



鴻林堂生物科技股份有限公司

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企業沿革

- 2014 年** 成立鴻林堂生物科技並進駐新竹科學園區
榮獲中華民國優良廠商協會臺灣生技大獎
- 2015 年** 上市電泳膠體觀測儀並取得 13 件專利
獲得勞動部「小型企業人力提升計畫」補助（連續五年）
- 2016 年** 接受美國馬里蘭州州政府邀請至馬里蘭大學
學育成中心成立分公司與研發中心
- 2017 年** 成為全球前三大蛋白質分子量標記物生產者
上市核苷酸、Q-PAGE 預鑄膠及勝任細胞等
三項新產品
- 2018 年** 榮獲勞動部遴選為小型企業優良辦訓企業
- 2019 年** 成為全球前十大核苷酸生產者
- 2020 年** 榮獲 ISO9001:2015 品質管理系統認證
成為臺灣核苷酸原料第一大生產廠
- 2021 年** 成為全臺唯一可生產 mRNA 全系列關鍵原料廠商
成為全球前 15 大 Q-PAGE 產品供應廠商並
導入自動化設備生產

2022 年 COVID-19 核酸檢測套組與印尼國立日惹大學投資公司 SWAYASA 共同合作取得印尼國家衛生部 EUA 許可

2023 年 進駐臺北南港國家生技研究園區
獲得經濟部「疫後特別預算升級轉型診斷輔導（低碳化）」補助
榮獲國際亞洲科學園區協會 (ASPA) 年度獎項
實施 ISO13485:2016 醫療器材品質管理系統標準認證

主要產品

- 基礎生醫檢測試劑系列產品，包括：分子生物學實驗用品及試劑、電泳預鑄膠片、去氧核糖核苷三磷酸 (dNTPs) 及 mRNA 相關原料等。

企業簡介

鴻林堂生物科技 (SMOBIO) 是一家兼具創業與創新研發型企業，以自身卓越的生物醫學和有機化學核心技

術為基礎，致力於研究與開發「生物醫學研究、基因工程和臨床診斷之蛋白質產品及套組」。在優秀又具碩博士學歷研發團隊和自主財務能力為後盾，並在經營決策團隊的引領下，SMOBIO 不斷研發、製造及全球銷售 128 種基礎生醫檢測試劑系列產品、儀器和其他相關產品，成功贏得全球學研機構研究人員採用，如美國哈佛大學、英國劍橋大學。近三年（2020-2022 年）平均全年出口營業額占總營業額九成左右。除了自有品牌產品行銷全球之外，為滿足全球客戶的特殊需求，SMOBIO 亦提供客製化產品服務。

出口實績及國際競爭力

1. SMOBIO 實現生技高等研究場域所使用的試劑產品國內自製—從進口國轉變為出口國。
2. SMOBIO 擁有高度自主研發能力，創新研發成果豐碩並在幾個領域成為我國首創和唯一，包括：完整開發生技高階試劑及原料、量產高純度核苷酸原料、生產大量假尿苷及生產大量正電脂質等。SMOBIO 在 mRNA 領域中成為具有特色的代表者。
3. 建立國際品牌的信譽和品質保證，並持續擴大全球銷售業績，自有品牌產品已銷售到全球 27 個國家以上。SMOBIO 提供全球客戶滿意度高的產品與服務。
4. 建立緊密的國內外產學研合作關係以持續提升內部研發人員創新能力。

營運管理與績效

1. SMOBIO 經營策略為「誠信經營、穩定發展、創造價值」。SMOBIO 經營決策團隊於 2019 年引入國際 ISO9001 品質管理系統標準，作為加強內部長期運營治理的方法。
2. 每年定期舉辦內部稽核並召開管理審查會議，以管控 ISO9001 品質管理系統的運作品質。
3. 嚴謹保護智慧財產權，研究人員必須遵守營業秘密和競業條款，研發成果文件由 ISO 文件管制中心或研發部主管保管以控管機密文件的流通。

永續經營

1. SMOBIO 向來關注 ESG 永續發展。2020 年取得 ISO9001 認證後，SMOBIO 更加留意 ESG 相關的風險管理。

2. 環境保護：確保業務活動對環境的影響最小化，並預計未來幾年內陸續導入國際標準溫室氣體排放與環境管理認證。
3. 社會責任：提供員工多元技能培訓機會、擴大國內外產學合作、參與大學人才培育或就業機會及擴大社區服務等。
4. 企業治理：秉持經營策略，落實 ISO 品質政策與運作模式，持續流程改善及提高企業經營管理效能。SMOBIO 期許能為全球生命科學做出更大貢獻。



綜合評語

1. 專注於生物科技產品研發、製造，主要出口至韓國、日本、美國等 20 餘國，是臺灣唯一工業化生產高濃度核苷酸的生物科技公司。
2. 擁有自主研發能力，成功創新研發了 128 種以上的基礎生醫檢測試劑系列產品，其中「蛋白質分子標記物（Protein Markers）」產品在全球市場上位居前三名。
3. 重視內部研發人員的持續創新研究與開發，積極與國內外學研機構專家合作，提升內部的創新能力。



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History

- 2014** Established "SMOBIO Biotechnology, Inc." in Hsinchu Science Park
Received Taiwan Biotechnology Great Award from the Republic of China Fine Manufacturers Association
- 2015** Launched blue light LED epi-illuminator and obtained 13 patents
Received subsidy for Small Business Human Resources Development Project from the Ministry of Labor (five consecutive years)
- 2016** Established a subsidiary and research center in the University of Maryland with invitation from the Maryland state government
- 2017** Become one of the top three producers of protein markers in the world
Launched three new products: nucleotides, precast gels, and competent cells
- 2018** Recognized as an outstanding training company for small businesses by the Ministry of Labor
- 2019** Ranked as the 10th global player in nucleotide production
- 2020** Achieved ISO9001:2015 certification for quality management system
Became the largest producer of nucleotides in Taiwan
- 2021** Became the sole manufacturer in Taiwan for mRNA multiple raw materials
Become the 15th of the world's highlighted pre-cast gel product suppliers with automatic equipment for production line
- 2022** Obtained EUA for COVID-19 testing kit in Indonesia with cooperation with the Indonesian UGM's associated company SWAYASA
- 2023** Established a new base in National Biotechnology Research Park in Taipei
Receive award from the international Asian Science Park Association
Implemented ISO 13485:2016 certification

Business Items

- A variety of biomedical reagents: analytical reagent/device for molecular biology, precast gels, dNTPs, and mRNA-related key raw materials.

Introduction

SMOBIO is an innovative research and development (R&D) corporation and is committed to the R&D of "protein products and kits for biomedical research, gene engineering, and clinical diagnosis ". With excellent R&D team with master's and doctoral degrees, independent financial capabilities, and decision-makers' leadership, SMOBIO has continued to develop, manufacture and globally sell 128 basic biomedical reagents, instruments and other related products, successfully adopted by researchers from global academic institutions, such as Harvard Univ., USA. During 2020-2022, the average annual export turnover accounted for about 90% of the total turnover. Besides selling own brand products, SMOBIO also provides customized product services for global customers.

Export Competitiveness

1. SMOBIO realizes domestic production of reagent products used in advanced biotechnology research fields - changing from an importing country to an exporting country.
2. SMOBIO possesses a high degree of autonomous R&D capability, and has achieved several unique milestones "Taiwan's first and only": complete development of high-level reagents and raw materials for the biotechnology sector; mass production of high-purity nucleotides, pseudouridine, and cationic lipids.
3. Establish the credibility and quality assurance of international brands and continue to expand global sales performance. Own brand products have been sold to more than 27 countries. SMOBIO provides products and services with high customer satisfaction around the world.

Operation Performance Management

1. SMOBIO's business strategy is "Integrity Management, Stable Development, and Value Creation", and business decision-makers introduced the international ISO9001:2015 Quality Management System in 2019 as a method to strengthen internal long-term operational governance.
2. Internal audits and management review meetings are held regularly every year to ensure the operational quality of the ISO9001 system.
3. Intellectual property rights are strictly protected.

Researchers must abide by business secrets and non-competition clauses. Documentation of R&D results are kept by the ISO Document Control Center or the head of the R&D department to control the circulation.

Sustainable Management

1. SMOBIO has paid more attention to ESG-related risk management after obtaining ISO9001 certification in 2020.
2. Environmental Protection: Ensure that the impact of business activities on the environment is minimized, and it is expected to introduce relevant international certifications within a few years.
3. Social Responsibility: Provide employee training opportunities, expand domestic and foreign industry-university cooperation, participate in university talent cultivation and expand community services, etc.
4. Corporate governance: Adhere to the business strategy, implement the ISO quality policy and operation model, continue to improve the process and improve the efficiency of corporate operation and management.

Protein Markers 310kDa~5kDa



SMOBIO's produced mRNA successfully transfected neural cells, emitting green fluorescence.