**「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
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| 2 | * Working with Global Teams
* Study Life Cycle
* Managing Workflow
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| 3 | * EDC System review - Rave and Datalabs
* Metrics and Reports
* Managing Timelines
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| 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
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| 5 | * Understanding the Study Set-up Process: User Acceptance Testing
* UAT Process
* UAT test data creation
* UAT related system (if applicable)
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| 6 | * Understanding the Study Conduct Stage or Ongoing processing: Data validation/ cleaning, Data Review, Query Generation and Closure
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| 7 | * Understanding the Study Conduct Stage or Ongoing processing: SDTM Introduction and Offline Listing Spec & Mockshell Introduction
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| 8 | * Understanding the Study Conduct Stage or Ongoing processing: Offline Listings, External data reconciliation, SAE reconciliation, Process Review, Dataset Review.
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| 9 | * Understanding the activities approaching Database Lock (DBL)
* Understanding of Project Close and Archiving Question
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| 10 | * Practical training in projects
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| 11 | * Practical training in projects
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| 12 | * Practical training in projects
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| 13 | * Practical training in projects
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| 14 | * Practical training in projects
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| 15 | * Practical training in projects
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| 16 | * Practical training in projects
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| 17 | * Student Presentation
* Sharing project experience
* Any idea on process improvement
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| 18 | * Final Evaluation/ Feedback collection
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