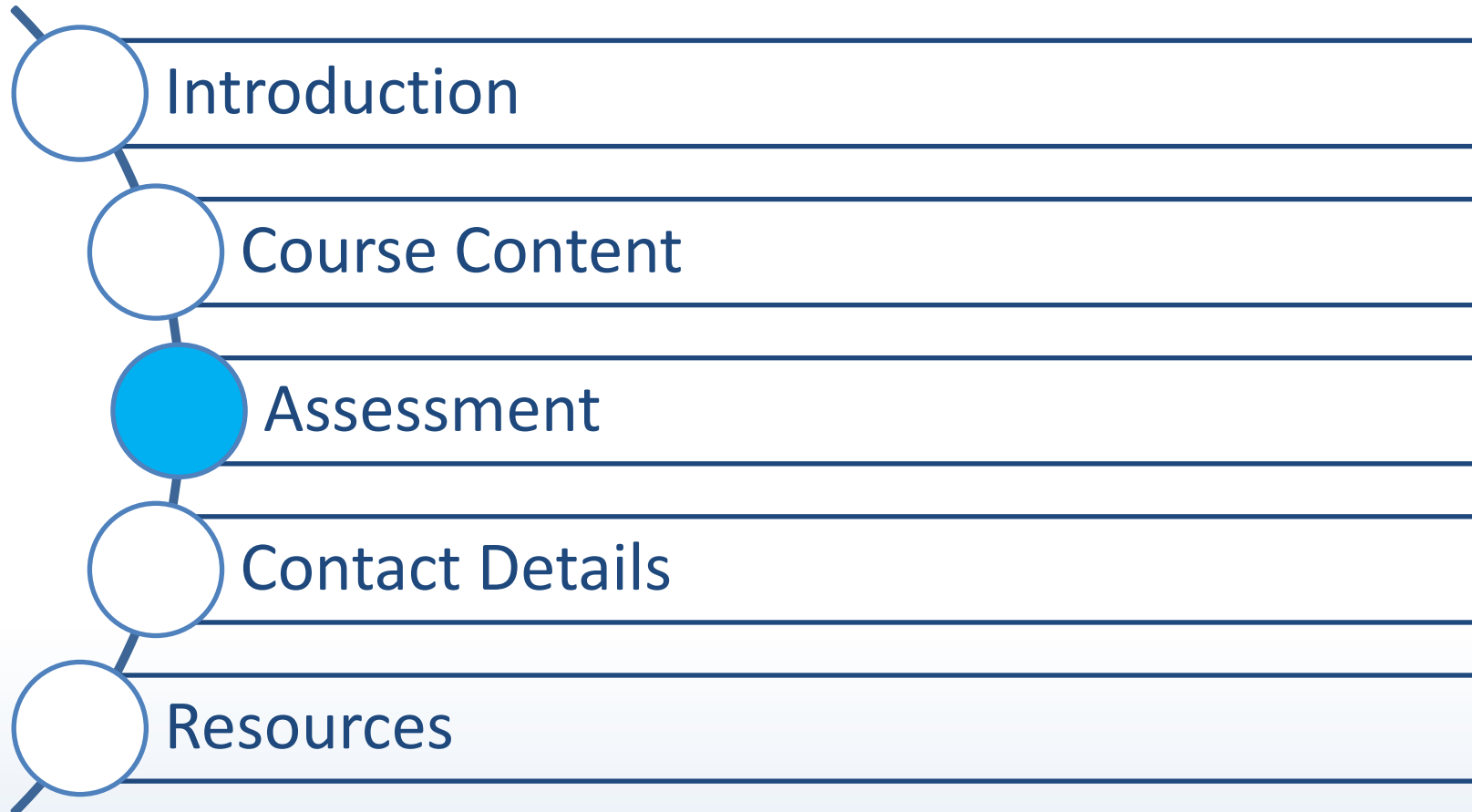


# **Please check your ATU Sligo email regularly**

**Please make sure that you have access to your ATU Sligo email  
and that you are checking it regularly**



# Topics





# Assessment

- Blend of online continuous assessment and final exams:
  - **Online Examinations:**
    - Exam 1 = MCQ (10% of grade)
    - Exam 2 = MCQ (10% of grade)
    - Exam 3 = End of term exam [LAQ questions] (30% of grade)
  - **Project**
    - Project (4000 - 6000 words) (40% of grade)
    - Online Project presentation (10%)



# Project

- You will be asked to write a report (literature review) on one of the subjects that will be covered during this course
- The report will contain minimum 4000 words and maximum 6000 words
- Google spreadsheet will be provided where you can put your name down for your preferred project
- Project Guidelines can be found on your Moodle page



# Project Presentation

- You will be asked to record and submit a 10min presentation on your project
- Some students will be randomly picked to do a live presentation in MS Teams – if you are picked to do a live presentation and you do not complete it, you will **FAIL THE MODULE**
- More details will be posted on your Moodle page
- Project Presentation is **MANDATORY**





# Plagiarism: Turnitin

- All of your submissions will be checked for plagiarism
- **For the final submitted project, similarity must be below 25% in total and no more than 10% from one individual source**
- A separate Turnitin Dropbox will be provided for you to check your similarity score before you submit your final version
- You will not be penalised for high similarity score in the earlier drafts



# Deadline Extension

- If you are unable to take the Moodle exams on the dates specified, you need to fill in the Application for the Deadline Extension (available on your Moodle page) and email it to me **no later than 4 days before the initial deadline**

An extension will NOT be granted for: ordinary work commitments; disk, printer or computer failure; issues around time management such as having more than one assignment to submit on the same date; transport difficulties; lack of knowledge of requirements of academic work; scheduled anticipated changes of address, moving house etc; demands of sport, clubs and societies or extra-curricular activities (other than to represent one's club, county or country in a national or international context); recreational travel; planned events such as weddings.

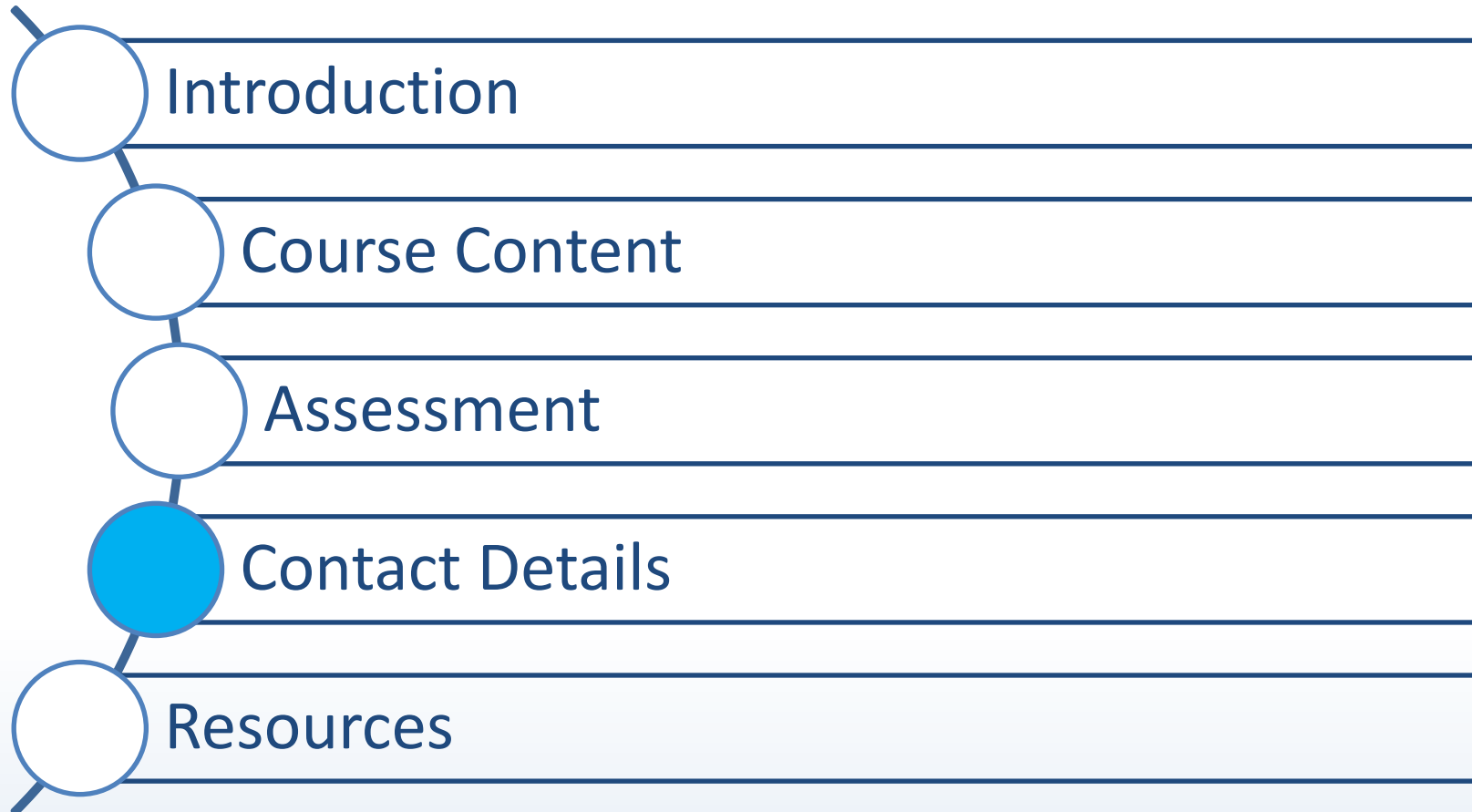


# Deferral

- Deferral
  - If you commence the module and are not in a position to complete the module you must apply for a deferral to the exam office in advance of the exam.
  - This involves filling out a deferral form (can be found on your Moodle page) and sending it to Examinations Office.
  - There is a fee for deferral applications
  - For more information, please contact the student advisor, Michelle Moore ([moore.michelle@atu.ie](mailto:moore.michelle@atu.ie))



# Topics





# Contact details

- Any questions, queries, comments:

Maja Kristek  
majakristek@gmail.com



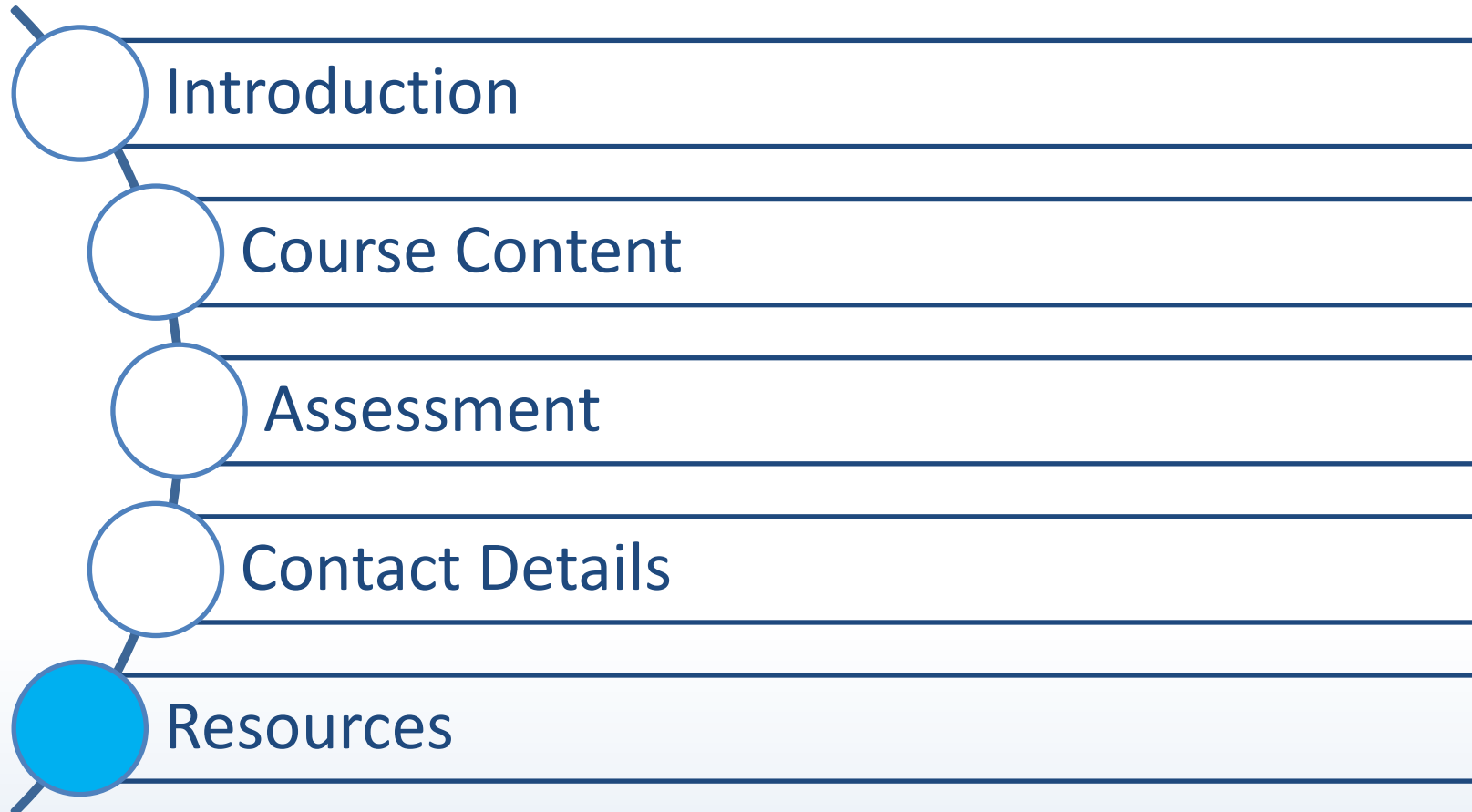
# Useful Contact Details

- **Course co-Ordinator:** Mary Butler  
(butler.mary@atu.ie)
- **NIBRT Academic Co-Ordinator:** Melissa Hoare  
(melissa.hoare@nibrt.ie)
- **Student Advisor:** Michelle Moore  
(moore.michelle@atu.ie)
- **Springboard Co-Ordinator:** Jean Gilligan  
(gilligan.jean@atu.ie)
- **Registration for Elective Modules:** Sarah Walsh  
(walsh.sarah@atu.ie)





# Topics





# Every week you will receive...

- Live lecture (link provided on main course page)
- Lecture notes (.pdf)
- Relevant reading material
- Links to websites
- Link to recorded live lecture



# Additional Resources

- I recommend that you subscribe to the free journals below and that you source relevant articles via the library.
- <http://www.pharmtech.com/>
- <http://www.biopharminternational.com/>
- ICH website: <http://www.ich.org/>



# Thank You

