**「生物科技產業實習」課程大綱明細**

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| 周次 | 內容 |
| 1 | * Data Management Handbook Review * General Rules and Policies * Parexel systems/ facility introduction: * PAREXEL CONNECT * TIME * LMS * Cisco Phone * Self-Management Organizational Skills * Central Files and PMED |
| 2 | * Working with Global Teams * Study Life Cycle * Managing Workflow |
| 3 | * EDC System review - Rave and Datalabs * Metrics and Reports * Managing Timelines |
| 4 | * How to read a Clinical Trial Protocol * Understanding the Study Set-up Process: * ECRF Spec/ ALS * DVS/ DVR * DMP/DCS * CCI(CCG) * PD Spec |
| 5 | * Understanding the Study Set-up Process: User Acceptance Testing * UAT Process * UAT test data creation * UAT related system (if applicable) |
| 6 | * Understanding the Study Conduct Stage or Ongoing processing: Data validation/ cleaning, Data Review, Query Generation and Closure |
| 7 | * Understanding the Study Conduct Stage or Ongoing processing: SDTM Introduction and Offline Listing Spec & Mockshell Introduction |
| 8 | * Understanding the Study Conduct Stage or Ongoing processing: Offline Listings, External data reconciliation, SAE reconciliation, Process Review, Dataset Review. |
| 9 | * Understanding the activities approaching Database Lock (DBL) * Understanding of Project Close and Archiving Question |
| 10 | * Practical training in projects |
| 11 | * Practical training in projects |
| 12 | * Practical training in projects |
| 13 | * Practical training in projects |
| 14 | * Practical training in projects |
| 15 | * Practical training in projects |
| 16 | * Practical training in projects |
| 17 | * Student Presentation * Sharing project experience * Any idea on process improvement |
| 18 | * Final Evaluation/ Feedback collection |