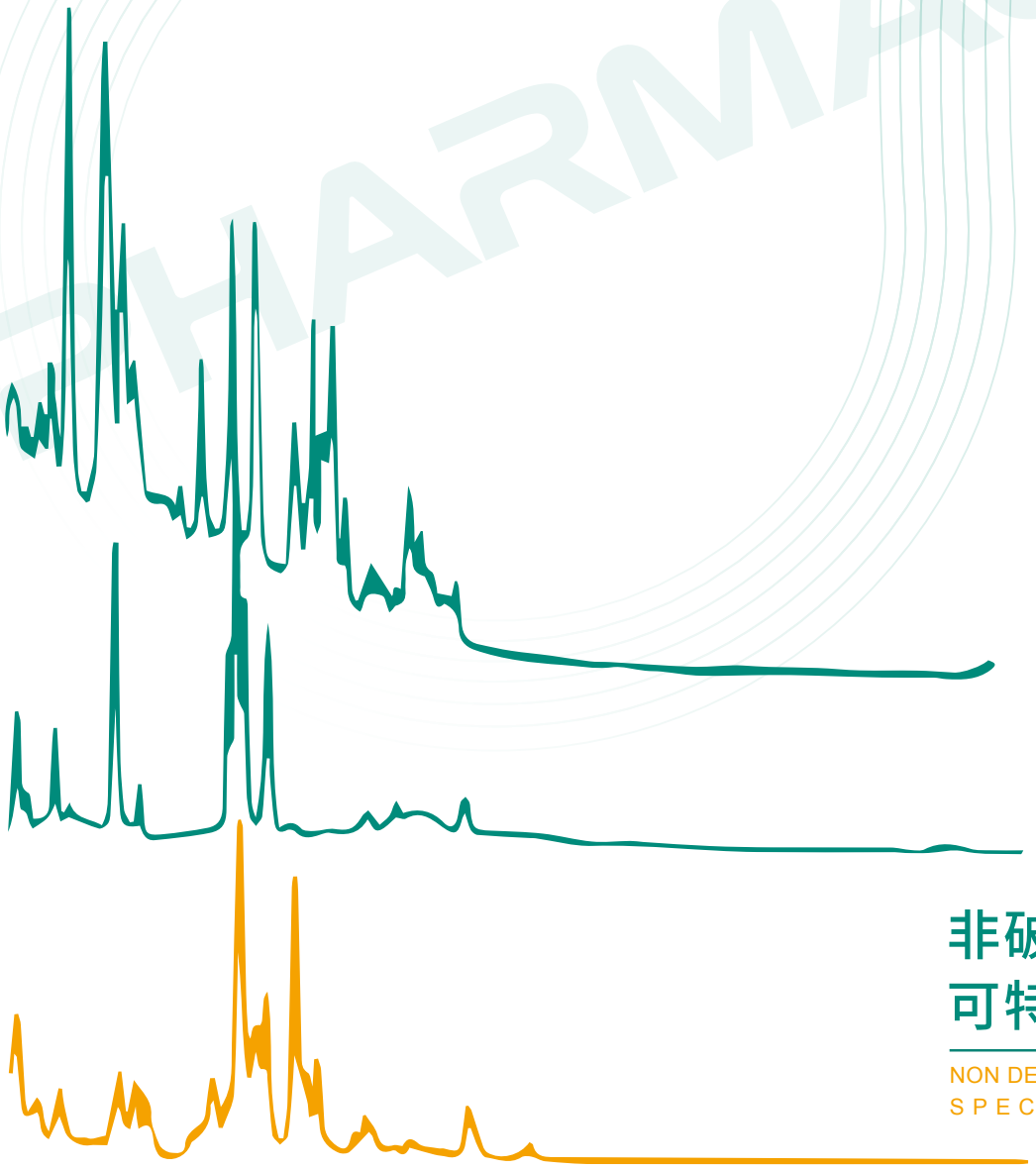
PHARMAC 珐成浩鑫

WorldTex

生物制药

RAMAN SPECTRA ONE-STOP
SOLUTION FOR BIOPROCESS

拉曼光谱一站式解决方案



非破坏性
可特异性

NON DESTRUCTIVE
SPECIFICITY

关于我们
ABOUT US

珐成浩鑫致力于为生物制药、日用化工、合成生物及相关行业提供**专业的洁净流体系统工程服务**。专注于推动**流体工艺技术突破和自主知识产权工艺装备**的打造，实现高质量、可持续的洁净流体设备**本土化制造之路**。

能为客户提供包括：**生物反应器、配液系统**、生物发酵系统、水机及分配系统等专业流体工艺设备。

PHARMAC，**引领洁净流体系统新方向，助力生命科学领域前行**。

PHARMAC is committed to providing professional clean liquid system engineering services for the pharmaceutical, daily chemicals, food, synthetic biology and related industries.We have been dedicated to driving breakthroughs in fluid process technology and the development of proprietary process equipment in order to achieve high-quality and sustainable localized manufacturing of clean fluid equipment.

We are capable of providing customers with professional fluid process equipment such as bioreactors, formulation systems, fermentation systems, PW & WFI generator & distribution systems.

Leading the way in the clean liquid system, making contribution to the advancement in life sciences.

拉曼光谱简介
INTRODUCTION TO RAMAN SPECTRA

PAT技术
PAT TECHNOLOGY

2004年，美国食品药品监督管理局（FDA）将过程分析技术（PAT）定义为一种通过测量影响关键质量属性（CQAs）的关键过程参数（CPP）来设计，分析和控制制药生产过程的机制。

PAT, which was defined by the U.S. Food and Drug Administration (FDA) in 2004, is a mechanism for designing, analyzing, and controlling pharmaceutical manufacturing processes by measuring Critical Process Parameters (CPPs) that affect Critical Quality Attributes (CQAs).

PAT技术
PAT TECHNICAL GUIDANCE

“一个通过**即时测量原料、过程中物料和过程本身的关键质量指标**来实现设计、分析和生产控制的系统，目的是确保最终产品的质量”

“A system that achieves design, analysis, and production control by real-time measurement of critical quality attributes of raw materials, in-process materials, and the process itself, with the goal of ensuring the quality of the final product.”

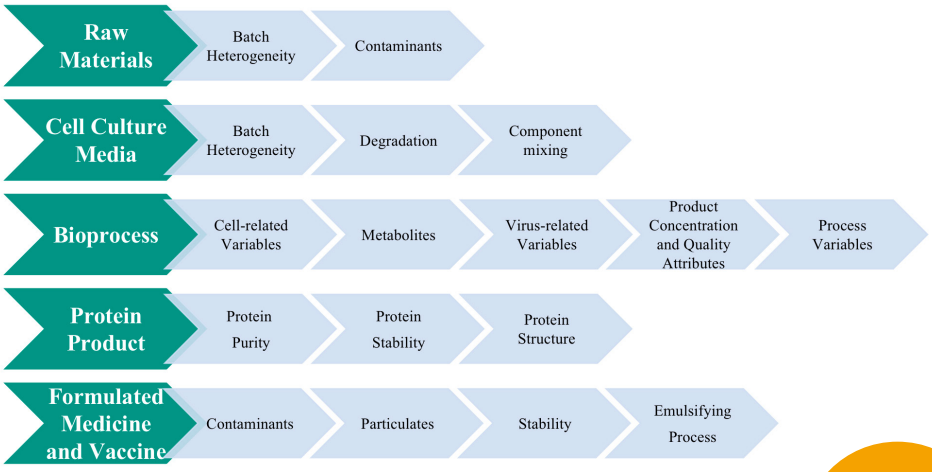
目标
TARGET

(1) 提升对过程的理解
(2) 确保批次稳定性
(3) 提高成品率
(4) 缩短生产周期
(5) 提高生产力
(6) 降低成本并改善质量

(1) Enhance the understanding of processes
(2) Ensure batch stability
(3) Increase the yield of good products
(4) Shorten the production cycle
(5) Enhance the productivity
(6) Reduce the cost and improve the quality

拉曼光谱技术具有非侵入性、高灵敏度和快速响应的特点，适用于生物制药领域的各个领域

Raman spectra technology, characterized by its non-destructive nature, high sensitivity, and rapid response, is suitable for various fields within the biopharmaceutical industry.



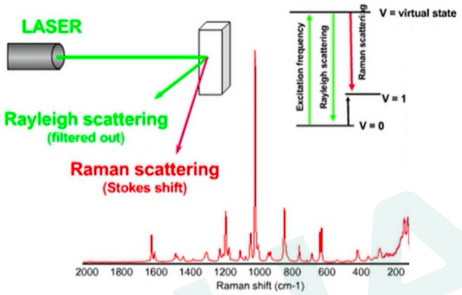
技术原理
PRINCIPLES OF RAMAN

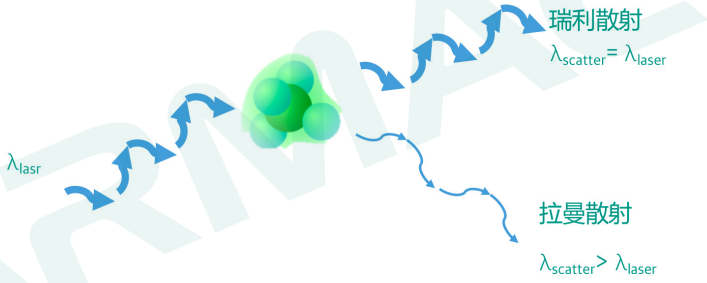
光散射的过程：激光入射到样品，产生散射光。

散射光
- 弹性散射（频率不发生改变-瑞利散射）
- 非弹性散射（频率发生改变-拉曼散射）

The process of scattering: a laser is aimed on the sample, generating scattered radiation.

Scattering
- Rayleigh scattering: The light frequency does not change
- Raman scattering: The light frequency changes





- 拉曼光谱是非破坏性检测方法
- 拉曼光谱可特异性检测多参数

Raman spectra is a non-destructive detection method.

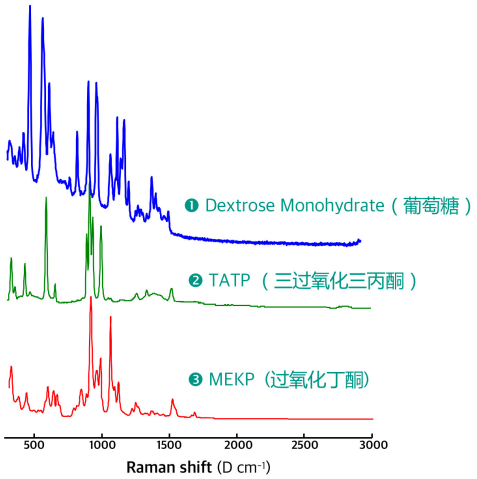
Raman spectra enables the simultaneous detection of multiple parameters.

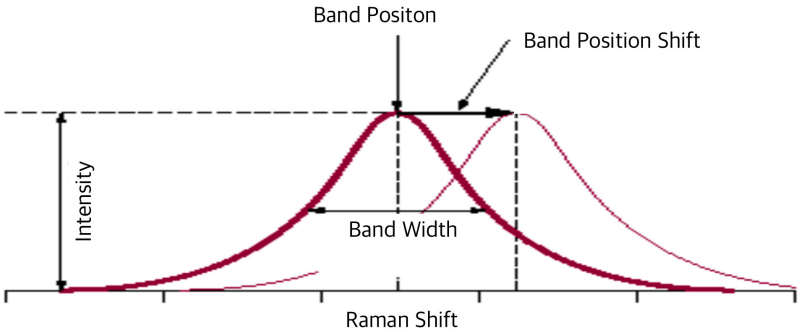
分子的特征“指纹”图谱，不同物质会有不同分子指纹

甚至于活细胞和由于裂解导致死亡的细胞分子组成不同，都可以很好的区分过来。

What the Raman probe obtains is a spectrum of the mixture in the broth

Each substance has a Raman fingerprint, even different cells (active or inactive)





定性的信息 Qualitative information

物质鉴定、结构、晶型、结晶度等

Material identification, structure, crystal form, crystallinity, etc

定量的信息 Quantitative information

光谱强度对应物质浓度分布

Spectral intensity corresponds to the concentration distribution of substances

拉曼光谱解决方案合作伙伴
RAMAN SPECTRA SOLUTIONS PARTNER

设备 – ThermoFisher
On-line Raman spectrometer- ThermoFisher

- 专利探头设计确保了灵敏度和准确性
- The patented probe design guarantees the sensitivity and accuracy

- 固态设计确保高稳定性，无需频繁校准
- Solid state design ensure high stability and no need for frequent calibration

- 堆叠式设计满足多通道检测的需求
- The stackable design can meet the requirements of multi-channel detection

- 模块化设计可在15分钟内快速部署
- The modular design enables rapid deployment within 15 minutes

拉曼光谱应用场景
APPLICATION OF RAMAN SPECTRA

	细胞培养	微生物发酵	蛋白纯化
关键工艺参数 (KPP)	• VCD (活细胞密度) • 葡萄糖 • 乳酸盐 • 谷氨酸 • 谷氨酰胺 • 产品 • NH4+ • LDH	• OD (光密度) • 葡萄糖 • 甘油 • 甲醇 • 乳酸盐 • 产品 • 铵离子 • 溶解磷	• 目标蛋白 • 蛋白杂质 • 其他
要求	• 高温可灭菌 • 多参数监控 • 持续和稳定运行	• 高温可灭菌 • 多参数监控 • 持续和稳定运行	• 多参数监控 • 持续和稳定运行
功能	• 培养基和生物工艺优化 • 工艺监控	• 培养基和生物工艺优化 • 工艺监控	• 工艺优化 • 工艺监控
优势	• 减少批次时间 • 提高产量 • 降低生产成本	• 减少批次时间 • 提高产量 • 降低生产成本	• 自动化工艺控制 • 提高蛋白回收率 • 降低生产成本

	Cell culture	Microbial fermentation	Protein purification
Key Process Parameters (KPP)	▪ VCDviable cell density ▪ Glucose ▪ Lactate ▪ Glutamate ▪ Glutamine ▪ Products ▪ NH4+ ▪ LDH	▪ OD ▪ Glucose ▪ Glycerin ▪ Methanol ▪ Lactate ▪ Products ▪ Ammonium ▪ Dissolved phosphorus	▪ Target protein ▪ Protein impurities ▪ Other
Requirements	▪ High temperature sterilizable ▪ Multi-parameter monitoring ▪ Continuous and stable operation	▪ High temperature sterilizable ▪ Multi-parameter monitoring ▪ Continuous and stable operation	▪ Multi-parameter monitoring ▪ Continuous and stable operation
Functions	▪ Medium and bioprocess optimization ▪ Process monitoring	▪ Medium and bioprocess optimization ▪ Process monitoring	▪ Process optimization ▪ Process monitoring
Benefits	▪ Reduction of the batch time ▪ Improvement of the titer ▪ Decreasing in the production cost	▪ Reduce the batch time ▪ Increase the titer ▪ Decrease the production cost	▪ Automatic process control ▪ Increase the protein recovery ▪ Decrease the production cost

拉曼光谱一站式解决方案简介
INTRODUCTION TO RAMAN SPECTRA ONE-STOP SOLUTION

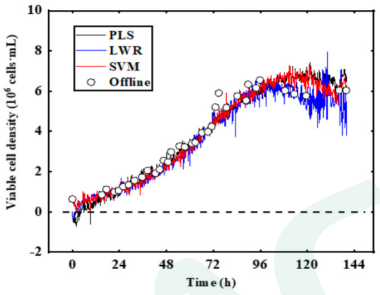
在线拉曼定量分析的技术实现
TECHNICAL IMPLEMENTATION OF ONLINE RAMAN QUANTITATIVE ANALYSIS

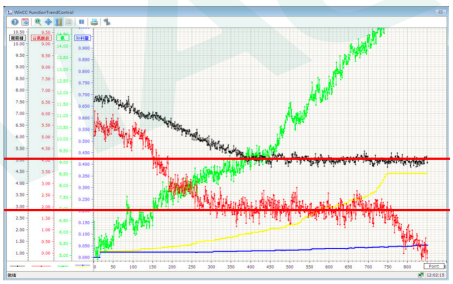
拉曼光谱在线数据获取
Data Acquisition

拉曼光谱预处理
Pretreatment of Spectrum

多元变量回归建模
Multivariate
Regression Modeling

离线检测数据
Off-line Data Detection





多元变量回归模型的构建
Construction of
multivariate regression model

预测实时监控浓度
Microbial and cell culture
process analysis support

自动化补料控制和工艺参数调节
Automatic feeding
control and optimization of Kpp

难点 DIFFICULTIES

(1) 离线数据采集耗时费力，且受检测设备的限制
(2) 建模需要专业化学计量学知识

(1) Offline data collection is time-consuming and laborious, and is limited by detection equipment
(2) Modeling requires specialized knowledge in chemometrics

(1) 稳定的过程数据采集分析软件

(1) Stable process data collection and analysis software

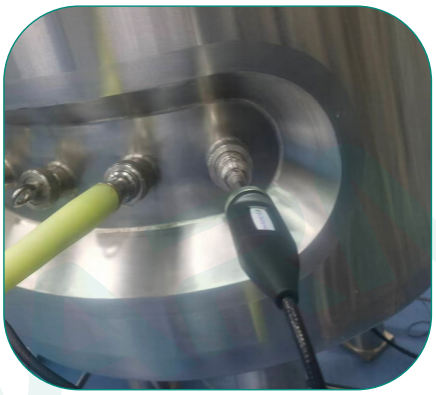
(1) 集成的反应器过程控制软件
(2) 对工艺过程的理解，培养基和工艺技术的支持

(1) Integrated reactor process control software
(2) Understanding of the process, support for the culture medium and process technology

硬件设施和测试条件
FACILITIES AND TEST INSTRUMENTS

华理技术中心多联反应器
PAT Center in ECUST

沃钛思研发中心研发平台
WorldTex R&D Center



珐成浩鑫大型反应器平台
500L - 3000L -5000L-15000L
Pharmac Large Bioreactor Platform
500-3000-5000-15000L

生化分析仪
Biochemical Analyzer

氨基酸分析仪
Amino Acid Analyzer

质谱分析仪
Mass Spectrometer

- **针对特定的培养过程在小型多联反应器快速收集数据，在自主研发的大型反应器上快速进行实验验证**
- **利用华东理工大学和沃钛思发中心丰富的离线测量设备，能够对生物过程中近百种过程变量进行测量**

- Bioreactors ranging from 3 to 15000 L, which allows rapid modeling in small parallel bioreactors and validation in large bioreactors.
- With the powerful off-line measuring instruments in ECUST and WorldTex R&D Center, nearly 100 parameters in bioprocesses can be measured.

专业的建模技术
SPECIALIZED MODELLING TECHNIQUE

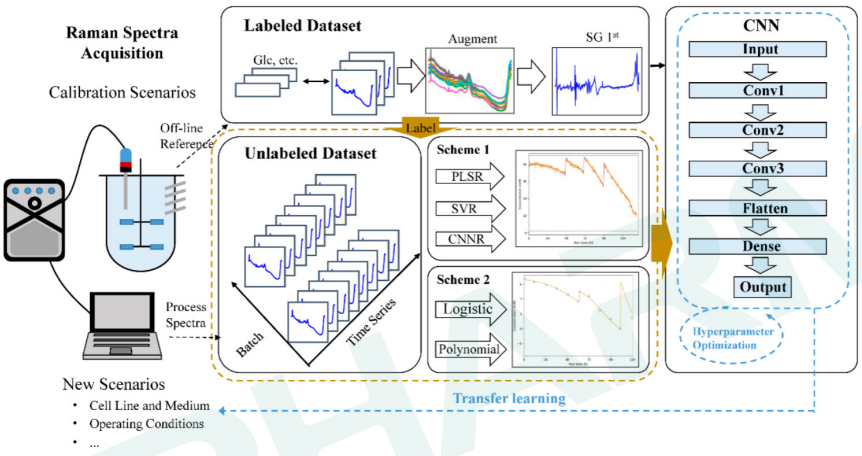
机器学习建模技术 Raman modeling process based on machine learning techniques

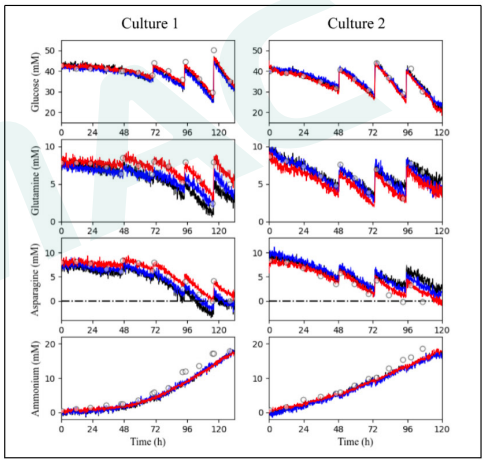
- *自主研发的拉曼光谱校准模型*

Self-developed Raman model: pretreatment, calibration, prediction, and model transfer

- *通过该方案可部署自动化光谱模型优化和应用平台*

The model can be optimized automatically and deployed rapidly in different applications





X-BIO过程数据采集软件
X-BIO DATA PROCESSING SOFTWARE

拉曼软件集成到
生物反应器控制软件

Raman software is integrated with the bioreactor control system.

实现实时数据采集
Collect Real-time Data

曲线分析
Acquisition Analysis

自动化闭环补料控制
Automatic Closed-loop Feeding Control

扫一扫 阅无限
WeChat Account

扫一扫 知产品
Product Encyclopedia

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