



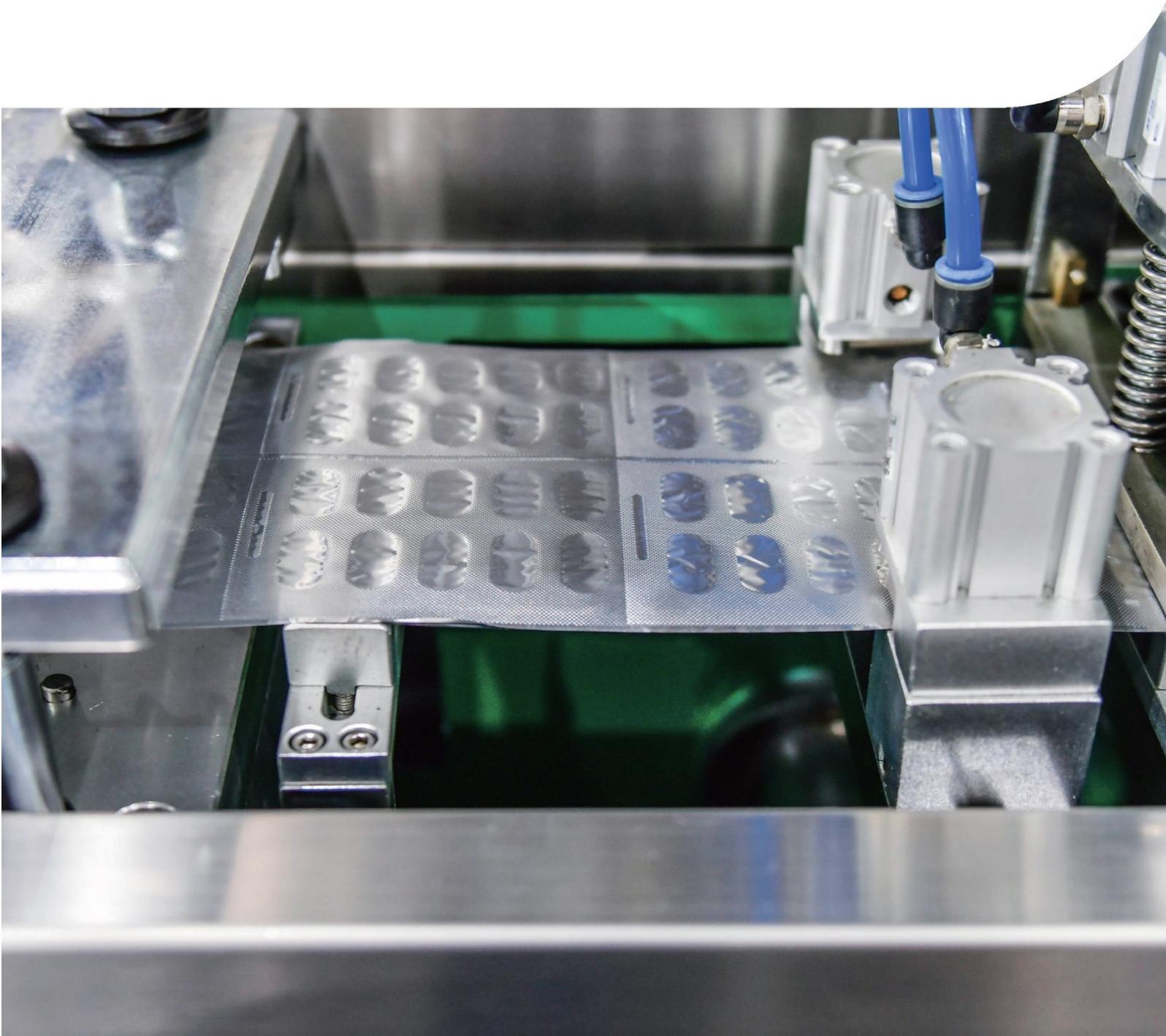
司騰達股份有限公司
BHP Industry Solution

NEXIOT

Your Partner in Smart Manufacturing

應用案例

醫療包材機台案例-
高速自動化生產、FDA規範 一次滿足



背景說明

客戶為生產皮膚貼片醫療包材機器的外銷廠商。

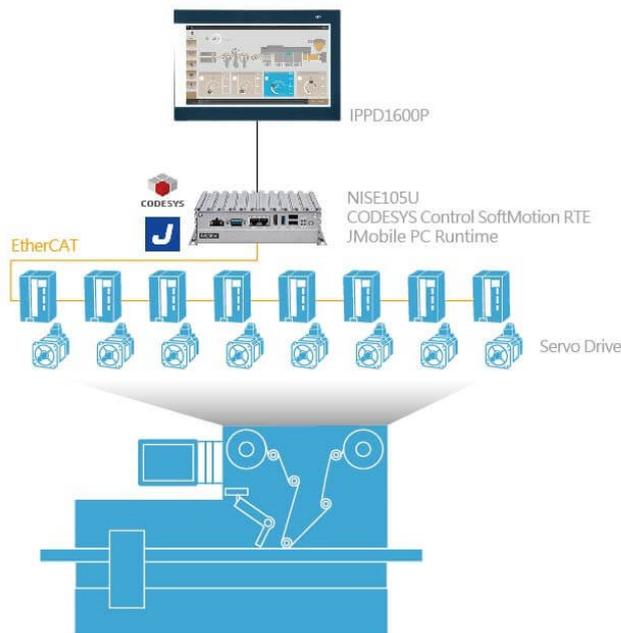
挑戰

1. 原使用日系PLC，但為封閉式系統，運動控制達不到產能要求，而如換德系PLC，要達到高速效能，運動控制系統成本相當高。
2. 由於客戶為生產皮膚貼片醫療包材機器的外銷廠商，牽涉到較精密的醫療器材及外銷商品，需符合美國食品暨藥物管理局(FDA, Food and Drug Administration) FDA 21 CFR Part 11，此法規訂了對封閉式及開放式電子紀錄保存系統控管的要求，以及在簽名和電子紀錄之間建立連結所須符合的要求。而市面上能符合此要求的解決方案並不多。

解決方案

- 物聯網閘道器(IIoT gateway)：NISE105U
 - 運動控制軟體：CODESYS Control SoftMotion RTE
 - 可視化軟體：JMobile PC Runtime
 - 可視化螢幕：IPPD1600P
1. 機台採用士林電機EtherCAT 伺服驅動器和馬達，並導入

解決方案系統架構



NISE105U 控制器加上CODESYS Control SoftMotion RTE，能同步控制8軸，可自動調整包材捲軸的張力，避免包膜於過程損壞，並量測封膜的適當長度，使包裝過程能達到高速、穩定的品質，減少機器故障。

2. NISE105U同時搭載JMobile PC Runtime，可支援大尺寸螢幕，將生產數據連結到15.6" IPPD1600P進行資訊可視化，除此之外，JMobile PC Runtime支援FDA 21 CFR Part 11規範，符合對封閉式及開放式電子紀錄保存系統控管的要求，以及在簽名和電子紀錄之間建立連結所須符合的要求。

成果及效益

1. 新漢智能提供的EtherCAT 多軸運動控制器NISE105U加上CODESYS Control SoftMotion RTE不僅擁有控制器的高穩定性、實時引擎，支援多種工業乙太網路協定，節省設備成本也省去網路線安裝繁複工程，生產數量也從每分鐘300片提升到每分鐘450片。
2. 市場上能符合FDA 21 CFR Part 11規範的解決方案屈指可數，新漢智能NISE105U搭載JMobile PC Runtime提供了經濟且使用友善的web-based 架構解決方案，支援HTML5、JavaScript和MQTT，也可在手機或平板開啟網頁瀏覽器功能，可讓管理者進行遠端監控及即時決策。更重要的是，此解決方案能使醫療器材及藥品等機台製造廠商能輕鬆達到FDA規範標準，成功外銷歐美市場。



Your Partner in Smart Manufacturing

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In addition to its own brand product, NexAIoT is able to provide tailor made ODM service for customers. NexAIoT is building Industry 4.0 OT/ IT information integration with ecosystem partners to co-create Industry Internet of Things alliance. We sincerely invite you to join the IIoT alliance team and enjoy a win-win result.

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