

# FILL & FINISH CONTRACT MANUFACTURING ORGANIZATION FOR INJECTABLES

注射剂灌封委托生产组织





# YOUR PREFERRED CMO – WHEREVER YOUR MARKET

#### 您首选的CMO-不论你的市场在哪里

With an in-country manufacturing site in Wuxi, China, Wuxi Griffin offers compliance to international GMP quality requirements for the global market. Wuxi Griffin provides Chinese established pharmaceutical companies to initially fill phase I to phase III pharmaceuticals for the markets in USA and Europe, followed by commercial filling for market approved products. Similarly, Wuxi Griffin offers Western pharmaceutical companies integration of their products to the lucrative Chinese pharmaceutical market as well as to the markets in West.

拥有在中国无锡的生产基地,无锡格莱福公司为全球市场提供符合国际GMP质量要求的产品。我们为中国的制药公司提供了美国和欧洲市场的I期临床到III期临床实验药物的灌装,或之后的上市产品的商业灌装。同样,我们也向西方制药公司提供了将其产品整合到利润丰厚的中国医药市场以及西方市场的机会。Wuxi Griffin is your preferred CMO and we will help you with a smooth market launch of your products, whether it is in China, Europe or USA.

无锡格莱福是您首选的CMO, 我们将帮助您将产品顺利推出市场, 无论是中国、欧洲或美国。

# Benefits of partnership with Wuxi Griffin as a CMO in China: 与中国CMO公司无锡格莱福合作的优势:

- Contract manufacturing in China for the global market 面向全球市场的中国委托生产
- Compliance to international GMP quality standards 符合国际GMP质量标准
- Access to the international pharmaceutical market, especially China, Europe and USA
   进入国际医药市场,特别是中国,欧洲和美国市场
- Assistance from project development to a successful market launch of your products to the chosen markets 协助从项目开发到选定的市场的产品的成功上市



"We understand that choosing the right CMO is of great importance to your success. Wuxi Griffin is dedicated to ensure you feel confident in your choice of a strategic partner"

"我们知道选择正确的 CMO 对您的成功非常重要。无锡格莱福致力于确保您对自己选择的战略合作伙伴的信心"

We help you with a smooth introduction of your products to the global market, whether in China, Europe or USA

我们能帮助您 将产品顺利推 出国际市场, 无论是中国、 欧洲或是美国





# CHOOSE WUXI GRIFFIN AS YOUR STRATEGIC PARTNER

选择无锡格莱福作为您的战略合作伙伴

- Biopharma and fill and finish experienced management 生物制药和灌封的管理经验
- State-of-the-art technology 最先进的技术
- Single-use system technology
   一次性系统技术
- Flexibility in batch sizes
   灵活的批量
- Safe and reliable production for high value products 高价值产品生产的安全和可靠
- Project management and technology transfer 项目管理和技术转移经验
- Supporting documentation for regulatory filings
   为注册文件的提供支持性文件
- Reliability 可靠性

As your strategic partner in pharmaceutical fill and finish we look forward to leveraging our expertise and experience at any stage of the development and production process. We adopt a transparent approach in every partnership to make sure you feel confident throughout the project and maintain control over your business distribution model and your products.

作为您在药品灌封行业的战略合作伙伴,我们期待着在开发和生产过程的任何阶段提供我们的专业知识和经验。我们与每一个合作伙伴采用透明合作,确保您在整个项目中都有信心,并保持对您的业务分布和产品的控制。

Our project management team will accommodate your needs and work together to identify the most suitable solutions for your strategic objectives. We will implement them with greatest safety, efficiency and reliability because we firmly believe: **Your Success Is Our Success.** 

我们的项目管理团队将满足您的需求,并共同努力找出最适合您的战略目标的解决方案。我们将以最大的安全、效率和可靠性来实现这些目标,因为我们坚信:**您的成功就 是我们的成功。** 



WUXI GRIFFIN IS YOUR FIRST-CHOICE CMO 无锡格莱福是您首选的CMO



#### **WHO WE ARE**

#### 无锡格莱福制药有限公司

Wuxi Griffin is a joint venture between Wuxi Fortune Pharmaceutical Co LTD in China and SialoCarb AB in Sweden. We serve as an international CMO in fill and finish of sterile injectables. Our management's extensive experience in the pharmaceutical industry average 15 years and we are experts in what we do.

无锡格莱福有限公司是中国无锡福祈制药有限公司和瑞典SialoCarb AB的合资公司。我们作为国际CMO服务于无菌注射剂的灌封。我们的管理人员在制药行业的平均经验是15年,我们是行业内的专家。

With our devoted team of professionals, we are here to provide you with customized production solutions throughout the project life cycle. Our dedication will continue throughout the project to ensure we meet your requirements. At the heart of our work is our customers' success and we strive to deliver timely results of highest quality.

在我们的专业团队中,我们将为您提供在整个项目生命周期中定制的生产解决方案。我们的奉献将贯穿整个项目,以确保我们满足您的要求。我们的工作的核心是客户的成功,我们努力及时交付最高质量的结果。



# TECHNICAL DETAILS 技术细节

With our 2550m<sup>2</sup> / 27450 sqft GMP compliant fill & finish facility, Wuxi Griffin offers a state-of-the-art RABS and Isolator filling technology with great flexibility to meet your needs. Our production technology is supported by modern utility systems.

我们拥有2550m<sup>2</sup> / 27450平方英尺GMP合规的灌封车间,无锡格莱福公司提供最先进的RABS和灵活的隔离灌装技术以满足您的需求。我们的生产技术得到了现代基础设施系统的支持。

# Vial Filling 西林灌装

- Isolator-based aseptic vial filling line for aqueous solution products 基于隔离器无菌灌装生产线的水针产品
- o Glass and polymeric vials (2–30ml; 13mm and 20mm stoppers) 玻璃和聚合物瓶(2−30ml;13mm和20mm胶塞)
- o 1200-1500 units per hour based on the smallest vial size of 2ml 1200-1500瓶/小时的2ml最小规格西林瓶灌装
- o 200 10 000 units per batch in automated filling 自动灌装200−10000瓶/批
- o Flexible batch sizes including clinical trial materials 包括临床试验材料的弹性批量
- On-going expansion of large-scale vial filling 大规模西林灌装的持续扩张

Wuxi Griffin has
the experience,
technology and
professionalism
for
collaborations
within the
pharmaceutical
business

无锡格莱福拥有 制药行业合作的 经验、技术和专 业精神



#### Ampoule Filling 安瓿灌装

 RABS-based ampoule filling line for aqueous solution products with terminal sterilization of filled product (superheated water autoclave)

基于RABS技术的非最终灭菌(超热水灭菌柜)安瓿水针灌装线

- o Glass ampoules (2-20ml) 玻璃安瓿瓶(2-20 ml)
- Up to 18000 units per hour for the smallest ampoule size of 2ml 高达18000支/小时的2ml最小规格安瓿瓶灌装
- o Flexible batch sizes 弹性批量

Formulation	Container System	Fill Volume	Capacity
Sterile Liquid Solution	Vials, Stoppers and Crimps (Aseptic processing and terminal sterilization)	1.5ml to 30ml	120 units up to 1200* units per hour
	Ampoules (Terminal sterilization)	2ml to 20ml	18000* units per hour

<sup>\*</sup>For size 2ml规格

#### Formulation Vial Filling 西林灌装配液系统

- 1 formulation single use mixing system 10–30L
   一个10到30L的一次性配液系统
- 1 formulation single use mixing system 20–50L
   一个20到50L的一次性配液系统
- 1 formulation single use mixing system 50–200L 一个50到200L的一次性配液系统
- Planned formulation vial filling line system 500L
   500L的计划配液系统

# Formulation Ampoule Filling 安瓿灌装配液系统

 2 formulation stainless steel tanks with total capacity of 50L and 150L with automatic CIP/SIP system 两个总容量50L与150L的不锈钢配液罐与自动CIP/SIP系统



Wuxi Griffin knows what it takes to become your trusted CMO. Contact us today and let us **fill your needs...** 

无锡格莱福知道如何成为您信任的CMO公司。 联系我们让我们满足您的需求... Our goal is to become your trusted CMO in fill and finish of pharmaceutical injectables

我们的目标是 成为您所信任 的药品注射剂 灌封 CMO 公司





# EQUIPMENT 设备



Isolator technology 隔离器技术



Formulation tanks with CIP/SIP 配液罐和CIP/SIP



Isolator based vial filling and stoppering line 基于隔离器西林灌装加盖线



RABS based high speed ampoule filling line 基于RABS的高速安瓿灌装线



Depyrogenation ovens and washing for vial and ampoule lines 西林、安瓿洗瓶及烘瓶烘箱



WFI, purified Water and purified steam for all filling 灌装用纯化水、注射用水、纯蒸汽





# Manufacturing Facility 生产地址

1. No.4Rongyang 1st Road, Xishan Economic Zone, Wuxi, Jiangsu Province, CHINA

中国江苏省无锡市锡山经济技术开发区蓉洋一路4号

# Sales and Marketing Office 市场及营销地址

2. Byavagen 16, 241 35, 223, Eslov, SWEDEN

# **WUXI GRIFFIN Pharmaceuticals Company LTD**

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