



工業技術研究院

Industrial Technology
Research Institute

MERCK

Elevate your expertise.

台灣-默克生技製藥產程研發暨培訓合作計畫

2018 培訓課程

線上報名網址：

<https://college.itri.org.tw/Default.aspx>

課程查詢 > 請輸入課程關鍵字 "默克" 兩個字

培訓日程：

- 生物科技入門課程 / 上游基礎課程培訓
(3月13日 / 9月5日)
- 上游製程培訓
(9月6日)
- 基礎層析理論課程培訓
(4月17日 / 9月12日)
- 常規過濾 / 切向流過濾理論課程培訓
(4月16日 / 9月11日)
- 一次性製程理論課程培訓
(6月27日 / 9月26日)
- 切向流過濾操作證書培訓
(5月24 - 25日)
- 切向流過濾應用優化和放大
(8月6 - 7日)
- 常規過濾製程操作證書培訓
(5月 15-16日 / 8月 15 - 16日)
- 常規過濾製程優化和放大
(7月17 - 18日)
- 自動化完整性測試操作證書培訓
(7月26-27日 / 10月17 - 18日)
- 一次性製程操作證書培訓
(11月 13 - 14日)
- 無菌測試證書培訓
(11月 2日)
- 環境監控證書培訓
(7月 6日)



指導單位: 經濟部技術處

主辦單位: ITRI、Merck

課程註冊連絡人:

MTBCatITRI@itri.org.tw (ITRI)

03-5743989 / 范佳玉

trainingtw@merckgroup.com (Merck)

0905-162-799 / Dianna 羅香耘



2018 Taiwan Customer Education Course Calendar

Taiwan Merck Biopharma R&D & Training Collaboration Program

Course	Course Description	Training Schedule	
		1 st	2 nd
Entry Course 生物科技入門課程	<p>This entry course provides an overview of Biopharma manufacturing process. Different unit operations and equipment used in biopharma industry will be reviewed. The course gives a basic understanding on the applications and challenges of clarification, bioreactor, process chemicals, chromatography process, aseptic filters and tangential flow filtration</p> <p>這課程提供生物製程的基本認識，由簡入深地介紹相關設備儀器的操作和應用。課程內容包括生物發酵槽，深層與除菌過濾器應用挑戰，層析填料特性與應用，製藥原料的需求及切向流過濾方法。</p>	3月13日	9月5日
Upstream I 上游基礎課程	<p>This course provides basic understanding of upstream process in biopharmaceutical industry. The course will review the types of cells used in research and biopharma industries, origin of mammalian cells for cell culture, growth kinetics of mammalian cells, cell culture medium/feeds used for mammalian cell culture and applications in biopharma industry.</p> <p>針對上游製程，本課程特別介紹在生技研究開發使用的細胞株種類，哺乳細胞之起始與生長動力學，細胞培養與餵養基的應用。</p>	3月13日	9月5日
Upstream II 上游製程培訓	<p>Provides basic understanding of: 1) Mammalian cell line dev 2) Mode of culture in Biopharma Industry 4) Introduction to bioreactors and applications in industry</p> <p>這課程講解細胞株開發，細胞培養方式以及細胞發酵槽的操作實務，並討論上游製程的工藝實現與挑戰。</p>	9月6日	—



Course	Course Description	Training Schedule	
		1 st	2 nd
Introduction to Normal Flow Filtration 常規過濾理論課程	<p>During this course, you will be introduced to the principles and steps of normal flow filtration (NFF) and its applications. The materials explain how normal flow filters are constructed and how they work. Basic NFF concepts and terminology are discussed. The course also includes the fundamentals of integrity testing filters.</p> <p>這半天的課程特別針對常規正向過濾的原理，步驟和應用進行講解。課程內容包括常規正向過濾器的構造和功能，使用原理和應用範圍，相關術語和基本的濾器完整性測試原理。</p>	4月16日	9月11日
Introduction to Tangential Flow Filtration 切向流過濾理論課程	<p>During this half-day course, you will be introduced to the principles and steps of tangential flow filtration (TFF) and its applications. The materials outline the different steps required in the operation of a TFF system: preparation, process, cleaning and storage, and explain why each is important. The course covers basic TFF concepts and terminology, how tangential flow filters are constructed and how they work and overviews how tangential flow filters are integrity-tested.</p> <p>這半天的課程特別針對切向過濾的原理，步驟和應用進行講解。課程介紹了操作切向流過濾系統的步驟，其中包括濾膜的安裝和系統的準備，過濾的操作，使用後的清洗和儲存。課程還講解了切向流的原理和術語，濾膜的構造和功能，以及切向流濾膜的完整性測試原理。</p>	4月16日	9月11日



Course	Course Description	Training Schedule	
		1 st	2 nd
Introduction to Single-Use Technologies 一次性製程理論課程	<p>This course goal is to provide a detailed introduction of single use technologies and its application in manufacturing of biopharmaceutical products. This course will provide answers and ideas for some of the following questions: What are single use technologies? What are the advantages and disadvantages of a single use system? Where should I start to consider single use? How are single use system made? How can I implement it for my project?</p> <p>這半天的課程講解一次性(拋棄式)工藝和其在生技製程上的應用。課程內容也會解答關於甚麼是一次性工藝，一次性工藝的利與弊，使用一次性工藝的時機，一次性工藝的組成和如何實現一次性工藝。</p>	6月27日	9月26日
Basic Chromatography 基礎層析理論課程	<p>This training course provides you with basic knowledge of chromatography, separation mechanism and chromatography operation. Resin screening and selection, column packing and quality control, separation strategy will also be the main discussion.</p> <p>這半天的課程會介紹基本的層析原理，分離的方法和層析的操作方法。課程內容也包括層析膠體的篩選，層析管柱充填和測試，以及在生技製程的純化策略。</p>	4月17日	9月12日
Operate Normal Flow Filtration Process Equipment 常規過濾製程操作證書培訓	<p>Understand the best practices techniques for filter installation, the importance of appropriate flushing procedures, and robust methods to carry out filter integrity tests • Implement best practice procedures for filter installation and flushing. • Optimize your flushing or wetting procedures. • Establish robust SOPs to integrity test filters. • Make appropriate decisions when there is a failed filter integrity test.</p> <p>課程採用理論和實踐指導相結合的模式，講解使用過濾器的最佳實踐技術，指導如何正確安裝過濾器，沖洗潤濕和測試濾器的完整性。通過實際操作和討論，改進沖洗或潤濕濾器的程序以建立穩定的完整性測試方法。此課程也會簡略討論完整性測試的故障與排除。</p>	5月15日 – 5月16日	8月15日 – 8月16日



Course	Course Description	Training Schedule	
		1 st	2 nd
Operate Tangential Flow Filtration Process Equipment 切向流過濾操作證書培訓	<p>Using a combination of theory and hands-on instruction, participants will learn the key procedures of tangential flow filtration process operations and basic process monitoring and data analysis techniques.</p> <p>This two-day course covers basic TFF operations such as filter installation, flush, clean-in-place, integrity testing, equilibration, and protein concentration, post use cleaning and NWP measurement.</p> <p>課程採用理論和實踐指導相結合的方式，使學員掌握切向流過濾(TFF)的關鍵操作步驟，製程管控和數據分析，進而提高工藝效率，產品質量和一致性。兩天的課程涵蓋了 TFF 的操作關鍵要素：濾膜安裝，沖洗，消毒，完整性測試，緩衝液平衡，蛋白濃縮以及使用後的處理(如清洗，清洗評估和儲存)。</p>	5月24日 – 5月25日	–
Sterility test 無菌測試證書培訓	<p>This course provides an in-depth review of the regulatory requirements of sterility testing, its validation and practical implementation. The course is based on the most recent editions of international pharmacopoeias and provides information about the harmonization and differences between the United States Pharmacopeia (USP) and the European Pharmacopoeia (EP). As an essential part of the course, you will participate in an interactive workshop on how to perform a sterility test. Participants' case studies will also be discussed. Our experienced instructors also provide valuable suggestions for regulatory compliance.</p> <p>本節課程主要提供無菌檢測相關法規更深入探討，包含確效及執行上的層面。課程內容都是以目前國際藥典最新的規範為基礎，並且比較美國藥典及歐洲藥典相同及差異的地方。學員將會實際參與討論並且操作無菌檢驗，這個是此課程的重要部分。而且參加者也可以提出實際案例進行討論，我們有經驗的講師也會根據藥典規範提供有參考價值的建議。</p>	11月2日	–



Course	Course Description	Training Schedule	
		1 st	2 nd
Environmental monitoring school 環境監控證書培訓	<p>This course provides an in-depth review of the regulatory requirements of environmental monitoring of cleanrooms, its validation and practical implementation. The course is based on the most recent editions of GMP and USP guidelines and provides information about cleanroom classification and monitoring according to the ISO standards. Helping to understand the lecture content with practical applications. Most critical handling steps in the microbial monitoring procedure and its consequences for test results are discussed and solutions are explained and demonstrated.</p> <p>本節課程主要提供無塵室環境監控相關法規的深入探討，包含確效及執行上的層面。課程內容都是以目前 GMP 及美國藥典最新的規範為基礎，並且提供無塵室分級資訊及如何依據 ISO 規範進行環境監測。借由實際的操作能幫助學員更加了解課程內容。我們會解釋跟示範，重要的關鍵操作步驟以及微生物監控流程和測試結果的相互邏輯。</p>	7月6日	—
Optimize and Scale up of Normal Flow Filtration Process 常規過濾製程優化和放大	<p>Using a combination of theory, hands-on instruction, and workshops, participants will learn the key principles and techniques involved in the development and optimization of normal flow filtration processes. This two day course covers all aspects of sizing and scale up of normal flow filters which include the “Vmax™ Technique” for sizing sterile filters, prefilter, virus filters, and the “Pmax™ - Tmax™ Techniques” for sizing depth filters.</p> <p>課程採用理論和手動操作結合的模式，學員可以學習到常規過濾工藝開發和優化的關鍵原理和技能。兩日的課程涵蓋常規過濾工藝中的過濾器選型和工藝放大，包括除菌過濾器，預過濾器和除病毒過濾器的選型配置的 “Vmax™” 技術，用於深層過濾器選型配置的 “Pmax™” 技術， “Tmax™” 技術。</p>	7月17日 – 7月18日	—



Course	Course Description	Training Schedule	
		1 st	2 nd
Optimize and Scale up of Tangential Flow Filtration Processes 切向流過濾應用優化和放大	<p>This two-day course examines the in-depth theory of tangential flow filtration (TFF) as well as the latest techniques to develop an efficient and effective TFF process. During a practical laboratory session, you will determine optimal operating conditions using a model feed stream in a laboratory system to perform concentration and cleaning steps. Then, through a real-life case study, you will scale-up and size a TFF process with specific product purity objectives.</p> <p>這兩天的課程將深度探討切向流過濾(TFF)工藝開發技術。在實驗室實操培訓環節當中，學員將動手在實驗室級別系統上用模擬料液進行實際 TFF 操作，確定最優的濃縮和清洗工況。最後，通過一個真實的案例，學員要根據設定的純化要求，設計一個 TFF 工藝，並達到指定的產品收率和純度。</p>	8月6日 – 8月7日	–
Operator Certification of Automatic Filter Integrity Testing 自動化完整性測試操作證書培訓	<p>Using a combination of theory and hands-on instruction, you will learn the key procedures of filter integrity testing, how to read printouts from automatic filter-integrity testers and troubleshoot filter-integrity test processes. This two-day course covers all current filter integrity tests; including bubble point, diffusive flow and water-flow integrity testing that apply to all liquid and gas membrane filtration applications.</p> <p>課程採用理論和實踐指導相結合的模式。您會學到過濾器完整性測試的主要步驟，如何讀取自動化過濾器完整性測試儀的測試結果，並排除過濾器完整性測試過程中可能出現的故障。這兩天的課程涵蓋當前所有的測試方法，包括用於液體或氣體過濾器的起泡點測試，擴散流測試和水侵入發測試。</p>	7月26日 – 7月27日	10月17日 – 10月18日



Course	Course Description	Training Schedule	
		1 st	2 nd
Operate Single-Use Technologies 一次性製程操作證書培訓	<p>Using a combination of theory and hands-on instruction, participants will learn the key procedures and “best practices” methods involved in the use and operation of disposable single-use components, including filters, connectors, bags, mixers and tubing. Installation, flushing, sanitization and integrity test procedures are also taught and discussed</p> <p>課程採用理論和手動操作結合的模式，學員可以學習到設計和使用一次性工藝的關鍵步驟和最佳實踐技術。課程中會介紹並使用多樣一次性的組件，包括過濾器，一次性連接器，袋子，攪拌器和管子。在根據範例設計和組成一次性的裝置後，學員們會實際操作：安裝，沖洗／消毒，完整性測試和產品回收，進而理解到一次性工藝如何實現提高生產量，減少操作時間的好處。</p>	11月13日 – 11月14日	—
** 課程名額：10人-30人 ** 課程費用與具體培訓時間，請與培訓連絡窗口連繫			

All training courses are conducted in English. Merck reserves the right to change the course dates, or to cancel the course.

