主论坛（大会主席）

任德权

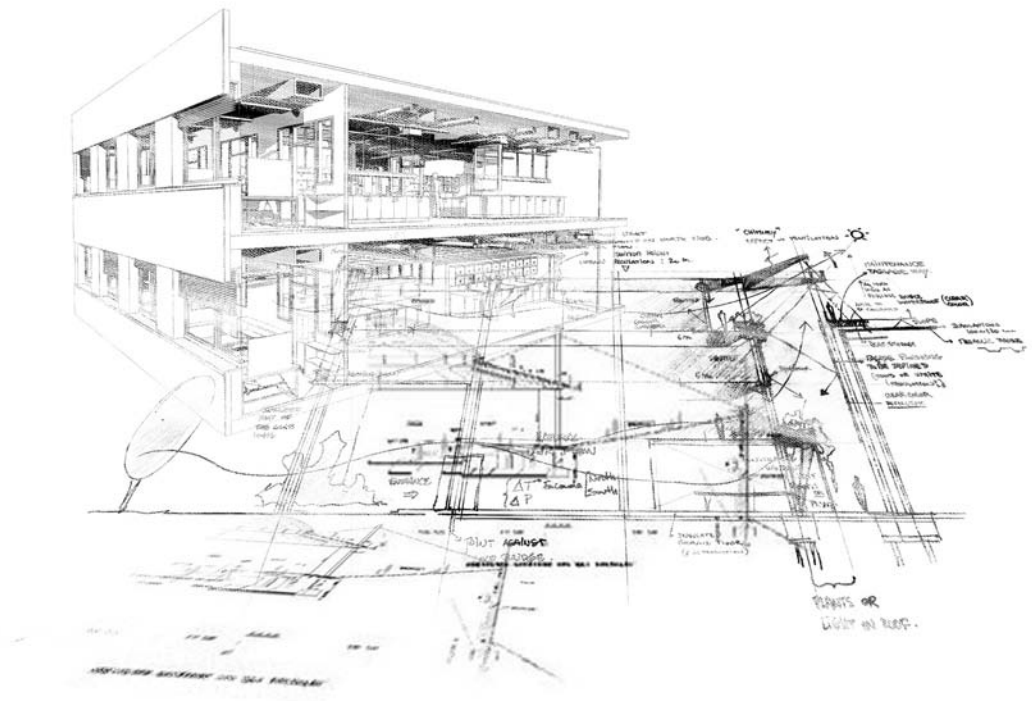
国家食品药品监督管理局原副局长

任德权先生，曾任中医药管理局副局长、国家药品监督局副局长、国家食品药品监督管理局副局长。

现任中国药学会制药工程专业委员会主任委员、现代中药国际协会名誉会长、中华全国工商联合会医药业商会名誉会长、中华中医药协会副会长、中国医药保健品进出口商会高级顾问、中国保健协会高级顾问、华东理工大学药学院名誉院长。

Mr. Ren Dequan served as Deputy Director of State Administration of Traditional Chinese Medicine, Deputy Director of State Drug Administration, Deputy Director of State Food and Drug Administration.

Currently Chairman of Pharmaceutical Engineering Committee under Chinese Pharmaceutical Association, Honorary President of Modernized Chinese Medicine International Association, Honorary President of Medical & Pharmaceutical Commercial Association All-China Federation of Industry & Commerce, Vice-president of China Association of Chinese Medicine, Senior Advisor of China Chamber of Commerce of Medicine & Health Products Importers & Exporters, Senior Advisor of China Health Care Association, Honorary President of School of Pharmacy of East China University Of Science and Technology.



分论坛：固体制剂及 API

孙鹤
天士力集团副总裁
（原 FDA 官员）

孙鹤博士 1982 年毕业于上海医科大学，1993 年获美国康涅狄格大学临床药理学博士，随后进入美国食品药品监督管理局（FDA）。由于在科学与法规方面的特殊贡献，七年内即由一般评审官跃升为 FDA 最高级别的首席科学家 / 评审专家之一，负责新药评审管理决策，提供学术顾问指导，参于全球药政协调化，及主持或参与制定药政法规管理政策等，同时负责 FDA 的计量药理学评审决策，及通过科学研究来创建 FDA 独特和创新的评审分析样板等职能。在 13 年 FDA 任职期间，主持或参与完成了七部药政法规的编写，并主持编撰了《FDA/CDER 群体药代动力学指导手册》、《OCPB PopPK 实用指南》等多项 FDA 药品研发指南性文件，为美国食品和药品审评工作框架的制订做出了突出贡献。孙鹤博士为十多个全球知名大企业的备选药物选择、研发及最佳应用、临床研究和临床药理学研究项目提供过关键性战略计划和指导并引为范例。

孙鹤博士在完成科学与管理工作的同时，积极承担社会责任。孙鹤博士曾担任美华专业组织联盟副会长等职，现任北美华人药学家协会会长；是美国临床药理和治疗学学会、美国临床药理学院和美国药学会会员；任美国药政管理杂志、美国临床实验研究杂志、美国临床药代动力学杂志、美国临床统计学杂志和美国药代动力学和药效学杂志等杂志编委。孙鹤博士正在筹办中国医药企业国际化联盟，争取协助中国企业尽快走出国门，进入世界市场。

Sun He, Vice-president of Tianjin Tasly Group

Ph . D of American University of Connecticut; an expert in pharmaceuticals research and development and management, clinical pharmacology and biopharmacy; former chief scientist and one of highest-level reviewers of metric clinical pharmacology of U.S Food and Drug Administration, member of U.S Federal Joint Committee of Asian Executives; currently, Vice-president of Tianjin Tasly Group, Director of U.S SunTech Research Institute, professor, doctoral supervisor and Faculty Director of Pharmacy Department of Tianjin University; concurrently specially invited scientist of U.S National Institutes of Health（NIH）, visiting professor of Medical School of Fudan University and Nutrition Department of Shanghai Institutes for Biological Sciences, senior researcher of Guangzhou Life Sciences Research Institute of Chinese Academy of Sciences and visiting professor of Medical Economics Research Center of Peking University etc.

Doctor Sun He has gathered rich experience in forging and operating strong alliance among domestic and foreign pharmaceutical enterprises. After returning home from abroad, he directed the team to complete the research, development of more than ten kinds of domestic new Chinese patent drugs, pharmaceutical chemicals and biopharmaceuticals and launch them in the market, all of which have been approved by China State Food and Drug Administration (SFDA) in the approval document concerning new drugs and production. Meanwhile, one Canadian approval document concerning the launch of traditional medicines in market, two U.S FDA approval documents and one Australian TGA approval document for clinical research on new medicines are obtained and three pharmaceutical intermediates are granted U.S DMF and European COS registration. Doctor Sun has successfully directed efforts to launch cooperative projects for Chinese enterprises, Indian Hetros Pharmaceutical Group, British COOP Group, American CureGen and Bay Capital and Hong Kong Morningside etc. He also made joint efforts in establishing China-Italy Joint Laboratory etc.

分论坛：无菌制剂

解馨

辉瑞制药有限公司，质量总监

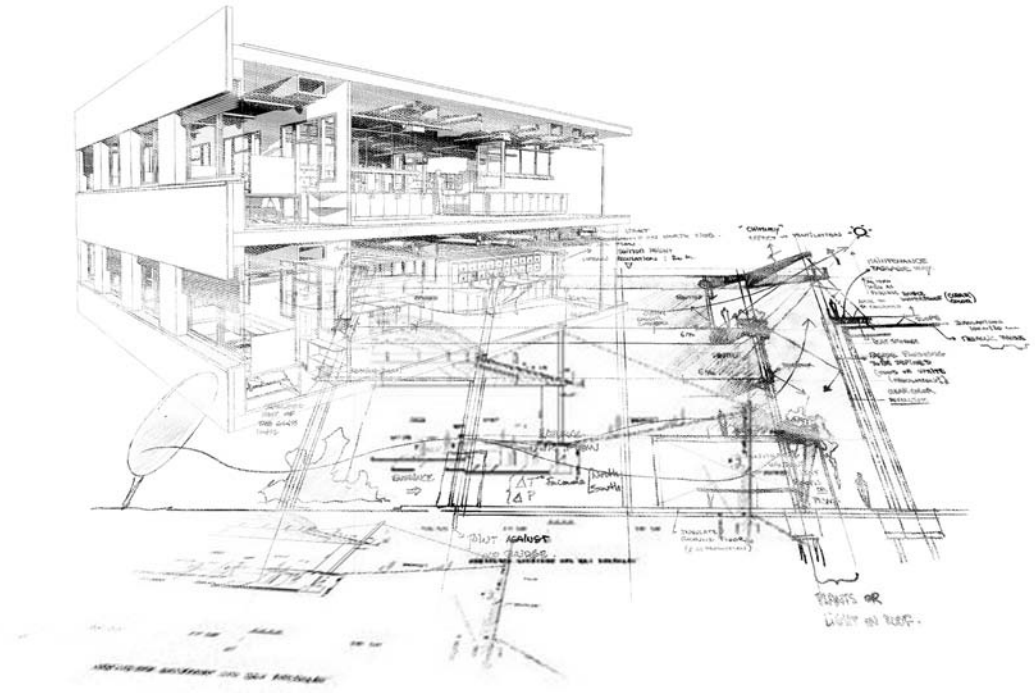
有机化工高级工程师，执业药师，现任辉瑞制药有限公司质量总监。全面负责质量相关问题及趋势的分析，改善，追踪及质量缺陷的预防、公司质量保证与质量控制体系的建立、运行、维护与持续改进。

解馨女士在辉瑞公司历任 RFT 经理、质量保证经理，组织协调质量认证、质量审计和 RFT 持续改进等项目，对质量体系的维护与改进中的偏差调查、趋势分析、产品工序能力评估、六西格玛持续改进、工艺验证、风险管理和变革文化的建立等方面有着丰富的实践经验与理论知识。

Xie Xin, Pfizer Pharmaceuticals Limited，Chief Quality Officer

Senior Engineer in Organic Chemical Engineering, Licensed Pharmacist, currently Chief Quality Officer of Pfizer Pharmaceuticals Limited, fully responsible for quality-related issues and trend analysis, improvement, tracking and quality defect prevention, establishment, operation, maintenance and continuous improvement of company's quality assurance and control system.

She served as RFT Manager, Quality Assurance Manager of Pfizer Pharmaceuticals Limited and was responsible for organizing and coordinating efforts in quality certification, quality audit and RFT continuous improvement and has rich experience in and theoretical knowledge about deviation survey of quality system maintenance and improvement, trend analysis, product process capability evaluation, Six Sigma continuous improvement, process validation, risk management and the fostering of change culture.



分论坛：生物制药

张兆伟

发泰（天津）科技有限公司，技术总监

天津经济技术开发区高技术指导委员会高指委委员，国家干细胞工程技术研究中心工程技术委员，天津财政局政府采购专家，天津科学技术委员会审评专家。

1965 年毕业于南开大学生物系，1979 年天津医药科学研究所免疫室主任，1986 年天津医药科学研究所所长，1993 年天津大学生命科学与工程研究院教授，1995 年山东金泰生物工程公司总工、山东齐鲁药厂生物工程公司总工、海南新大洲药业有限公司副总、总工，1998 年天狮集团副总裁、物流公司总经理、药业公司总经理，2004 年上海天士力生物制药有限公司技术总监，2006 年天士力金纳生物技术（天津）有限公司副总经理，2008 年天津发泰有限公司技术总监。

曾获轻工部科技成果二等奖、卫生部科学进步二等奖，在中华肿瘤杂志、生物化学与生物物理进展等杂志发表文章数篇。

主持设计、实施生物技术：基因工程药物干扰素、白细胞介素 2、GCSF、尿激酶原、亚单位流感疫苗、甲肝疫苗、乙脑疫苗等产品的产业化项目。

Zhang Zhaowei

Member of Steering Committee for High Technology of Tianjin ; Economic-Technological Development Area ; Engineering Technology Member of National Research Center for Stem Cells Engineering Technology ; Government Procurement Expert of Tianjin Municipal Finance Bureau ; Evaluation Expert of Tianjin Municipal Science and Technology Commission .

1965 Graduated from Biology Department of Nankai University, 1979 Director of Immunity Department of Tianjin Research Institute of Medical & Pharmaceutical Science, 1986 Director of Tianjin Research Institute of Medical & Pharmaceutical Science, 1993 Professor of Tianjin Research Institute of Life Sciences and Engineering of Tianjin University, 1995 Chief Engineer of Shandong Jintai Biotechnology Co., Ltd, Chief Engineer of Shandong Qilu Pharmaceutical Factory Biotechnology Co., Ltd, Deputy General Manager and Chief Engineer of Hainan SUNDIRO Holding Co., Ltd, 1998 Vice-president of Tiens Group Co. Ltd, General Manager of Logistics Company, General Manager of Pharmaceutical Company, 2004 Chief Technology Officer of Shanghai Tasly Pharmaceutical Co., Ltd, 2006 Deputy General Manager of Tasly Jinna Biotechnology (Tianjin) Co., Ltd, 2008 Chief Technology Officer of PHARM-TECH (Tianjin) Co.,Ltd.

Awarded the second prize for scientific research achievements by the Ministry of Light Industry, the second prize for technological advancement by the Ministry of Health;published many articles on Chinese Journal of Oncology, Progress in Biochemistry and Biophysics. Directed the design and implementation of biotechnology:Industrialization projects covering genetically engineered drug interferon, interleukin 2, GCSF, prourokinase, influenza subunit vaccine, hepatitis A vaccine, epidemic encephalitis B vaccine etc.

分论坛：药厂自动化

赵云霞
发泰（天津）科技有限公司，
质量部质量经理

赵云霞，毕业于华西医科大学药学院药学专业。具有十五年跨国制药企业的工作经历，积累了丰富的质量管理、审计、注册及工程经验。

质量管理及验证：对于质量保障系统全面的知识及工作经验。4 年以上作为 TSKF/GSKT 代表接待来自国家及总部的各种审计 / 检查经验。熟悉国家、GSK 的各种质量法规。负责工厂新法规（中国、EU），QMS，质量警示的分析，措施制定及跟踪汇报工作。多年的产品放行、变更控制、偏差处理、内审经验。验证小组成员及产品验证经验。

第 3 方审计：具有 4 年以上独立审计经验，审计次数超过 50 次，其中包括 API，辅料，包材及合同商，有海外审计经验。熟悉 ICH Q 系列。有与 SMAP、RPS 合作审计经验。独立完成各种审计报告。参加过 GSK AUDITOR CERTIFICTION 培训。

产品委托生产及质量改进项目：作为质量部代表参加芬必得软胶囊项目（委托生产），进行预审计，协调 SMAP 审计，进行审计后合同商整改支持，及相关质量事宜。目前该合同商已预批准。进行 EYE MO 小瓶供应商纤维绩效改进支持，目前小瓶的纤维绩效有了大幅度的进步，实现了无退货。

制药工程项目：参与了天士力圣特项目的全过程。负责工作包括项目质量管理、供应商审计、试运行 / 验证计划及管理实施、EMS 系统验证管理、项目资料管理、项目会议组织及管理。参与的工作包括：工艺相关设计、设计审核等。

Pharmaceutical engineering

- Involve in the whole process of TTS(OSD) new plant project
- The responsibility in the project include:
- Design review
- Critical supplier audit and selection
- Construction quality control
- System Commissioning
- Critical system supplier Validation Management(PW generation units/PW loop/CA loop/EMS)
- Communication management
- Project documentation management
- Handover management

Quality assurance and validation

- Ages of OSD and Ointment production and quality management experience.
- Overall quality assurance experience and knowledge.
- Co-ordinate all internal and external quality/regulatory inspection on behalf of TSKF quality function for 4 years, be very familiar with QMS and Chinese GMP/GSP and relative regulations.
- Conducted gap analysis of site quality system vs. QMS, quality alert, new regulatory, addressed how to fill the gaps.
- Ages of product release, change control, deviation handling and internal audit experience.
- Ages of participant in site validation program, especially in product validation.

Audit

- Independent supplier/contractor audit experience for over 4 years, lead over 50 times audit. Have overseas supplier audit experience. Be familiar with ICH Q system.
- Have joint audit experience with SMAP and RPS.
- Independently writes quality reports for distribution within and outside of GSK for times.
- Attended GSK auditor certificate program in Y2005.

Registration

- Overall knowledge of Chinese registration regulatory; Working experience of product license renewal and supplement registration; Accepted Registration inspection as owner; Responsible of registration dossier management.
- Working experience of overseas product registration/Exported product registration, preparation the registration file for license renewal and supplement registration; Familiar with RADAR system.
- Familiar with RTD and TTS.

专家致辞

Gerd Kielburger
PROCESS ,Publisher

Dr. Kurt Wagemann
DECHEMA ,President

库尔特瓦格曼（Kurt Wagemann）先生于 1959 年出生。1989 年他在马克斯普朗克量子光学学院获得博士学位。自 1989 以来，他担任德国化学工程与生物技术协会（DECHEMA）一些主要部门（比如，研究规划、会议以及研究管理部门）的负责人。除此之外，他还担任德累斯顿 fms 协会和法兰克福 ProcessNet 论坛的执行理事。2010 年他成为德国化学工程与生物技术协会的执行理事。

Dr. Kurt Wagemann was born 1959 in Munich. He received his PhD in 1989 at the Max-Planck-Institut für Quantenoptik. Since 1989 he headed some of the large departments at the DECHEMA, as those for Research Planning, Congresses and for Research Management and Administration. Beside this, he held the offices of Executive director of fms e.V. in Dresden and of ProcessNet in Frankfurt. Since 2010 he is DECHEMA's executive director.

张奇
中国医药集团联合工程有限公司，总经理

张奇先生 1963 出生于湖北，1983 年毕业于武汉化工学院有机化工专业。历任国家医药管理局武汉医药设计院工艺设计室主任、院长助理、院长、党委书记，主持武汉医药设计院工作多年，为武汉医药设计院的发展作出了重要贡献，现任中国医药集团联合工程公司总经理、党委书记，教授级高级工程师、国家注册化工工程师。

Mr.Zhang Qi was born in Hubei Province in 1963 and graduated from Wuhan Institute of Chemical Technology and majored in organic chemical engineering. He served as Director of Process Design Office of Wuhan Pharmaceutical Design Institute under State Pharmaceutical Administration, Director Assistant, Director, and Party Secretary of Wuhan Pharmaceutical Design Institute under State Pharmaceutical Administration and has in charge of the work in Wuhan Pharmaceutical Design Institute for many years and has made important contribution to the development of Wuhan Pharmaceutical Design Institute. Currently, he serves as General Manager, Party Secretary, and Professor-level Senior Engineer of SINOPHARM United Engineering Corporation and is Sate Certified Chemical Engineer.

演讲人介绍

张宝林 博士
Baolin Zhang, Ph.D.

张宝林 博士

2001 – 至今美国食品药品监督管理局 (FDA)/ 生物技术药物评审办 (OBP)，资深评审，主任研究员 (Principal Investigator)

1997– 2001 美国田纳西大学医学院 (University of Tennessee, College of Medicine)/ 研究学者 (Senior Research Scientist)

1994– 1997 北京生化免疫制剂中心 / 北京实验动物研究中心研究员，总工程师

1993 – 1994 南京大学化学系，副教授

1992 – 1993 南京大学化学系，博士后

1989 – 1992 北京大学化学系，博士

1986 – 1989 兰州大学化学系，硕士

1982 – 1986 兰州大学化学系，学士

积十年 FDA 药物审批经验，精于蛋白质药物的生产工艺设计和产品的质量控制，熟悉相关的法规。

主持多项 FDA 重点研究课题 (Critical Path projects)，发表学术论文 70 余篇。对抗肿瘤药物的设计和优化有突出建树。担任多家国际学术刊物的编委。

Baolin Zhang, Ph.D.

2001-Now Senior Reviewer, Principal Investigator of Office of Biotechnology Products (OBP) of U.S Food and Drug Administration
1997-2001 Senior Research Scientist of College of Medicine, University of Tennessee
1994-1997 Researcher, Chief Engineer of Beijing Biochemical Immuno-preparations Center
Beijing Laboratory Animal Research Center
1993-1994 Associate Professor of Chemical Department, Nanjing University
1992-1993 Postdoctor, Chemical Department of Nanjing University
1989-1992 Doctor, Chemical Department of Peking University
1986-1989 Master, Lanzhou University
1982-1986 Bachelor, Chemical Department of Lanzhou University

He has ten years of experience in FDA drug examination and is skillful in design of protein drug production process and product quality control and is familiar with relevant laws and regulations. He took charge of many FDA Critical Path projects and has published more than seventy academic theses and has scored an achievement in design and optimization of antitumor drugs. He serves as editorial board member of many international academic journals.

演讲内容摘要

生物技术药物往往代表着最新的生物医学研究成果，而且对一些人类疑难病症有着奇特的功效，所以成为全球制药行业竞逐的领域。相对于化学合成药物，生物技术产品（比如蛋白质和抗体药物，Therapeutic proteins and monoclonal antibodies for human use）具有分子量大，结构和作用机制复杂，生产工艺特殊等特点。生产工艺的微小变化，比如原材料 (Raw materials)，细胞表达系统 (Cell banks)，生产设备，甚至生产规模的改变 (Scale-up)，都可能对产品质量造成巨大的影响。生产过程还往往带有感染病原体 (Adventitious agents) 的危险性。生产工艺不仅决定一个生物技术产品的物理化学属性 (Physicochemical attributes)，而且决定其生物活性 (Potency) 和临床安全性 (Clinical safety)。

同时需要考虑的是，蛋白质药物的稳定性 (Stability) 受多种环境因素的影响，比如温度，光照等。由此就更增加了产品的不均一性 (Heterogeneity) 和对质量控制 (Quality control) 的难度。另外，蛋白质药物具有潜在的引起人体免疫反应的能力 (Immunogenicity)。抗药抗体（Anti-drug antibodies）的形成不仅会影响到临床治疗效果 (Clinical efficacy)，而且会影响到药物的安全性。产品的不均一性，进一步使这一情况复杂化。这里将就生物技术药物生产过程中的有关问题进行讨论，并将对如何控制产品的质量，尤其是建立不同生产批次 (Manufacturing batches) 之间的可比性（Comparability）提出个人的一些看法。

程毓渡

上海新科咨询，执行总裁

程毓渡博士，上海新科咨询，执行总裁

GMP 高级审计师、咨询师，加拿大新科咨询有限公司执行总裁。

专业知识、资历、专长和技能：GMP（ICHQ7，cGMP，EU/GMP）审计，包括官方陪同审计、供应商审计和模拟审计 GMP（ICHQ7，cGMP，EU/GMP）培训，包括公开培训和内部培训 GMP（ICHQ7，cGMP，EU/GMP）咨询，包括建立 GMP 系统、缺陷整改体系外包项目的质量管理中国新版 GMP（欧盟版）解读与实施，GMP 培训中国国家食品药品监督管理局培训中心（SFDA-TC）高级培训师，国际制药工程协会（ISPE）会员；美国注射用药协会（PDA）会员。

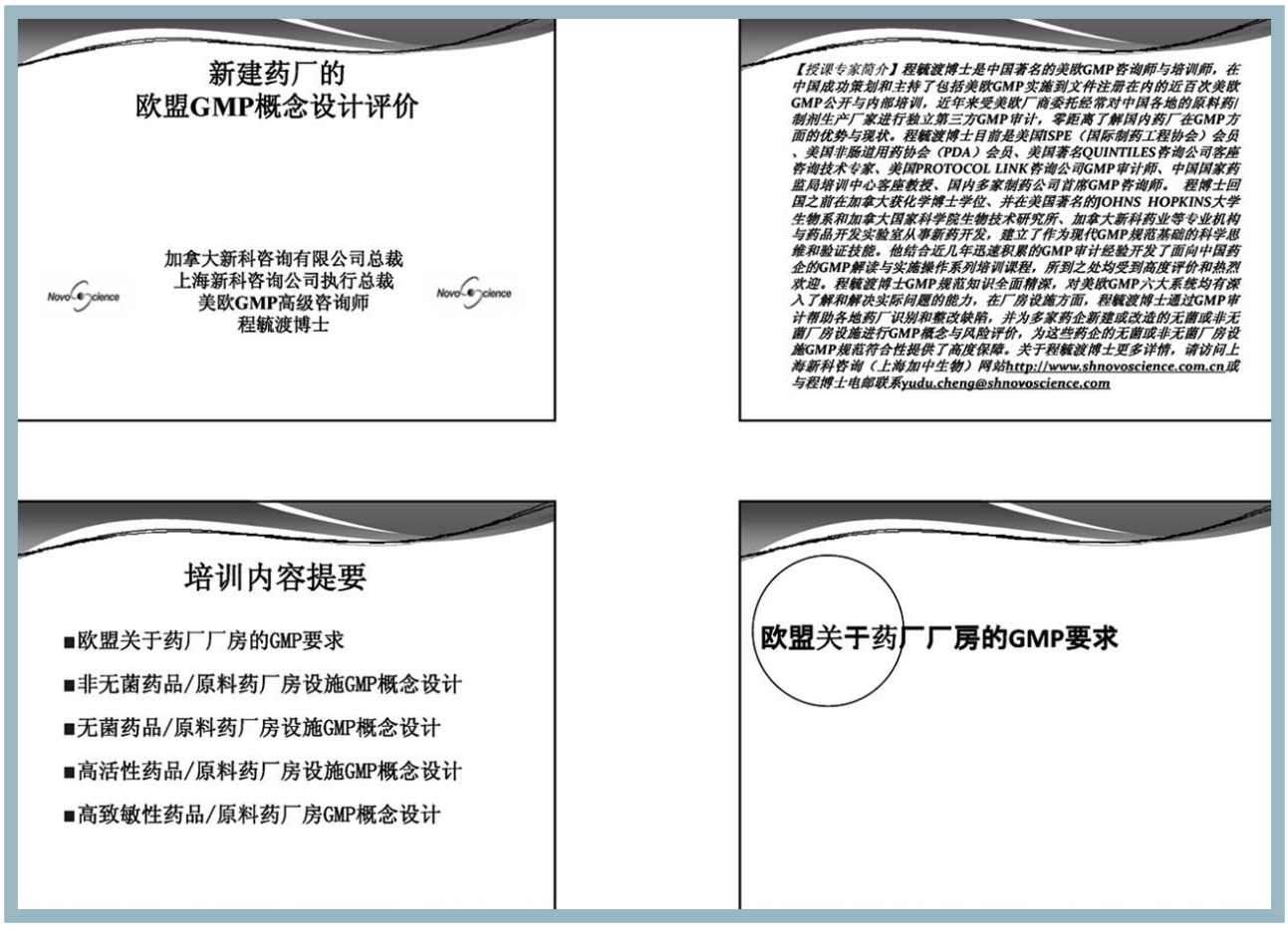
Dr.Frank.Cheng，Shanghai NovoScience Consulting,Executive President

Senior GMP Auditor, Consultant, Executive President of Canada NovoScience Consulting Co., Ltd.

Professional knowledge, qualification, expertise and skills：GMP（ICHQ7，cGMP，EU/GMP）audit，including authority, supplier and mock audit, GMP（ICHQ7，cGMP，EU/GMP）training, including public and in-house training, GMP（ICHQ7，cGMP，EU/GMP）consulting, including establishing GMP system, CAPA systems and quality management of outsourced projects, new Chinese GMP(EU version) analysis and implementation. He is Senior GMP Trainer of SFDA-TC and ISPE/PDA member.

演讲内容摘要

欧盟关于药厂厂房的 GMP 要求
非无菌药品 / 原料药厂房设施 GMP 概念设计
无菌药品 / 原料药厂房设施 GMP 概念设计
高活性药品 / 原料药厂房设施 GMP 概念设计
高致敏性药品 / 原料药厂房 GMP 概念设计



Ole Broch Nielsen

恩宜珐玛（天津）工程有限公司上海分公司，总经理

恩宜珐玛（天津）工程有限公司

恩宜珐玛是一家在制药和生物科技领域提供工程和咨询服务的世界领先公司。总部位于丹麦哥本哈根，在全球 20 多个地区的员工超过 1500 人。1995 年进入中国，目前总部位于天津，分公司位于上海和广州。恩宜珐玛为客户提供全面的服务，在中国我们有 300 多名员工，数目不断增长。对制药产业的所有环节有着独到深刻的认识，拥有广为认可的项目执行方案，恩宜珐玛帮助客户规划建造满足所有生产要求并符合法规的先进厂房设施。服务包括咨询、工程设计、施工管理、验证以及自动化、洁净室、模块化设施的全套解决方案。

Ole Broch Nielsen，恩宜珐玛（天津）工程有限公司上海分公司，总经理

Ole Broch Nielsen 先生是恩宜珐玛上海分公司的总经理。他在医药生物领域有超过 18 年的项目管理、项目启动、试运行以及验证经验。他曾管理过葛兰素史可生物、辉瑞、诺和诺德等客户在世界各地的项目。在 2005 年，由 Ole 管理的项目获得由 ISPE 颁发的"年度最佳项目"大奖。这是一个诺和诺德的 Factor VII 项目，Ole 十分成功地将生物技术模块化设计应用到项目建设中，显示了他卓越的管理能力。

NNE pharmaplan (Tianjin) Co., Ltd.

NNE Pharmaplan is the world's leading engineering and consulting company focused exclusively on the Pharma and Biotech industry.Headquartered in Copenhagen, Denmark, NNE Pharmaplan employs over 1,500 people in more than 20 locations around the world.NNE Pharmaplan entered China in 1995 and is currently presented with the headquarter in Tianjin and branch offices in Shanghai and Guangzhou. NNE Pharmaplan is a full-service provider with a workforce of more than 300 employees in China and the number is continuously growing.With unique knowledge of the entire supply chain and a proven project execution model, we help our clients plan and execute state-of-the-art facilities that meet all production and regulatory demands. Our services include consulting, engineering, construction, validation and complete solutions for automation, clean rooms and modular facilities.

Ole Broch Nielsen，NNE Pharmaplan (Tianjin) Co., Ltd Shanghai Branch Company，Managing Director

Mr. Ole Broch Nielsen is the Managing Director of Shanghai Office of NNE Pharmaplan in China. He has over 18 years experience of program management, start-up, commissioning & qualification management of Pharmaceutical and Biotech. He has managed a number of projects for GSK bio, Pfizer, Bavarian Nordic, Novo Nordisk, etc. around the world.

In 2005, Factor VII project, managed by Ole was awarded as "Facility of the Year" by ISPE. He has shown his outstanding management skills in a great successful biotech module construction.

演讲内容摘要

大型 cGMP 无菌生产快建项目，包括从设计、土建、试运行、验证到最终交付。案例分析：一个在 11 个月内完成的复杂项目此项目，展示了在设计工艺模块的同时建立生产工厂的快速管理方案。面对挑战的解决方案；快速决策和风险管理；快速设计和施工；项目经验总结。

张福利

上海医药工业研究院，化学制药部主任

张福利，上海医药工业研究院，化学制药部主任

1993 年 7 月硕士生毕业至上海医药工业研究院工作至今
1999 年 9 月获得博士（在职）学位
2002 年 12 月晋升研究员
2004 年 7 月担任化学制药部主任
2006 年 6 月评为博士生导师

现为上海医药工业研究院化学制药部主任，院学术委员会委员和学位委员会委员，上海市药化专业委员会委员，上海市生物工程学会终身会员，中国医药工业杂志编委，浙江海正药业 - 上海医药工业研究院联合实验室主任，江苏康缘药业 - 上海医药工业研究院联合研究中心主任。长期从事药物重大品种工艺研究和化学创新药物研究，研究领域涉及心脑血管疾病、老年痴呆、哮喘、肿瘤、真菌感染、免疫抑制剂等治疗药物的基础研究和应用开发研究，尤其在手性药物的不对称合成以及重大品种的产业化方面形成技术优势，先后负责 20 余项课题的研制开发，包括国家和省部级重点科研项目 5 项。在国内外期刊发表论文 15 篇，参与编写专著 1 部，近年来已申请发明专利 40 项（授权 9 项，其中美国专利 1 项），申请 PCT 专利 6 项。已培养博士生 3 名，硕士生 9 名。2001 年获得上海市科委青年科技启明星称号，2010 年获得上海市优秀学科带头人称号。

Zhang Fuli，Shanghai Institute of Pharmaceutical Industry, Director of Chemical Pharmaceutical Department

Zhang Fuli，male，born in 1968，PhD，Researcher，Doctoral Supervisor; currently Director of Chemical Pharmaceutical Department of Shanghai Institute of Pharmaceutical Industry, member of Academic Committee and Academic Degree Committee of Shanghai Institute of Pharmaceutical Industry, member of Shanghai Chemical Pharmaceutical Committee, life member of Shanghai Society for Biotechnology, editorial board member of Chinese Journal of Pharmaceuticals magazine, Director of joint laboratory of Zhejiang Hisun Pharmaceutical Co. Ltd and Shanghai Institute of Pharmaceutical Industry, Director of Joint Research Center of Jiangsu Kanion Pharmaceutical and Shanghai Institute of Pharmaceutical Industry. He has been engaged in research on processes for major drug varieties and innovative chemical drugs and basic research and application research and development of therapeutic drugs for cardiovascular and cerebrovascular diseases, senile dementia, asthma, tumour, fungal infections and immunosuppressant for a long time especially he enjoys technical advantages in asymmetric synthesis of chiral drugs and commercialization of major varieties. He successively performed research and development on more than twenty research subjects including five national, provincial and ministerial key research projects. He has published fifteen papers in domestic and foreign periodicals and participated in compiling one monograph and has applied for forty invention patents (with nine granted, of which one is U.S patent) and six PCT patents. He has cultivated three doctoral students and nine master students. He was awarded the title of Youth Science and Technology Morning Star by Science and Technology Commission of Shanghai Municipality in 2001 and the title of Academic Pacesetter of Shanghai Municipality in 2010.

演讲内容摘要

第一部分　前言
第二部分　工艺改进实例分析
（一　新反应新技术的应用、二　绿色化学的要求、三　抓住异常现象深入研究、四　装备技术的应用）
第三部分　工艺改进中的辩证法
第四部分　几点体会

王伟
上海净泽洁净设备有限公司，总经理

上海净泽洁净设备有限公司

上海净泽洁净设备有限公司是一家专业工艺设计，安装和验证的工程公司。公司的客户主要是国际制药厂，国内正在通过 FDA 或 EMEA 认证并出口的制药厂，以及国际工程咨询公司。公司的业务范围包括洁净公用设施（USP 纯水、注射用水、纯蒸汽、洁净压缩空气、氮气）和工艺生产设备（液体混合、CIP、SIP、自动化系统）的设计、施工和验证。公司同时致力于标准设备的模块化制造和验证。国际客户的经验和来自于国际公司的员工是我们的真正优势。

王伟 上海净泽洁净设备有限公司，总经理

毕业于华东理工大学化学工程专业，曾任职于 UNILEVER，GEA 公司，担任项目经理，业务发展经理，长期从事于制药行业的工艺设计，安装与确认的管理工作。在 2003 年创办净泽洁净设备有限公司，主要为外资药厂和本土领先药企提供 cGMP 工艺安装和确认服务，曾为北京大学，SFDA GMP 培训中心提供过相关的培训课程。

Winatech Process Engineering (Shanghai) Co., Ltd.

Winatech Process Engineering (Shanghai) Co., Ltd. is a specialized engineering firm who focus on process design, installation and qualification. It's clients are majorly multinational pharmaceutical companies, leading local pharms which are targeting FDA and EMEA approval for export business, and the leading international engineering consulting firms. The delivery package cover the clean utilities (USP purified water, WFI, Pure steam, Clean Compressed Air, N2) and process equipment (Mixing, CIP ,SIP, Automation) . It also now provide the modular system manufacturing and qualification. It strength lies in that our extensive international references and our team member's multinational working experience.

William Wang，Winatech Process Engineering（Shanghai）Co.,Ltd，General Manager

Graduated from Chemical Engineering Major of East China University of Science and Technology, William worked as project manager, business development manager for Unilever and GEA. He has more than 10 years management experience of the process installation and qualification in pharm industry. In 2003, he set up Winatech Process Engineering (Shanghai) Co,, Ltd., which provides cGMP installation and qualification service for foreign pharmaceuticals such as Abbott ,Roche, MSD, Novartis, Baxter ,Novozyme and leading local pharms such as Tasly, Yilin, Haisun. He has provided related training course for Pekin University and SFDA GMP training center.

余翔

拜耳技术工程(上海)有限公司，过程分析技术主管

拜耳技术工程（上海）有限公司

拜耳技术工程 (上海) 有限公司作为拜耳集团全资子公司，成立于 2003 年 11 月，面向化工和医药行业生产装置的整个生命周期，从项目投资决策，到工厂设计施工，乃至技术去瓶颈和研发支持，依托拜耳集团百年技术底蕴，秉承不断创新的理念，为内、外部客户创造持久而有效的竞争优势。

拜耳技术工程 (上海) 有限公司的项目成功案例遍及全世界。其项目及施工管理服务包括：进度表协调、施工现场组织、施工监理、冷试车模拟培训及装置开工，从工程咨询到一揽子交钥匙工程，帮助客户实现风险最小化，以便专注于核心业务。自建立以来，已完成包括拜耳上海一体化基地聚碳酸酯项目、聚氨酯项目、拜耳医药保健北京药厂扩建等项目，并为瓦克化学、朗盛化学、科宁化学、云南白药、抚顺高新技术开发区等客户和机构提供了国际级的项目管理和工程规划、建设服务。

余翔，拜耳技术工程（上海）有限公司，过程分析技术主管

从德国卡尔斯鲁厄大学获得硕士学位，主修化学工程（理科硕士学位）。自 2004 年以来，她在拜耳技术工程（上海）有限公司从事过程分析技术领域的工作。现任拜耳技术工程（上海）有限公司过程分析技术主管。

Bayer Technology and Engineering (Shanghai) Company Limited

Bayer Technology and Engineering (Shanghai) Company Limited (BTES) offers fully integrated solutions along the life cycle of chemical/pharmaceutical plants - from development through engineering and construction to process optimization for existing plants, as well as market evaluation and investment consultation and services in China and Asia. BTES sees you through the capital investment process, aiming for better quality as well as increased productivity and profitability. The innovative services cover from engineering consultation, training simulators to online analysis system (SpectroBAY), manufacturing execution systems (MES) and supply chain optimization.

Ms. Xiang YU

Ms. Yu received Master Degree from the University of Karlsruhe in Germany major in Chemical engineering (Master of Science). Since 2004, she has been working in the area of Process Analyzer Technology at Bayer Technology and Engineering Shanghai Co., Ltd. Currently she is the head of Process Analyzer Technology at BTES.

演讲内容摘要

许多常规在线分析方法如 pH，插入式全光谱分析法及应用于发酵罐废气监测的分析技术已被广泛应用于制药工艺中并得到推广。另外越来越多的实验室分析法如细胞计数和色谱法在逐渐被在线化应用。

在报告中简要介绍了制药工业中在线分析技术的现状，此外对常规在线分析工具包所含的新技术也作了案例分析讨论。

谢京军

恩宜珐玛 (天津) 工程有限公司，质量验证经理

恩宜珐玛 (天津) 工程有限公司

恩宜珐玛是一家在制药和生物科技领域提供工程和咨询服务的世界领先公司。总部位于丹麦哥本哈根，在全球 20 多个地区的员工超过 1500 人。1995 年进入中国，目前总部位于天津，分公司位于上海和广州。恩宜珐玛为客户提供全面的服务，在中国我们有 300 多名员工，数目不断增长。对制药产业的所有环节有着独到深刻的认识，拥有广为认可的项目执行方案，恩宜珐玛帮助客户规划建造满足所有生产要求并符合法规的先进厂房设施。服务包括咨询、工程设计、施工管理、验证以及自动化、洁净室、模块化设施的全套解决方案。

谢京军，恩宜珐玛 (天津) 工程有限公司，质量验证经理

谢京军是恩宜珐玛中国的质量验证经理。他在医药，生物生产和咨询服务领域有超过 10 年的工作经验。他曾担任质量经理，质量工程师和 GMP 顾问。谢京军从生产到仓库物流有丰富的 GMP 验证经验。他掌握自动阀的 cGMP 要求，灭菌验证和供应商审计。他曾在丹麦和中国负责很多项目的质量验证和 GMP 验证。

NNE pharmaplan (Tianjin) Co., Ltd.

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Xie Jingjun, Quality Manager, NNE Pharmaplan (Tianjin) Co., Ltd.

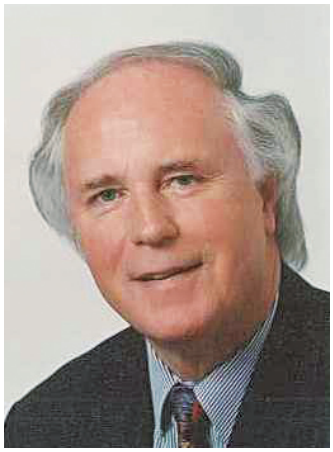
Mr. Xie Jingjun is Quality Manager of NNE Pharmaplan in China. He has more than 10 years of experience within Pharma/Bio production and delivering consultancy services to the industry. He has taken roles as Quality Project Manager, Quality Engineer and GMP Consultant.

Jingjun has rich GMP compliance experience from production and warehouse logistics. His knowledge also covers cGMP requirements for autoclaves, sterilization validation and supplier auditing. He has been responsible for GMP compliance and Qualification & Validation execution for a number of projects both in Denmark and China. In the ISPE-CCPIE China Training 2009, Jinjun had been invited as speaker to give the training on ″GMP Principle in Engineering and Concept Design″ .

演讲内容摘要

医药行业和医药工程系统必须面对的挑战：政府对医药生产工厂的设计，施工，试运行和验证有严格规定，药厂需要满足卫生局 cGMP 要求和符合其他法律法规工程方案和实施，必须为药厂在节约成本的基础上按时完成并达到质量要求。为了在医药项目中建立与 GEP 紧密连接的验证原则 / 系统，应对以上挑战是至关重要的。

讲演中将会介绍以下论题：良好工程管理规范；GMP 和 GEP 联系；试运行和质量验证；一种在医药工程项目中建立验证原则 / 系统的方法；项目客户要求；医药工程项目中的风险管理；定义系统边界；系统影响评估；设计审核 / 提高设计审核 / 文件验证



h.c. Herbert Hüttlin

首席执行官

INNOJET Herbert Hüttlin 公司

h.c. Herbert Hüttlin 博士（巴登）是一名德国企业家、制药行业的开拓者以及 Hüttlin-Kugelmotor 的设计者。他拥有流体工程师、制药技师的资质，是 INNOJET Herbert Hüttlin 公司的创始人和首席执行官。他也是 INNOMTO 公司的大股东和总裁，该公司负责研制 Hüttlin-Kugelmotor 的样机并出售许可。他已经采用大量专利，大部分专利正在使用当中。

他因在制药技术方面取得的成就而获得多项殊荣。多年来，他与位于弗莱堡市的艾伯特路德维希大学和其他德国和国际专业人士（在制药技术和生物制药方面）展开密切合作。

Herbert Hüttlin 已经将 100 多项专利技术应用于 10~25 个工业国家。多年来，Herbert Hüttlin 博士所开发的技术被德国固体剂型制药技术方面的教科书所采纳。

另外，在包衣和造粒新技术方面，Herbert Hüttlin 博士开发了 Hüttlin-Kugelmotor 新型混合技术和范围扩展器并在很多重要的工业国家获得 50 多项专利。

h.c. Herbert Hüttlin，Innojet，CEO

Dr. h.c. Herbert Hüttlin is a German entrepreneur, developer of improvement in the pharmaceutical sector and designer of Hüttlin-Kugelmotor.

He has the qualification as a fluid engineer, pharmaceutical technologist as well as founder and CEO of INNOJET Herbert Hüttlin. Furthermore he is majority shareholder and SB-President of INNOMTO AG, which develops prototype of Hüttlin-Kugelmotor and sells licenses. He has applied for a large number of patents, of which most are in use, too.

For his lifelong achievement in pharmaceutical technology he was awarded with high tributes and honor. For several years he worked very closely with Albert-Ludwigs-University in Freiburg (pharmaceutical technology and bio pharmacy) and other German and international professorships.

Hüttlin has applied for more than 100 patents for such technologies, each in 10 – 25 industrialized countries.

Technologies developed by Dr. h.c. Herbert Hüttlin are part of German educational books on pharmaceutical technology for solid dosage forms for many years.

Next to new technologies for coating and granulation Dr. h.c. Herbert Hüttlin developed the Hüttlin-Kugelmotor as a new engine technology, also as Hybrid, and Range Extender with more than 50 patents in all important industrialized countries.

戴维 • 文森特

David W. Vincent

首席执行官

演讲内容摘要

I. 符合清洗验证的法规要求说明并达到美国 FDA 要求、欧盟要求以及行业标准；阐述与清洗相关的检查指导文件；评估最新的法规趋势及问题；为共用设备及产品设定“最差状况”条件。

II. 清洗技术及开发研究进行实验室级别研究；如何进行工艺分析清洗评估 (PACE) 研究；设定关键工艺参数；为（在线清洗）CIP 及（拆卸清洗）COP 制订关键操作范围。

III. 清洗工艺验证清洗验证计划；制订清洗验证方案；清洗数据总结报告。

IV. 设定允许残留物限度确定潜在污染源或残留物；计算出科学合理的残留物限度；学习如何计算清洁剂残留限度以及其他非治疗性残留物限度；使用“目视清洁”作为清洗标准；计算产品残留限度。

V. 取样及测试清洗试样熟悉各种不同类型的取样技术擦拭取样；淋洗取样；确定不同取样方法的优劣；熟悉取样技术概念及其重要性；确定最适合清洗试样的分析方法。

验证技术有限公司（VTI）

验证技术有限公司（VTI）致力于为医药、生物技术以及医疗器械行业提供专业、卓越的验证及试车服务。

公司可提供全方位的专业服务，包括：计算机验证、清洁验证、工艺验证、洁净室验证、温度分布监测、工艺设备及设施确认等，致力于为客户提供优质、个性化的技术支持。

戴维 • 文森特（David W. Vincent）博士，首席执行官

文森特先生从事卫生保健行业工作超过 25 年，涉足制药、医疗设备、生物技术和生物制药行业。他获得机械工程技术和工业微生物专业学历。他已经在验证领域工作 19 年之久。他专长于监管事务、质量保证、验证和工程（包括监管资料申报、工程设计审查、试运转、施工、质量体系的实施、项目管理、公共设施和工艺设备合格证明）特别是试运转、合格证明、工艺开发和工艺验证以及环境监测和清洁验证计划的开发和实施。

文森特先生在最近 17 年间向各公司提供工程验证和质量咨询服务，在这期间，他为众多国内外客户提供项目管理和项目执行服务。他负责管理和支持各种产品发布。他是 VTI 的质量保证协调员，负责实施和维持 VTI 的内部质量计划、ISO 认证和公司培训。他在州立圣迭戈大学讲授验证技术（RA-776）领域监管事务硕士学位课程。

VTI Technologies

Validation Technologies strives to maintain and inspire professional excellence by providing Validation and Commissioning Services to the Pharmaceutical, Biotechnology and Medical Device Industries.

We offer a full spectrum of services such as computer validation, cleaning validation, process validation, clean room certification, temperature mapping, process equipment and facility qualification, and much more. Dedication to quality, personalized support and the success of your projects are the foundation of our company.

David W. Vincent, PhD，CEO

Mr. Vincent has over twenty-five (25) years experience in the health care industry specializing in the Pharmaceutical, Medical Device, Biotechnology and Biopharmaceutical industries. He has degrees in Mechanical Engineering Technology and Industrial Microbiology. He has over (19) nineteen years dedicated to the field of validation. He has expertise in many areas of Regulatory Affairs, Quality Assurance, Validation and Engineering including; Regulatory Submission preparation, Engineering Design Review, Commissioning, Construction, Quality Systems implementation, Project Management, Utility and Process Equipment Qualification implementation. He is especially strong in the areas of Commissioning, Qualification, Process Development and Process Validation as well as developing and implementing Environmental Monitoring and Cleaning Validation Programs.

Mr. Vincent has spent the last seventeen (17) years providing engineering validation and quality consultant services to various companies. During this time, Mr. Vincent has provided both project management and project execution for numerous clients

national and international. He is responsible for managing and supporting many

different product launches. He is the Quality Assurance Coordinator for VTI and is responsible for implementing and maintaining VTI's Internal Quality Programs, ISO certification and corporate training. He teaches at San Diego State University (SDSU) for their Masters of Regulatory Affairs Degree program in the Field of Validation Technology RA-776.Mr. Vincent has expertise in many areas of Regulatory Affairs, Quality Assurance, Validation and Engineering including; Regulatory Submission preparation, Engineering Design Review, Commissioning, Construction, Quality Systems implementation, Project Management, Utility and Process Equipment Qualification implementation. He is especially strong in the areas of Commissioning, Qualification, Process Development and Process Validation as well as developing and implementing Environmental Monitoring and Cleaning Validation Programs.

王建宇

安卓物料自动化系统（天津）有限公司，总经理

安卓物料自动化系统（天津）有限公司

AZO 致力于全自动化流程中对原材料可靠的处理。无论是散状物料、小宗物料还是液体物料，我们都能给出完美的解决方案、精确的时间和准确的数量。具有未来竞争力的工艺流程、创新性的过程技术以及面向未来的过程 -IT 技术是满足食品、制药、合成材料和化工等领域中最高质量标准的基础。

AZO 的成功首先要归功于其解决方案的质量和可靠性以及在自动化物料处理领域里 60 多年积累的丰富经验。今天，AZO 是在原材料、配料、香料、添加剂、色素、小宗物料和液体物料等自动化处理方面的世界级领军企业之一。在全球范围内，AZO 利用未来科技帮助成功企业实现其具有创新性的项目。

王建宇，安卓物料自动化系统（天津）有限公司，总经理

2004 年 8 月 ～2006 年 12 月：AZO GmbH & Co. KG（德国），地区销售经理

2007 年 1 月 ～ 今：安卓物料自动化系统（天津）有限公司，总经理

AZO Ingredients Automation System (Tianjin) Co.,Ltd

AZO is committed to reliable handling of raw materials in full automation process. We can provide perfect solutions with accurate time and quantity, regardless of bulk materials, small lot materials and liquid materials. Process flow with competitiveness in the future, innovative process technology and future-oriented process-IT serve as the foundation for reaching the highest quality standard in foodstuff, pharmaceutical, synthetic material and chemical industry.

Our success is firstly attributable to high quality and reliability of our solutions and our rich experience in automatic handling of materials for more than 60 years. Currently, we are one of the world leading enterprises in automatic handling of raw materials, auxiliary materials, condiments, additives, coloring matters, small lot materials and liquid materials. We adopt future science and technology to help successful enterprises launch innovative projects worldwide.

Wang Jianyu, General Manager of AZO Ingredients Automation System (Tianjin) Co.,Ltd

August, 2004 – December, 2006: Regional Sales Manager of AZO GmbH & Co. KG (Germany)

January, 2007 – Now: General Manager of AZO Ingredients Automation System (Tianjin) Co.,Ltd

Tonny Evan Jørgensen

丹麦恩宜珐玛有限公司，
高级项目经理

恩宜珐玛（天津）工程有限公司

恩宜珐玛是一家在制药和生物科技领域提供工程和咨询服务的世界领先公司。总部位于丹麦哥本哈根，在全球 20 多个地区的员工超过 1500 人。1995 年进入中国，目前总部位于天津，分公司位于上海和广州。恩宜珐玛为客户提供全面的服务，在中国我们有 300 多名员工，数目不断增长。对制药产业的所有环节有着独到深刻的认识，拥有广为认可的项目执行方案，恩宜珐玛帮助客户规划建造满足所有生产要求并符合法规的先进厂房设施。服务包括咨询、工程设计、施工管理、验证以及自动化、洁净室、模块化设施的全套解决方案。

Tonny Evan Jørgensen，丹麦恩宜珐玛有限公司，高级项目经理

Tonny Evan Jørgensen 先生是制药厂项目管理的专家。他具有 20 多年全球大型跨专业项目的执行经验。Tonny Evan Jørgensen 先生在建造方面的深厚背景加之工程执行的相关知识确保高水准进行项目准备、工艺过程管理、项目执行、项目管理以及全面交付项目建设成果。Tonny Evan Jørgensen 先生是诺和诺德制药公司在全球众多无菌工程项目的设计、建造、试运转和合格证明的主要参与者。

NNE pharmaplan (Tianjin) Co., Ltd.

NNE Pharmaplan is the world's leading engineering and consulting company focused exclusively on the Pharma and Biotech industry.Headquartered in Copenhagen, Denmark, NNE Pharmaplan employs over 1,500 people in more than 20 locations around the world.NNE Pharmaplan entered China in 1995 and is currently presented with the headquarter in Tianjin and branch offices in Shanghai and Guangzhou. NNE Pharmaplan is a full-service provider with a workforce of more than 300 employees in China and the number is continuously growing.With unique knowledge of the entire supply chain and a proven project execution model, we help our clients plan and execute state-of-the-art facilities that meet all production and regulatory demands. Our services include consulting, engineering, construction, validation and complete solutions for automation, clean rooms and modular facilities.

Tonny Evan Jørgensen, Senior Project Manager, NNE Pharmaplan, Denmark

Mr. Tonny Evan Jørgensen is an expert of project management of pharmaceutical plant. He has more than 20 years of project execution experience within multidisciplinary big size projects worldwide.

Tonny's background in construction combined with his knowledge of engineering execution, ensures a high level of project preparation, process engineering, project executions, project management and overall deliverables.

Tonny has been the main player for the engineering, construction, commissioning and qualification for a number of aseptic projects for Novo Nordisk around the world.

演讲内容摘要

该演讲阐述了项目的建立及设计阶段的关键点，以确保实现业主的核心需求，并以一个国内的无菌灌装项目进行案例分析：业主及工程项目定义阶段；概念设计和关键的交付；基础设计，目标及执行模式涵盖的内容；业主与工程师的关系；生产设施生命周期管理；执行期间的知识积累与提高；风险管理。

施凯

拜耳技术服务(上海)有限公司，
高级暖通工程师

拜耳技术工程（上海）有限公司

拜耳技术工程 (上海) 有限公司作为拜耳集团全资子公司，成立于 2003 年 11 月，面向化工和医药行业生产装置的整个生命周期，从项目投资决策，到工厂设计施工，乃至技术去瓶颈和研发支持，依托拜耳集团百年技术底蕴，秉承不断创新的理念，为内、外部客户创造持久而有效的竞争优势。 拜耳技术工程 (上海) 有限公司的项目成功案例遍及全世界。其项目及施工管理服务包括：进度表协调、施工现场组织、施工监理、冷试车模拟培训及装置开工，从工程咨询到一揽子交钥匙工程，帮助客户实现风险最小化，以便专注于核心业务。自建立以来，已完成包括拜耳上海一体化基地聚碳酸酯项目、聚氨酯项目、拜耳医药保健北京药厂扩建等项目，并为瓦克化学、朗盛化学、科宁化学、云南白药、抚顺高新技术开发区等客户和机构提供了国际级的项目管理和工程规划、建设服务。

施凯，拜耳技术服务（上海）有限公司，高级暖通工程师

高级暖通工程师，国家一级注册公用设备工程师，曾工作于上海医药设计院，具有十多年医药厂房洁净空调系统设计经验，并对空调系统节能优化方面有较深研究。

Bayer Technology and Engineering (Shanghai) Company Limited

Bayer Technology and Engineering (Shanghai) Company Limited (BTES) offers fully integrated solutions along the life cycle of chemical/pharmaceutical plants - from development through engineering and construction to process optimization for existing plants, as well as market evaluation and investment consultation and services in China and Asia. BTES sees you through the capital investment process, aiming for better quality as well as increased productivity and profitability. The innovative services cover from engineering consultation, training simulators to online analysis system (SpectroBAY), manufacturing execution systems (MES) and supply chain optimization.

Shi Kai，Bayer Technology and Engineering (Shanghai) Co.,Ltd，Senior HVAC Engineer

First-grade State Certified Public Equipment Engineer, worked in Shanghai Pharmaceutical Design Institute.He has more than ten years of experience in designing clean air-conditioning system for pharmaceutical factory building and has in-depth research on energy optimization of air-conditioning system.

演讲内容摘要

随着新版 GMP 将在 2010 年正式推行，HVAC 系统设计方案面临着运行效果和能耗效率的双重挑战，将就以下几点展开讨论：如何选取合理的设计参数去应对新要求导致的 HVAC 系统的扩容问题（比如：如何建立“B”环境，如何选择合适的压差。）；如何采用局部处理来降低工艺设备负荷对空调系统的影响，以全面降低系统容量；采用先进的控制逻辑来降低运行时系统冗余的容量；合理选用有效的热回收；空气处理系统中除湿段的运用。

苏帮廷
上海新旭发机械科技有限公司，
副总经理

上海新旭发机械科技有限公司

自 1994 年建立以来一直从事液体药品制剂洗烘灌联动生产线和双扉门干热灭菌柜的研发、制造和市场推广并得到了国内用户的广泛认可，同时也深受国外用户的青睐，不同形式的联动线运行在南美洲、东南亚、西亚地区、中东地区、欧洲、俄罗斯及其独联体等国家中的用户多达 60 多家。新旭发灌装联动生产线已经在行业中主流药厂的心目中不可被忽视的供应商。随着 GMP 规范的不断提升，传统的、仅仅满足灌装需求的联动线已经远远不能符合用户的需求，新旭发也因此在 2008 年就开始开发多种更符合 c-GMP 的、应用于从洗瓶机、隧道烘箱到灌装机的功能并同时开始了 RABS 系统、隔离罩系统和无菌转移系统的研制，将灌装联动生产线演绎成了一个正真意义上的独立的无菌灌装系统，从而将人介入的潜在污染风险被隔离于无菌灌装工艺过程之外。

苏帮廷，上海新旭发机械科技有限公司，副总经理

从事药品质量、生产管理 24 年。曾担任湖北制药联合有限公司厂长、山西通盛医药物流有限公司总经理，具有丰富的规范药品生产流程经验。

Shanghai Xinxufa Machine S&T Co., Ltd

Since its inception in 1994, the Company has specialized in research, development, manufacturing and marketing of liquid pharmaceutical preparations cleaning, drying and filling interlocking production line and dry heat sterilization cabinet with two-leafs door which have been widely recognized by domestic users and enjoy great popularity among foreign users. Interlocking lines in various forms are operated by more than sixty users from South America, Southeast Asia, West Asia, Middle East, Europe, Russia and its Commonwealth of the Independent States. Xinxufa has become the interlocking bottling production line provider to be reckoned with for mainstream pharmaceutical factories in the industry.

With continuous improvement in GMP, conventional interlocking lines which only meet bottling demand have been much incapable of satisfying user's demand. In response to this, Xinxufa started developing various functions of bottle washer, tunnel drying oven and filling machine which more comply with c-GMP and RABS system, isolation hood system and sterile transfer system in 2008, which makes interlocking bottling production line into the real standalone sterile bottling system and thus helps isolate potential human-induced pollution risks from sterile bottling process.

Su Bangting, Deputy General Manager of Shanghai Xinxufa Machine

He has been working in drug quality, production management for 24 years. He served as Factory Director of Hubei Pharmaceutical Co., Ltd and General Manager of Shanxi Tongsheng Pharmaceutical Logistics Co., Ltd. He has rich experience in standardized pharmaceutical production process.

朱雄亮

瑞士可瑞水技术集团，自控及售后服务经理

瑞士可瑞水技术集团（Christ Water Technology Group）

成立于 1939 年，是全球最大的水处理公司之一。1972 年将反渗透（RO）应用到制药行业；1994 年研发出卷式 EDI（电法去离子），获得专利并在制药与生命科学行业推广；至 2008 年底，可瑞在全球超过 1000 套带 EDI 的纯化水装置为制药与生命科学企业制备高品质的纯化水。

2003 年开始，可瑞水技术集团进入中国，成立了可瑞制药用水处理设备（上海）有限公司 Christ Pharma & Life Science (Shanghai) Ltd. 将世界领先的纯化水制造技术引进中国，为中国的制药企业提供了适合中国国情、并完全符合欧美药典和中国药典规定要求的纯化水制备、存储和分配装置。公司组装工厂位于上海青浦高新技术开发区，全套采用瑞士可瑞设计理念及制造工艺，外籍专家常驻指导，提供符合美国 FDA 要求和 GAMP 要求的高品质纯化水装置。在中国的客户有罗氏制药、雅培制药、中美史克、西安杨森、北京诺华、石药集团、扬子江集团、浙江海正等。

可瑞水技术集团已经为 80 多个国家和地区的 540 多家制药企业提供过水处理制备装置。

可瑞中国工厂主要产品：

纯化水制备装置 OSMOTRON

注射用水制备装置 MULTITRON

纯蒸汽制备装置 VAPOTRON

纯化水、注射用水分配装置 LOOPO

朱雄亮

浙江宁波人，2005 年开始从事纯水系统自控的设计工作和纯水系统调试服务工作。

曾参与国内多家药厂如：上海莱士、上海雅培、成都蓉生，和国外著名药厂如：韩国 Hanmi、巴西的 Europharma 等。

期间也从事过 蒸馏水机和纯蒸汽发生器自控设计和调试工作，目前就职于可瑞（上海）任自控及售后服务经理。

Christ Water Technology Group

Christ Water Technology Group was established in 1939, is one of the biggest water treatment company in the worldwide. Christ first used reverse osmosis (RO) in pharmaceutical industry in 1972; in 1994, Christ researched & developed volume Electro De Ionization (EDI) which got patent to apply in pharma & life science; Until end of 2008, there are more than 1000 Christ purified water generation units with EDI produce high quality water for pharma & life science companies.

Christ Water Technology Group came into China in 2003, established Christ Pharma & Life Science (Shanghai) Ltd. Fetch in one-up water treatment technology to China, supply good water generation, storage, distribution machines to Chinese pharma companies for meet FDA, Europe & China GMP requirements. Christ Shanghai manufactory locates Qingpu high-tech district. Uses Christ Swiss design and manufacture process. Experts from Europe supervise in Shanghai. The reference in China such as Roche, Abbott, GSK, Novartis, Yangtze River, Hisun…

Christ had supplied water treatment machines for more than 540 companies in more than 80 countries & area.

Main production:

Purified water generation unit- OSMOTRON

Water for Injection generation unit- MULTITRON

Purified steam generation unit- VAPOTRON

PW, WFI distribution unit- LOOPO

Zhu Xiongliang

Zhu Xiongliang, native of Ningbo City, Zhejiang Province, started work in design automation and debugging of pure water system, served in many domestic pharmaceutical factories such as Shanghai Raas, Shanghai Abbott, Chengdu Rongsheng, and famous foreign pharmaceutical factories such as South Korea Hanmi, Brazilian Europharma., worked in automatic design and debugging of water distiller and pure steam generator. Currently, he serves as Automation and After-sale Service Manager of Christ (Shanghai).

Johan de Hoon

IMA Edwards，产品经理

IMA 集团

IMA LIFE 公司在液体、粉剂的无菌和非无菌工艺灌装领域提供广泛系列的产品。设计满足严苛的制药要求，产品囊括传统的到最为先进的一系列灌装密封设备。集设备供应商与客户解决方案提供商为一体，IMA LIFE 公司可以满足无菌制药市场的日益增长新的需求，提供的产品不仅体现了坚实的技术基础，多年经验成果，而且来源于世界范围内跨国制药企业持续的合作伙伴关系。在灌装领域年产约 150 台设备，几乎都是整体的生产线，我们对设备一体化及功能连线逻辑控制理论有深入的理解，这一切通过资深的员工及专门用于设备整合的设施加以保证。

Johan de Hoon，IMA Edwards，产品经理

Johan de Hoon 在 IMA Edwards（伊马爱德华）公司工作将近 22 年。在早期，该公司（当时名叫 Calumatic）涉及无菌灌装设备业务。大约在 1994 年，该公司被 BOC 公司收购。2008 年 1 月，BOC 公司的分公司低压冻干系统公司被 IMA 伊马公司接管。Johan de Hoon 在其职业生涯中担任过各种职务。在其职业生涯开始时担任灌装设备地区销售经理，随后出任项目经理、市场营销经理、销售支持和项目管理经理以及现场管理小组成员。在最近 10 年间里，他担任由位于荷兰的伊马爱德华工厂设计制造的加载系统的产品经理。Johan de Hoon 拥有机械工程专业学士学位。

IMA Group

IMA LIFE, in the field of liquid powder and aseptic and non-aseptic processing, can today offer a wide range of machinery, particularly designed to meet the most stringent pharmaceutical requirements, from very advanced machinery and applications through to traditional filling and closing machines. Combining the role of machinery supplier with the added ability of being a solution provider for its customers, IMA LIFE can satisfy new requirements of aseptic and pharmaceutical markets, offering a product which represents not only consolidated technology, gained during many years of experience, but which also derives from a continuous partnership with pharmaceutical multinationals worldwide. Almost 150 machines a year are produced in the filling field, most of which are integrated in complete processing lines, due to an intimate knowledge of machine integration and line functioning logic, which is guaranteed by dedicated facilities and staff for equipment assembly integration.

Johan de Hoon，IMA Edwards，Product Manager

Johan de Hoon is working for nearly 22 years at IMA Edwards.

In the early days the company (named Calumatic) was involved in Aseptic Filling Equipment. Around 1994 the company was acquired by BOC . The Lyophilisation Systems branch of BOC was taken over by IMA in Jan. 2008

During his career he has been active in a variety of jobs. Starting as an Area Sales manager for filling equipment followed by Project Manager – Marketing Manager and lately as Manager Sales Support and Project management plus member of the Site Management team.

Last 10 years he is the Product Manager for Loading System which are designed and produced in the IMA Edwards factory in Holland.

Johan holds a bachelor degree in Mechanical Engineering.

演讲内容摘要：

随着全球各国 GMP 要求的提高，企业对高标准洁净化生产流程的需求日益凸现，IMA Edwards 作为世界领先的制药设备供应厂家，始终关注于处于变化中的市场要求。在全自动装料 / 卸料系统的开发上，IMA Edwards 始终是西林瓶自动处理装置的先驱，并一直处于行业的领导地位。在此次论坛上，将会对自动装料 / 卸料技术进行介绍：自动装料 / 卸料系统的分类；自动装料 / 卸料系统的装载次序；低温上料技术；与罐装机和轧盖机的整合；与冻干机的整合；环境保护方式；环境监测方法；错误恢复；烟雾试验；案例讲解。

郑效东

上海东富龙科技股份有限公司
董事长、总经理

上海东富龙科技股份有限公司

东富龙公司成立于 1993 年年底，是一家以冻干系统核心区域设备（真空冷冻干燥机：简称“冻干机”）为产业的优秀提供商。应用于生物制品、化学制品、天然药物、热敏性药物抗菌素，瓶冻（冻干注射剂）、盘冻（原料药）、口服冻干片剂、双室袋 、冻干胶囊、预灌针等制药业界。

冻干机作为公司目前的核心产业，拥有国内最大面积的冻干机制造基地，具有年产 300 多台各种规格的冻干机能力，以满足全国 500 多家各大冻干注射剂制药企业的长期使用及 700 多种冻干药品生产需求，总销量至今已有 1500 多台，占国内中高端市场前列。

东富龙公司自创立伊始，就以专业雄厚的技术实力，卓越的产品质量，高标准的质保体系和尖端内在的技术含量，“更好、更快、更新”的服务宗旨奉献于中国制药工业。东富龙作为中国首选冻干机真正的自主品牌，已在行业中赢得了良好的声誉和口碑。

郑效东先生，上海东富龙科技股份有限公司董事长、总经理。

国内著名的药品冻干专家，中国国家食品药品监督管理局培训中心客座教授、中国制药装备行业协会专家委员会委员。近年来共发表论文数十篇，并参与了国内仅有的两本冻干设备类书籍的编写（《冷冻干燥技术与冻干机》《冷冻干燥技术与设备》另外，"人脐带血有核细胞冷冻干燥保存实验初步研究 " 和 " 有机溶剂的冷冻干燥研究 " 还得到了国家自然科学基金和上海市教委重点学科建设项目资助。

Shanghai Tofflon Science and Technology Co.,Ltd.

Tofflon established in 1993, is the world's largest pharmaceutical freeze dryer manufacturer. The freeze dryers are manufactured according to cGMP guidelines and FDA recommendations, under an ISO9001 Quality Assurance System. Up to 2009, Tofflon has supplied more than 1500 freeze dryers to pharmaceutical and biotech industry worldwide, including North America, Europe,South Asia,Northeast Asia, Southeast Asia, Latin America and Africa, and widely applied in the fields of bio-products(vaccine,blood plasma), herbs, antibiotics, healthcare foods and animal drugs,etc.

To strengthen our core competence, Tofflon is making important investments in advanced innovation, facility expansion and organization restructuring. To ensure our local presence, Tofflon has established joint ventures and partnership with the top quality companies from USA, Europe and Japan, and has set up local offices and agencies all around the world. All contributes to offer our customers not only top quality freeze dryers but also complete global lyophilization solutions.

Zheng Xiaodong, Chairman and General Manager of Shanghai Tofflon Science and Technology Co.,Ltd.

In recent years, dozens of papers on Lyophilization technology have been published by Mr. Zheng as the domestic well-known pharmaceutical lyophilization expert, the visiting professor of State Food and Drugs Administration Training Center and the expert committee member of China Association for Pharmaceutical Equipment, as well.

In addition, Mr. Zheng was awarded the finical support from National Natural Science Foundation of China and Shanghai Municipal Education Commission for his issue on ´Primary Research of Freeze Drying Reservation Experiment for Human Cord Blood Nucleated Cells' and ´Lyophilization Research of Organic Solvent'.

中村健太郎

日挥株式会社（JGC），机械工程师

日挥株式会社（JGC）

成立于 1928 年，其是日本第一家工程承包商。在 80 多年的经营历程中，作为“无国界技术革新者”，日挥株式会社已经从大约 70 个国家的 2 万多项工程中积累了丰富经验。日挥集团在全球有 9200 名员工。日挥株式会社为其至尊客户完成各类项目工程，其涉及碳氢化合物、石油天然气开发、石油加工、液化天然气、天然气加工、石油化学等领域以及环境保护、核电、有色金属、化学制品、医药品和医疗中心。

中村 健太郎，日挥株式会社（JGC），机械工程师

中村先生作为机械工程师，在医药工程领域特别是无菌生产设施方面累积了 12 年的丰富经验。主要经验包括：传统层流罩内的安瓶的全自动无菌分装系统的设计；最终灭菌产品（安瓶）的全自动分装；安玻和安瓶的设有冻干机的多产品无菌分装生产线、高活性注射产品的设有隔离器无菌分装生产线；设有开放式或封闭式 RABS 的安瓶全自动分装系统；分装前注射器的高压灭菌柜的全自动投料 / 出料系统，还有包括隔离器的除染周期发展工作等的这些设备的试运行和确认工作。

JGC Corporation

JGC Corporation was founded in 1928 as Japan's first engineering contractor. Over its 80 years of operation as a "technological innovator without borders", JGC has the accumulated experience gained from over 20,000 projects performed in approximately 70 countries There are 9200 employees in JGC group around the world.

The wide range of projects performed by JGC for its valued clients cover the fields of hydrocarbons, including oil and gas development, petroleum refining, LNG, gas processing, and petrochemicals, as well as involvement in environmental protection, nuclear power, nonferrous metals, chemicals, pharmaceuticals and medical centers.

Kentaro NAKAMURA，JGC Corporation，Mechanical engineer

Mr. Nakamura has over 12 years' experience in engineering for the pharmaceutical industry as a mechanical engineer, particularly for sterile manufacturing facilities. He has participated in more than 15 pharmaceutical facility construction projects.Major experience include: Design of automatic aseptic filling line system with conventional laminar flow booth for vial; automatic filling line system for terminal sterilized vial products; multiproduct aseptic filling lines with lyophilizers for vials and ampoules, aseptic filling line with isolators for high potency syringe products; automatic aseptic filling line system with open and closed RABS for vials; and automatic autoclave loading/unloading system for syringe before filling, as well as commissioning and qualification works for such facilities including decontamination cycle development work for isolators.He delivered a presentation on “Efficient Multi-Product Manufacturing Systems” in Barrier Isolation Technology Forum at the ISPE Berlin conference in 2004. He has a Master's degree in mechanical engineering from Kyoto University.

演讲内容摘要：

无菌产品在亚洲医药产业具有广阔的发展前景。为了确保高质量的无菌产品的高效生产，需要有完善的规程来设计这些生产设施。本次演讲主要根据本公司长期累积的经验与大家讨论关于设计无菌生产设施的相关方面问题。我们所讨论的课题有：GMP 概念；A` 级洁净区的关键点；无菌分装设施的分区；生产设施设计的关键点。

姚军

梅特勒 - 托利多仪器（上海）有限公司，高级技术服务工程师

梅特勒 - 托利多

梅特勒 - 托利多是全球领先的过程检测设备的供应商，为最终用户和系统集成商提供液体分析测量解决方案以达到控制生产工艺的目的。

在生物技术领域，梅特勒 - 托利多专注于 pH、溶解氧、电导率、浊度和 CO_2 等参数的在线测量，其解决方案具有测量准确、寿命长等优点，在全球和国内有广泛的用户基础，在国内设立了 30 多家办事处，以向中国用户提供优质的服务。

姚军，梅特勒 - 托利多仪器（上海）有限公司，高级技术服务工程师

1992 年 7 月毕业于唐山工程技术学院（现河北理工大学）自动化系工业自动化仪表专业，1992 年 8 月进入张家口制药总厂 201 车间工作。

在药厂工作期间任职车间仪表工、计控室工程师、工程部项目工程师等职，在生化制药在线仪表检测及自控系统的安装调试、使用维护及应用方面积累了丰富的实践经验。曾独立完成发酵车间自控系统的全部设计工作并全面负责安装调试，该系统正常运行至今已十多年。

2005 年 3 月进入梅特勒 - 托利多仪器（上海）有限公司工作至今。

在 MT 公司工作期间任职技术支持工程师、高级技术服务工程师，专业的技术水平和丰富的实践经验获得用户的一致好评。曾获得公司中国区优秀服务工程师和亚洲区优秀服务工程师等奖项。

Mettler Toledo

METTLER TOLEDO Process Analytics is a leading supplier to end users and system integrators for liquid analytical measurement solutions to control production processes.

In biotechnology application, Mettle Toledo specialized on the parameters pH, DO, conductivity, turbidity and CO_2, which is well known for high performance and long life time globally. To offer better service to China customers, Mettler Toledo owns more than 30 offices in China.

Yao Jun，Mettler Toledo Process Analytics，Senior Technical Engineer

July 1992,Graduated from Automation department Hebei Polytechnic University

Aug.1993-Feb 2005, Project Engineer, Zhangjiakou Gist-brocades Pharmaceutical Co., Ltd.

Mar. 2005-present Senior Technical Engineer, Mettler Toledo Process Analytics

Mr. Yao Jun have more than 10 years experience in biopharm workshop as instrument engineer and process engineer, in charge of online analyzers installation, maintenance and automation system. He ever designed independently automation system of fermentation workshop, which have worked more than 10 years.

As a technical engineer in Mettler Toledo, Yao Jun was rewarded to be excellent service engineer in China and Asia pacific.

演讲内容摘要

在生物发酵工艺中，pH 值和发酵液中的氧气含量将影响最终产物的质量和收率，通常采用在线测量以更好地控制发酵过程。

本次演讲主要是根据梅特勒 - 托利多公司在生物发酵领域 60 多年的经验，和大家讨论生物发酵过程中使用在线监测的必要性和好处，主要内容有：

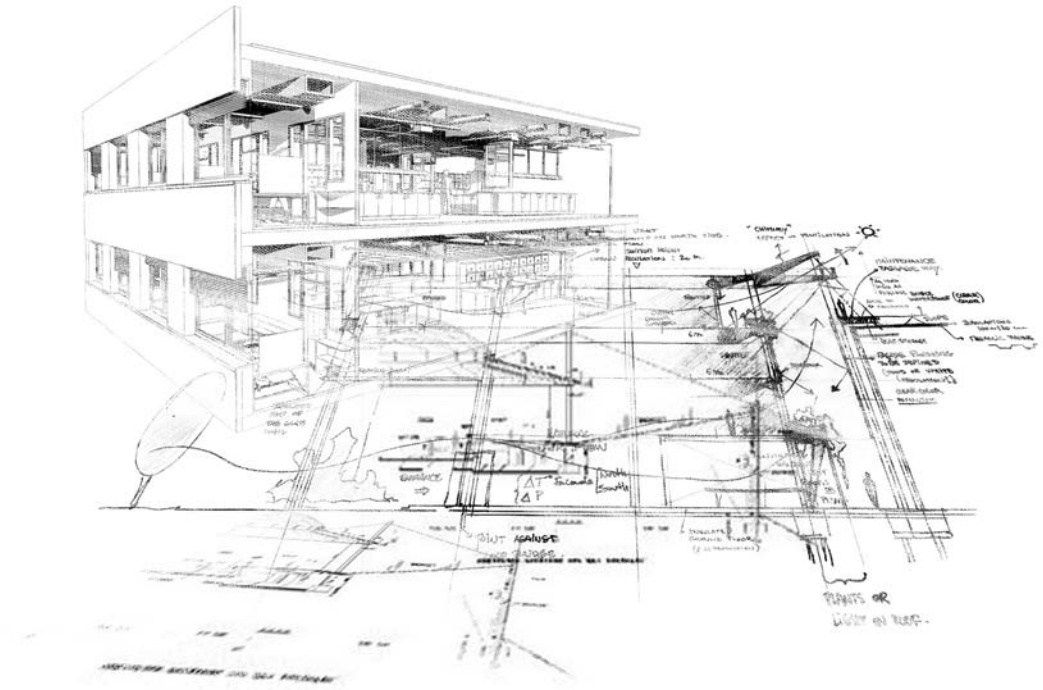
- 生物发酵过程中涉及到的在线测量；
- 生物发酵过程对于在线测量设备的要求；
- 使用在线测量设备的好处。

戴晓云

瑞士比欧生物工程公司（Bioengineering AG），资深工程师

戴晓云，瑞士比欧生物工程公司（Bioengineering AG），资深工程师

Dai Xiaoyun, Senior Engineer in Bioengineering AG



陈筱潇

赛默飞世尔科技，高级产品经理

赛默飞世尔科技

赛默飞世尔科技（纽约证交所代码：TMO）是科学服务领域的世界领导者，致力于帮助客户使世界更健康、更清洁、更安全。公司年销售额超过 105 亿美元，拥有员工约 35,000 人。主要客户类型包括：医药和生物技术公司、医院和临床诊断实验室、大学、科研院所和政府机构，以及环境与工业过程控制行业。借助于 Thermo Scientific 和 Fisher Scientific 两个首要品牌，公司将持续技术创新与最便捷的采购方案相结合，为客户、股东和员工创造价值。其产品和服务有助于加速科学探索的步伐，帮助客户解决在分析领域所遇到的从复杂的研究项目到常规检测和工业现场应用的各种挑战。

陈筱潇，赛默飞世尔科技，高级产品经理

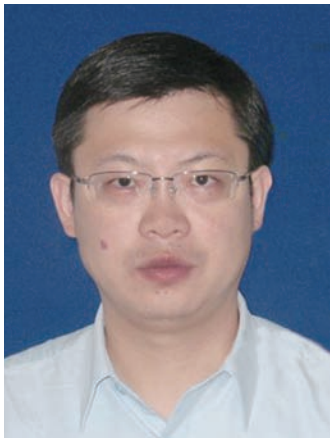
陈筱潇，女，博士。1996 年毕业于华西医科大学药学院。1996-2003 年于重庆医科大学检验系任讲师，其间于 1998-2004 年在重庆医科大学检验系及军事医学科学院二所攻读药理学硕士、临床检验诊断学博士学位。2004-2007 年为爱尔兰都柏林大学微生物系博士后研究员，从事致病菌致病性分子机理研究工作。2008 年至今为赛默飞世尔科技中国实验室耗材部高级产品专家。

Thermo Fisher Scientific

Thermo Fisher Scientific Inc. (NYSE: TMO) is the world leader in serving science. Our mission is to enable our customers to make the world healthier, cleaner and safer. With revenues of more than $10 billion, we have approximately 35,000 employees and serve customers within pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as in environmental and process control industries. We create value for our key stakeholders through two premier brands, Thermo Scientific and Fisher Scientific, which offer a unique combination of continuous technology development and the most convenient purchasing options. Our products and services help accelerate the pace of scientific discovery, and solve analytical challenges ranging from complex research to routine testing to field applications.

Xiaoxiao Chen ,Thermo Fisher Scientific Inc., senior product specialist

Xiaoxiao Chen, PhD, female. Graduated from Department of Pharmacology, West China Medical University in 1996. Became lecture in Department of Clinical Diagnostics, Chongqing University of Medical Sciences in 1996. During 1998-2003, she has been doing researches in Department of Clinical Diagnostics, Chongqing University of Medical Sciences and Academy of Military Medical Sciences (Major in Pharmacology and Clinical Diagnostics). She received her PhD degree in 2003. She then worked as a postdoc researcher for four years (2004-2007) in Department of Microbiology, University College Dublin, Ireland. Dr. Chen began her career as senior product specialist in LCD China, Thermo Fisher Scientific from 2008.



潘利

罗克韦尔自动化（中国）有限公司，上海 OEM 销售经理

罗克韦尔自动化有限公司

在全球工业自动化动力、控制与信息技术解决方案等领域占据领先地位，致力于帮助客户提高他们的竞争优势。罗克韦尔自动化公司整合了工业自动化领域的知名品牌，其中包括艾伦 - 布拉德利的控制产品和工程服务及罗克韦尔软件开发的自动化管理软件。罗克韦尔自动化总部位于美国威斯康星州密尔沃基市，在 80 多个国家设有分支机构，现有雇员约 20,000 人。

潘利，罗克韦尔自动化（中国）有限公司，上海 OEM 销售经理

1996-1998 上海宝钢集团 电气工程师

1998-2008 欧姆龙（中国）有限公司

曾任销售工程师，区域销售经理，产品经理多个职位

2008- 罗克韦尔自动化（自动化）公司 上海 OEM 销售经理

多年来一直专注于工业自动化产品，如 PLC、运动控制、HMI、变频器等在 OEM 行业中的应用。工业电气自动化学士，项目管理工程硕士，美国项目管理协会项目管理师（PMP）。

Pan Li, OEM Sales Manager of Rockwell Automation (China) Co., Ltd

1996-1998 Electric Engineer of Shanghai Baosteel Group

1998-2008 Sales Engineer, Regional Sales Manager, Product Manager of Omron (China) Co., Ltd

2008-OEM Sales Manager of Rockwell Automation (China) Co., Ltd

Always focusing on industrial automation products, such as applications of PLC, motion control, HMI, frequency converter in OEM industries.

Bachelor of Industrial Electric Automation, Master of Project Management Engineering, Project Management Professional (PMP) of U.S Project Management Institute.

Dr. Udo Ammerah

拜耳技术服务（上海）有限公司

拜耳技术工程（上海）有限公司

拜耳技术工程 (上海) 有限公司作为拜耳集团全资子公司，成立于 2003 年 11 月，面向化工和医药行业生产装置的整个生命周期，从项目投资决策，到工厂设计施工，乃至技术去瓶颈和研发支持，依托拜耳集团百年技术底蕴，秉承不断创新的理念，为内、外部客户创造持久而有效的竞争优势。 拜耳技术工程 (上海) 有限公司的项目成功案例遍及全世界。其项目及施工管理服务包括：进度表协调、施工现场组织、施工监理、冷试车模拟培训及装置开工，从工程咨询到一揽子交钥匙工程，帮助客户实现风险最小化，以便专注于核心业务。自建立以来，已完成包括拜耳上海一体化基地聚碳酸酯项目、聚氨酯项目、拜耳医药保健北京药厂扩建等项目，并为瓦克化学、朗盛化学、科宁化学、云南白药、抚顺高新技术开发区等客户和机构提供了国际级的项目管理和工程规划、建设服务。

Dr. Udo Ammerah，拜耳技术服务（上海）有限公司

2000 年加入拜耳集团从事过程分析技术在化学生产和制药工业的执行系统领域中的不同技术与管理岗位。2008 年 9 月，开始担任 BTES 包含工艺过程自动化领域的应用先进制造解决方案部门的领导人。

Bayer Technology and Engineering (Shanghai) Company Limited

Bayer Technology and Engineering (Shanghai) Company Limited (BTES) offers fully integrated solutions along the life cycle of chemical/pharmaceutical plants - from development through engineering and construction to process optimization for existing plants, as well as market evaluation and investment consultation and services in China and Asia. BTES sees you through the capital investment process, aiming for better quality as well as increased productivity and profitability. The innovative services cover from engineering consultation, training simulators to online analysis system (SpectroBAY), manufacturing execution systems (MES) and supply chain optimization.

Dr.Udo Ammerahl,Bayer Technology and Engineering (Shanghai) Co.,Ltd.

Dr. Udo Ammerahl received his PhD in Physics and Material Science from University of Cologne, Germany, and University Paris XI, France, and joined the Bayer Group in 2000. Since then he worked in different technical and managerial positions with focus on Process Analyzer Technology in chemical production and Manufacturing Execution Systems for pharmaceutical industry. Since September 2008 he is head of the Advanced Manufacturing Solutions Department within BTES covering the area of process automation.

演讲内容摘要

在制药生产中，MES 是能够支持包括生产计划，仓库管理，生产制造，偏差管理，物料追踪，文档控制以及性能评估等在内的所有生产相关步骤，从而保证产品的质量和安全性，且保证更好地满足合规性。典型的 MES 功能，最佳实践案例以及在制药生产中安装 MES 的优点将在以下几个案例分析中展开讨论。

林洪

上海西门子工业自动化有限公司，流程行业技术中心（制药，制造执行系统），项目总监，部门经理

西门子（中国）有限公司

全球第三大且增长最快的电气市场

三大业务集团：工业，能源，医疗

价值链：生产，工程，研发，软件开发，采购

林洪女士，上海西门子工业自动化有限公司，流程行业技术中心（制药，制造执行系统），项目总监，部门经理

专注于制药市场分析与开拓计划，特别是计算机验证及合规领域的项目执行与实施。自 2003 年组建流程行业技术中心以来，坚持以专业化 & 系统化的业务模式、方法论来拓展、积累制药工业的行业知识。并基于风险管理的方法，把制药理论与项目的执行模式推广及应用于食品 & 饮料行业和一些高风险高技术及合规需求的业务，如制造执行系统（MES）。长期参与瑞士罗氏公司（现帝斯曼公司）在中国的一系列新改建（十几个）项目和西安杨森，苏州诺华制药（瑞士）在可行性报告和环境调研阶段，对过程控制系统或电气 / 自控的投资估算项目，之后在包括系统验证的项目中承担系统质量保证 & 验证支持 、验证经理、审计等职务。以保证整个项目是遵循 GAMP 4.0/GAMP5.0 指导书的生命周期模式和制药企业的具体指导方针进行实施的。

Siemens Limited China

Third largest and fastest growing electrical and electronics market worldwide

Three Groups: Industry, Energy, Healthcare

Value chain: manufacturing, engineering, R&D, software development, procurement

Lin Hong, Center of Competence Branch (CoC Pharma,F&B and MES) from Siemens Industrial Automation Ltd.Shanghai(SIAS) , Project Director/Section manager

Is dedicated her life in Pharmaceutical marketing analysis&Penetration planning, and project execution, special in computer system validation and compliance in this field. She established the CoC Pharma team in 2003 in SIAS, and she insist on developing, accumulated Knowledge in professionalize methodology from pharma industry branch and roll out in cross industry such as in Food &Beverage and some High risk, high technology, high compliance business such as Manufacturing Execution System (MES) by a risk based approach She is a Member of International Science Pharmaceuical Engineering (ISPE) and the China Affiliate Steering Committee She was invited to participate and gave the speaking/training in Seminar which organized by some Industry committee and SFDA/CCPIE.She is one of the speakers of GAMP5 in the ISPE Conference in 2008.She delegated by ISPE as the project manager and final viewer of A Risk-Based Approach to Compliant GxP Computerized Systems (acronym: GAMP5) in 2009. She ever work in a series Roche vitamin (current DSM),Xian Janssen and Novartis HUA project,etc as an automation & electrical investment consultant during the Feasibility study & Environmental study phases, after that She also work as SQA & Validation Support and Validation manager & audit covers all stages of the implementation of CSV Pharmaceutical project , the life cycle module is in accordance with the guidelines specified of GAMP4.0 or GAMP 5 and the guidelines specified by pharmaceutical production plant.

李爽
发泰（天津）科技有限公司

李爽，发泰（天津）科技有限公司

2008 年 10 月 - 至今，天津软联科技有限公司副总经理，承担天津市重点技术支撑和创新项目若干。

2007 年 1 月 -2008 年 10 月，天津雅玛科技有限公司副总经理，负责产品线管理和市场运营。期间完成天津广电、天津新华集团、天津西青政府、天津保密局、天津技术监督局、天津报业集团、天津市政府信息化办公室、天津联通、天津移动等单位的行业、企业信息化项目的设计和拓展和研发组织工作。是天津经信委信息化社会专家。

2006 年 1 月 - 2006 年 12 月，北京得实信息科技有限公司 COO（运营副总裁），负责公司业务的整体市场运营，并管理分支机构。带领全国 15 个办事处，顺利完成公司任务，实现就亏为赢。

Li Shuang,Pharm-Tech Co.,Ltd

October, 2008 –,Deputy General Manager of Tianjin Softlian Technology Co., Ltd.

Undertook several key technology supporting and innovative projects in Tianjin Municipality.

January, 2007 – October, 2008,Deputy General Manager of Tianjin .Yamma Technologies Co., Ltd

Responsible for product line management and market operation, completed the task for organizing efforts in designing, expanding and developing information-based projects for such enterprises and departments as Tianjin Guangdian, Tianjin Xinhua Group, the Government of Xiqing District, Tianjin Municipality, Tianjin State Bureau of Secrecy, Tianjin Municipal Quality and Technical Supervision Bureau, Tianjin Municipal Informatization Office, Tianjin Unicom, Tianjin Mobile etc; the information-based society expert from Tianjin Economic and Informatization Technology Commission

January, 2006 – December, 2006:Chief Operating Officer（Vice-president for Operations）,Dascom Technology (Beijing) Ltd.

Responsible for overall market operation for company business and management of branches, led fifteen offices nationwide to smoothly complete company's tasks and turn from deficits to profit.